OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

LAWS AND REGULATIONS IN RELATION TO NEW DRUG

U.S. Government Regulation of Drug and Biological Products

In the United States, the Food and Drug Administration ("FDA") regulates drugs under the Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, and the FDA regulates biologics under the FDCA and the Public Health Service Act (the "PHSA") and their implementing respective implementing regulations. Both drugs and biologics also are subject to other federal, state, and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals to manufacture or market drugs and biologics in the United States and the subsequent compliance with appropriate federal, state, local, and non-U.S. applicable statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative actions, government prosecution, judicial sanctions or any combination of them in the U.S. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any agency or judicial enforcement action could have a material adverse effect on our business, financial condition and results of operations as well as the market's acceptance of our products and our reputation. Outside the United States, drugs and biologics are regulated under other statutory and regulatory systems with which we would need to comply if we were to manufacture or market drugs or biologics outside the United States, and failure to comply there could also subject us to administrative actions, government prosecution or judicial sanctions (or any combination of them) there.

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations and other applicable federal and state laws and regulations. A sponsor of an Investigational New Drug Application ("IND") must submit the results of the preclinical tests (such as animal tests), manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. Although information a sponsor submits in an IND is confidential information, general clinical trial information such as the number of patients involved and the

type of adverse events studied can be made public information and can be available for public review through publication on government websites such as www.clinicaltrials.gov.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice and human subject research regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board ("IRB") often arranged through a university or other independent organization must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or federal regulations governing human subject research, or if the product has been associated with unexpected serious harm to subjects such that the IRB determines patients are at risk.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase II clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetics (PK) and pharmacodynamic (PD) information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in that use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA before marketing approval is received. Safety reports must be submitted to the FDA and the clinical trial investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in

no case later than 7 calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at **www.clinicaltrials.gov**.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with the FDA's current good manufacturing practices ("cGMP") requirements.

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a New Drug Application ("NDA") or Biologics License Application ("BLA"). Unless deferred or waived, NDAs or BLAs, or supplements must contain data adequate to assess the safety and efficacy of the product for the claimed indications including in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The submission of an NDA or a BLA is subject to the payment of a user fee, a manufacturing fee and an annual prescription drug product program fee to FDA in addition to NDA or BLA submission fees.

Within 60 days of its receipt, the FDA reviews the NDA/BLA to ensure that it is sufficiently complete for substantive review before it accepts the NDA/BLA for filing. After accepting the NDA/BLA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving the NDA/BLA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA/BLA to an advisory committee, a panel of experts, for review whether the application should be approved and under what conditions and considers such recommendations when making decisions.

The FDA may refuse to approve the NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a "Complete Response Letter" describing all of the specific deficiencies that the FDA identified in the NDA/BLA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the "Complete Response Letter" may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may either resubmit the NDA/BLA, addressing all of the deficiencies identified in the letter, withdraw the application, request an opportunity for a hearing, and, in appropriate cases, request an opportunity for further communication and with action with FDA staff.

The regulatory approval may be limited to specific diseases, dosages populations, and ages, or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling among other mandatory labeling requirements. In addition, the FDA may require post-approval studies, including Phase IV clinical trials, to further assess a product's safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In the United States, products composed of components (e.g., drugs and medical devices) that would normally be regulated by different centers at the FDA are known as combination products. Typically, the FDA's Office of Combination Products assigns a combination product to a specific Agency Center as the lead reviewer. The FDA determines which Center will lead a product's review based upon the product's primary mode of action. Depending on the type of combination product, its approval, clearance or licensure is usually obtained through the submission of a single marketing application. However, the FDA sometimes will require separate marketing applications for individual constituent parts of the combination product which may require additional time, effort, and information. Even when a single marketing application is required for a combination product, the relevant Centers may participate in the review. An applicant will also need to discuss with the Agency how to apply certain premarket requirements and post-marketing regulatory requirements, including conduct of clinical trials, adverse event reporting and good manufacturing practices, to their combination product.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the U.S. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstance. An orphan designation also could provide the sponsor (1) a tax credit of 50 percent of the cost of conducting human clinical trials, and (2) federal research grants for clinical testing of new therapies to treat and/or diagnose rare diseases.

Post-Marketing Requirements

Following approval of a new product, the manufacturer and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse events ("AE"), complying with labeling, promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The

FDA and other agencies, such as the Department of Justice actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities as well as potential tort liability. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication.

Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy ("REMS"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities, according to approved manufacturing processes and in accordance with cGMP regulations. We rely on third parties for the production of clinical quantities of our drug candidates in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. The manufacturer is ultimately responsible for its products and the manufacturing practices of its contract manufactures, therefore the manufacturer must take responsibility for the failure for the contract manufacturers to manufacture according to cGMPs.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including recall.

Once an approval is granted, if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug or biologic reaches the market, the FDA may take enforcement actions such as issuing Warning Letters or Untitled Letters, ordering

removal of the product from the market until deficiencies are remedied, withdrawing the approval of the product, or imposing civil and criminal penalties. Corrective action could delay drug or biologic distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug or biologic, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the drug or biologic, suspension of the approval, complete withdrawal of the drug from the market or product recalls;

- fines, warning letters or holds on post-approval clinical trials;

- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug or biologic approvals; drug or biologic seizure or detention, or refusal to permit the import or export of drugs; or

- injunctions or the imposition of civil or criminal penalties.

Recent FDA Regulatory Activity Concerning mRNA

Recently, the FDA took several regulatory steps related to mRNA-based COVID-19 vaccines. Specifically, in October, 2021, FDA authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 to include children 5 through 11 years of age. The authorization was based on safety and efficacy data provided to the FDA. The Pfizer-BioNTech COVID-19 Vaccine was approved by FDA in August, 2021 for the prevention of COVID-19 disease in individuals 16 years of age and older, and the FDA had granted emergency authorization for the Pfizer-BioNTech COVID-19 Vaccine for those individuals 12-15 and up in May, 2021. Subsequently, in September, 2021, after Pfizer-BioNTech submitted a supplement to their application, FDA amended the emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine to allow for the use of a single booster dose in certain populations, including those 65 years of age and older, those at high risk of severe COVID-19, and those whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19. In October, 2021, FDA took additional action and amended the emergency use authorizations (EUA) for all COVID-19 vaccines (Moderna, Pfizer-BioNTech, and Jansen) to allow for the use of each of the available COVID-19 vaccines as a heterologous or "mix and match" booster dose in eligible individuals following completion of primary vaccination. Those eligible include individuals who received the Moderna or Pfizer-BioNTech COVID-19 vaccines who are 65 years of age in older, are at high risk of severe COVID-19, and whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of

COVID-19, and those who received Jansen and are over the age of 18. In November of 2021, FDA in coordination with the Centers for Disease Control issued emergency use instructions to provide information about the use of the vaccine as an additional primary series dose or as a booster dose in individuals who completed vaccination with certain non-FDA-authorized or -approved COVID-19 vaccines. Shortly thereafter, FDA amended the emergency use authorizations (EUA) for both the Moderna and Pfizer-BioNTech COVID-19 mRNA vaccines authorizing use of a single booster dose for all individuals 18 years of age and older after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine.

Expedited Development and Review Programs

Accelerated Approval

Under FDA's accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trial to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA. Even if accelerated approval proves unavailable, the candidate can proceed through the customary FDA approval process in the regular course.

Breakthrough Designation

Another program potentially available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the product's marketing application, including by meeting with the sponsor throughout the product's development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable. Even if breakthrough designation proves unavailable, the candidate can proceed through the customary FDA approval process in the regular course.

Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively the "ACA") became law in the United States in March, 2010, and it has driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare is financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA, among other things, expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through expansion of the Medicaid program and mandatory increased rebates for both generic and brand drugs reimbursed by Medicaid programs, the exclusion of certain manufacturer discounts from the average manufacturer price (AMP), extended eligibility for Medicaid rebates provided through Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and new federal taxes in the form of an annual fee based on pharmaceutical companies' share of sales to federal health care programs. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Since January 2017, President Trump has signed Executive Orders (EOs) and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Several of the EOs now remain on hold pending review by the Biden Administration.

In addition, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed, for example, the Tax Cut and Jobs Act (TCJA) enacted by the Congress in 2017, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently repealed, effective January 1, 2020, the ACA- mandated "Cadillac" tax on high-cost employer-sponsored health coverage and the medical device tax, effective January 1, 2021, the health insurance tax was repealed. There may be other efforts to challenge, repeal or replace the ACA. Notably, the U.S. Supreme Court, on June 17, 2021, ruled 7-2 that Republican states, led by Texas, lacked standing to challenge the individual mandate. It's the third time the Supreme Court has upheld the law. Although there are no similar existential threats to the ACA at this time, the Supreme Court is expected to continue to hear ACA-related litigation including, but not limited to, litigation concerning the health insurance tax and hospital reimbursement policies.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product

development and FDA review of an NDA or a BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and NDA/BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, collectively and in the aggregate for both up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for extension, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for extension no later than 60 days after approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term extension. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year, and it may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which an NDA or a BLA has not been submitted.

OVERVIEW OF LAWS AND REGULATIONS IN THE PRC

This section summarizes the principal PRC laws, rules and regulations that are relevant to our business.

REGULATORY REGIME

In the PRC, the primary regulatory agency for pharmaceutical products and businesses was the China Food and Drug Administration, or CFDA. Upon the government reorganization in March 2018, the competent authority of this industry has been changed to re-established National Health Commission, or NHC, the SAMR, National Healthcare Security Administration, or NHSA, and NMPA, etc. The NMPA is the primary regulatory agency for pharmaceutical products and businesses, like CFDA, and implements the same laws, regulations, rules, and guidelines as the CFDA, and it regulates almost all the key stages of the life-cycle of pharmaceutical products, including nonclinical studies, clinical trials, marketing approvals, manufacturing, advertising and promotion, distribution, and pharmacovigilance (i.e., post-marketing safety reporting obligations). The Center for Drug Evaluation, or CDE, which remains under the NMPA, conducts the technical evaluation of each drug and biologic application to assess safety and efficacy.

The NHC (formerly known by the names: the Ministry of Health and National Health and Family Planning Commission), is China's primary healthcare regulatory agency. It is

responsible for overseeing the operation of medical institutions, some of which also serve as clinical trial sites. NHC plays a significant role in drug reimbursement.

The Ministry of Human Resources and Social Security, or MHRSS is China's primary regulatory agency for medical insurance. It draws up the policies, plans and standards of medical insurance and maternity insurance; organizes to draw up the management and settlement methods of medical insurance service and maternity insurance service of designated medical organizations and pharmacies, as well as the scope of payment; and prepares the *National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance* (《國家基本醫療保險、工傷保險和生育保險藥品目錄》).

LAWS AND REGULATIONS RELATING TO DRUGS

The National People's Congress, or the NPC and the National Medical Products Administration, or the NMPA has been revising the fundamental laws, regulations and rules regulating pharmaceutical products and the industry, which include the framework law known as the *PRC Drug Administration Law* (《中華人民共和國藥品管理法》), or DAL. The DAL was promulgated by the Standing Committee of the NPC on September 20, 1984, and which was subsequently amended and implemented in 2001, 2013, 2015 and the latest amendment took effect as of December 1, 2019. The DAL is implemented by a high-level regulation issued by the State Council referred to as the DAL Implementing Regulation (《中華人民共和國藥品管理法實施條例》). The NMPA has its own set of regulations further implementing the DAL; the primary one governing clinical trial applications, or CTAs, marketing approval, and post-approval amendment and renewal is known as the *Drug Registration Regulation* (《藥品注冊管理辦法》), or DRR. The DRR was promulgated by the State Drug Administration on October 30, 2002 and the latest amended DRR, by the State Administration for Market Regulation, or SAMR, took effect from July 1, 2020.

Regulations on Drug Research and Development

Pursuant to the DAL, the dossier on a new pharmaceutical research and development, including the manufacturing method, quality specifications, results of pharmacological and toxicological tests and the related data, documents and the samples, shall, in accordance with the regulations of NMPA be truthfully submitted to the said department for approval before clinical trial is conducted. The medical products administration under the State Council shall, within 60 working days from the date on which the application for such clinical trial is accepted, decide on whether to approve it and then notify the clinical trial applicant. In the case of failure to notify the applicant within the prescribed time limit, it shall be deemed as approved. When a new pharmaceutical has gone through the clinical trial and passed the evaluation, a pharmaceutical registration certificate shall be issued upon approval by the NMPA.

Non-Clinical Studies and Animal Testing

The NMPA requires preclinical data to support registration applications for imported and domestic drugs. According to the DRR, non-clinical safety studies shall comply with the *Administrative Measures for Good Laboratories Practice of Non-clinical Laboratory Studies of Drugs* (《藥物非臨床研究質量管理規範》), or the GLP. On August 6, 2003, the State Food and Drug Administration, or SFDA promulgated the GLP, which was latest revised on July 27, 2017, to improve the quality of non-clinical research, and began to conduct the Good Laboratories Practice. Pursuant to the *Circular on Administrative Measures for Certification of Good Laboratory Practice for Non-clinical Laboratory* (《關于印發藥物非臨床研究質量管理規範認證管理辦法的通知》) issued by the CFDA on April 16, 2007, the NMPA is responsible for the certification of non-clinical research institutions nationwide and local provincial medical products administrative authorities is in charge of the daily supervision of non-clinical research institution. The NMPA decides whether an institution is qualified for undertaking pharmaceutical non-clinical research by evaluating such institution's organizational administration, its research personnel, its equipment and facilities, and its operation and management of non-clinical pharmaceutical projects, etc. A GLP Certification will be issued by the NMPA if all the relevant requirements are satisfied, which will also be published on the NMPA's website. Any entity without such certification must engage a qualified third party to conduct such non-clinical activities regulated under relevant laws and regulations.

Pursuant to the Regulations for the Administration of Affairs Concerning Experimental Animals (《實驗動物管理條例》) promulgated by the State Science and Technology Commission on November 14, 1988 and latest amended on March 1, 2017, by the State Council, the Administrative Measures on Good Practice of Experimental Animals (《實驗動物質量管理辦法》) jointly promulgated by the State Science and Technology Commission and the State Bureau of Quality and Technical Supervision on December 11, 1997, and the Administrative Measures on the Certificate for Experimental Animals (Trial) (《實驗動物許可證管理辦法(試行)》) promulgated by the Ministry of Science and Technology and other regulatory authorities on December 5, 2001, using and breeding experimental animals shall be subject to rules and performing experimentation on animals requires a Certificate for Use of Laboratory Animals. Any entity without such certification must engage a qualified third party to conduct such non-clinical activities regulated under relevant laws and regulations.

Clinical Trials Approval

Upon completion of preclinical studies, a sponsor typically needs to conduct clinical trials in the PRC prior to registering a new drug. The NMPA has taken a number of steps to increase efficiency for approving CTAs, and it has also significantly increased monitoring and enforcement of the *Administrative Regulations of Quality of Drug Clinical Practice* (《藥物臨床試驗質量管理規範》), or the PRC's GCP, to ensure data integrity. The PRC's GCP was promulgated by SFDA on August 6, 2003 and the latest amended PRC's GCP took effect from July 1, 2020.

Clinical trials could not proceed until being approved by the NMPA previously; according to the latest amended DRR, the NMPA now has adopted a system for clinical trials of new drugs where trials can proceed if the applicant has not received any objections from the CDE within 60 days thereafter. After the issuance of the *Announcement of the China Food and Drug Administration on Several Policies on the Appraisal and Approval of Drug Registration* (《國家食品藥品監督管理總局關于藥品注冊審評審批若干政策的公告》) on November 11, 2015, as for clinical trial applications for new drugs, the one-time approval is implemented and the declaration, appraisal and approval at different levels are replaced. The one-time approval mechanism was restated in the *Announcement of the National Medical Products Administration on Adjusting Evaluation and Approval Procedures for Clinical Trials for Drugs* (《國家藥品監督管理局關于調整藥物臨床試驗審評審批程序的公告》), or the Announcement on Adjusting Evaluation and Approval Procedures, which was issued on July 24, 2018 by NMPA. When the clinical trial has been approved and such clinical trial is divided into several phases, prior to conducting subsequent phases, the applicant of such clinical trial shall submit the corresponding drug clinical trial scheme and supporting materials for NMPA's review and consult with the NMPA before initiation of the subsequent phase clinical trial. Once the NMPA reviews the relevant materials and has no objection to the clinical trial protocol for the subsequent phase clinical trial, which is amended as appropriate based on the clinical trial data and consultation with the NMPA, the applicant is permitted to proceed with the subsequent phase clinical trial.

The NMPA promulgated the *Administrative Measures for Communication on the Research, Development and Technical Evaluation of Drugs* (《藥物研發與技術審評溝通交流管理辦法》) in December 2020, during the research and development periods and in the registration applications of, among others, the innovative new drugs, the applicants may propose to conduct communication meetings with the CDE. The communication meetings can be classified into three types. Type I meetings are convened to address key safety issues in clinical trials of drugs and key technical issues in the research and development of breakthrough therapeutic drugs. Type II meetings are held during the key research and development periods of drugs, mainly including meetings before the IND application, meetings upon the completion of Phase II trials and before the commencement of Phase III trials, meetings before submitting a marketing application for a new drug, and meetings for risk evaluation and control. Type III meetings refer to meetings not classified as Type I or Type II.

Pursuant to the DRR, where a clinical trial is approved, the sponsor shall, prior to conducting subsequent phases of the clinical trial, formulate the clinical trial protocol, carry out the trial upon obtaining approval by the ethics committee, and submit the clinical trial protocol and supporting materials on the CDE website. On September 6, 2013, the CFDA released the *Announcement on Drug Clinical Trial Information Platform* (《關于藥物臨床試驗信息平台的公告》), providing that all clinical trials approved by the CFDA and conducted in China shall be registered on and trial information shall be published through the Drug Clinical Trial Information Platform under management of the CDE. The applicant shall complete trial preregistration within one month after obtaining the clinical trial approval to obtain the trial's

unique registration number and shall complete registration of certain follow-up information before the first subject's enrollment in the trial and submit it for publicity. If submission for publicity of the foregoing pre-registration and registration is not completed within one year after obtaining the clinical trial approval, the applicant shall submit an explanation, and if the procedure is not completed within three years, the clinical trial approval shall automatically be annulled.

According to the *Technical Guiding Principles for Clinical Trials of Anti-tumor Drugs* (《抗腫瘤藥物臨床試驗技術指導原則》) issued by the SFDA in May 2012, the clinical study staging of anti tumor drugs is not a fixed developmental sequence. The rapid development of anti-tumor drug research theories and technologies is likely to have an impact on future anti-cancer drug development models. Therefore, applicants can actively explore more scientific and rational research methods and promptly seek advice from the drug registration department under the SFDA.

On November 15, 2021, the CDE issued the *Clinical Value-Oriented Anti-tumor Drug Clinical Research and Development Guidelines*《以臨床價值為導向的抗腫瘤藥物臨床研發指導原則》), or the Anti-Tumor Guidelines. The Anti-Tumor Guidelines states that the fundamental purpose of the drug market is to address the needs of patients, and emphasizes that drug research and development should be based on patient needs and clinical value. With respect to clinical development, especially for early-stage clinical trial design and key clinical trial design, the Anti-Tumor Guidelines encourage (i) the use of scientific tools such as establishing models to guide drug development, and (ii) the use of efficient clinical trial design, setting decision-making metrics and carrying out necessary interim analysis to reduce the invalid exposure of patients, protect the curative effect and interests of patients while improving the efficiency of research and development. The Anti-Tumor Guidelines also emphasize that attention should be paid to the representativeness of the patient population and the development of drugs for special patient populations so as to meet the demand for drugs by different types of populations in a safe manner to the maximum extent in clinical practice.

On November 18, 2021, the CDE issued *a Notice for Soliciting Opinions on the Statistical Guidelines for Clinical Studies of Drugs for Rare Diseases* (關於公開徵求《罕見疾病藥物臨床研究統計學指導原則（徵求意見稿）》意見的通知), or the Draft Statistical Guidelines, which is currently at a stage of seeking public comments and has not yet officially taken effect. The Draft Statistical Guidelines introduce clinical study design and analysis of drugs for rare diseases, also review the problems and considerations in clinical trials for rare diseases, including the selection of study center, patient compliance, study period, enrollment criteria, data quality and follow-up, etc. In view of the characteristics of rare diseases, the evaluation of evidence on drugs for rare diseases shall include the evaluation of evidence on effectiveness and safety as well as benefit risk evaluation. The Draft Statistical Guidelines encourage sponsors to communicate with regulatory authorities in a timely manner on key statistical issues in the design of the program.

International Multi-Center Clinical Trials

According to the International *Multi-Center Clinical Trial Guidelines (Trial)* (《國際多中心藥物臨床試驗指南(試行)》, the "Multi-Center Clinical Trial Guidelines"), promulgated by the SFDA on January 30, 2015 and effective from March 1, 2015, international multi-center clinical trial applicants may simultaneously perform clinical trials in different centers using the same clinical trial protocol. Where the applicants plan to implement the international multi-center clinical trials in the PRC, the applicants shall comply with relevant laws and regulations, such as the Revised Drug Administration Law of the PRC, the Implementing Regulations of the Drug Administration Law of the PRC and the Measures for the Administration of Drug Registration, execute the PRC's GCP, make reference to universal international principles such as the ICH-GCP, and comply with the laws and regulations of the countries involved in the international multi-center clinical trials. Where the applicants plan to use the data derived from the international multi-center clinical trials for approval of a drug registration in the PRC, it shall involve at least two countries, including China, and shall satisfy the requirements for clinical trials set forth in the Multi-Center Clinical Trial Guidelines and Measures for the Administration of Drug Registration and other related laws and regulations.

Human Genetic Resources Approval

According to the *Interim Measures for the Administration of Human Genetic Resources*(《人類遺傳資源管理暫行辦法》), promulgated by the Ministry of Science and Technology and the MOH jointly on June 10, 1998, an additional approval is required for any foreign companies or foreign affiliates that conduct trials in China. Prior to a clinical trial, the foreign applicant and the Chinese clinical trial site are required to obtain approval from the Human Genetic Resources Administration of China, or HGRAC, which is an agency under the Ministry of Science and Technology, to collect any biological samples that contain the genetic material of Chinese human subjects, and to conduct any cross-border transfer of the samples or associated data. Furthermore, one of the key review points for the HGRAC review and approval process is the intellectual property sharing arrangement between Chinese and foreign parties. The parties are required to share patent rights to inventions arising from the human genetic resources. Conducting a clinical trial in the PRC without obtaining the relevant HGRAC approval will subject the sponsor and trial sites to administrative liability, including confiscation of human genetic resources and associated data, and administrative fines.

On July 2, 2015, the Ministry of Science and Technology issued the Service Guide for Administrative Licensing Items concerning *Examination and Approval of Sampling, Collecting, Trading, Exporting Human Genetic Resources, or Taking Such Resources out of the PRC* (《人類遺傳資源采集、收集、買賣、出口、出境審批行政許可事項服務指南》), which provides that foreign-invested sponsors that sample and collect human genetic resources in clinical trials shall be required to file with the HGRAC through its online system. On October 26, 2017, the Ministry of Science and Technology issued the *Circular on Optimizing*

the Administrative Examination and Approval of Human Genetic Resources (《關於優化人類遺傳資源行政審批流程的通知》), which simplified the approval for sampling and collecting human genetic resources for the purpose of commercializing a drug in the PRC. On October 19, 2020, HGRAC issued the *Circular on Further Optimizing the Administrative Examination and Approval of Human Genetic Resources* (《關於進一步優化人類遺傳資源行政審批流程的通知》) to further simplify and streamline the approval procedure for sampling and collecting human genetic resources and the international cooperation in scientific research. On May 28, 2019, the State Council of PRC issued the *Administration Regulations on Human Genetic Resources* (《人類遺傳資源管理條例》), which became effective on July 1, 2019. The Administration Regulations on Human Genetic Resources formalized the approval requirements pertinent to research collaborations between Chinese and foreign-owned entities. Pursuant to the new rule, a new filing system (as opposed to the advance approval approach originally in place) is put in place for clinical trials using China's human genetic resources at clinical institutions without involving the export of human genetic resources outside of China.

On October 17, 2020, Standing Committee of the NPC promulgated *Biosecurity Law of the PRC* (《中華人民共和國生物安全法》), taking effect from April 15, 2021. This Biosecurity Law establishes a comprehensive legislative framework for the pre-existing regulations in such areas as epidemic control of infectious diseases for humans, animals and plants; research, development, and application of biology technology; biosecurity management of pathogenic microbials laboratories; security management of human genetic resources and biological resources; countermeasures for microbial resistance; and prevention of bioterrorism and defending threats of biological weapons. As per this Biosecurity Law, the research and development activities of high-risk and medium-risk biotechnology shall be carried out by a legal person organization established within the territory of China, upon obtaining the approval or record-filing; the establishment of a pathogenic microorganism laboratory shall be subject to approval or record-filing requirements in accordance with the law; (i) collecting human genetic resources of important genetic families or specific areas in China, or collecting human genetic resources of which the types and quantities are subject to provisions of the competent department of science and technology under the State Council, (ii) preserving China's human genetic resources, (iii) using China's human genetic resources to carry out international scientific research cooperation, or (iv) transporting, mailing, and carrying China's human genetic resource materials out of the country shall subject to approval of the competent department of science and technology.

Acceptance of Foreign Data

The NMPA may reduce requirements for clinical trials and data, depending on the drug and the existing data. The NMPA has granted waivers for all or part of trials and has stated that it will accept data generated abroad (even if not part of a global study), including early phase data, that meets its requirements. On July 6, 2018, the NMPA issued the *Technical Guidance Principles on Accepting Foreign Drug Clinical Trial Data* (《關于發布接受藥品境外臨床試驗數據的技術指導原則的通告》), or the Guidance Principles. According to the Guidance

Principles, the data of foreign clinical trials shall meet the authenticity, completeness, accuracy and traceability requirements and such data shall be obtained in consistent with the relevant requirements under the GCP of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, or ICH. Sponsors must be attentive to potentially meaningful ethnic differences in the subject population.

Clinical Trial Process and Good Clinical Practices

Typically, drug clinical trials in the PRC have four phases. Phase I refers to the initial clinical pharmacology and human safety evaluation studies. Phase II refers to the preliminary evaluation of a drug candidate's therapeutic efficacy and safety for target indication(s) in patients. Phase III (often the registrational study) refers to clinical trials to further verify the drug candidate's therapeutic efficacy and safety in patients with target indication(s) and ultimately provide sufficient evidence for the review of a drug registration application. Phase IV refers to a new drug's post-marketing study to assess therapeutic effectiveness and adverse reactions when the drug is widely used to evaluate overall benefit-risk relationships of the drug when used among the general population or specific groups and to adjust the administration dose, etc. The NMPA requires that the different phases of clinical trials in China receive ethics committee approval and comply with the PRC's GCP. The NMPA conducts inspections to assess the PRC's GCP compliance and will cancel the CTA if it finds substantial issues.

On August 6, 2003, the SFDA promulgated the PRC's GCP to improve the quality of clinical trials. According to the latest PRC's GCP, the sponsor shall provide investigators and the clinical trial institution with legal and economic insurance or guarantee relating to the clinical trial, and ensure that such insurance or guarantee is appropriate to the nature and degree of risks of the clinical trial. But the damages caused by the negligence of investigators or the clinical trial institution are not included. Pursuant to the newly amended DAL, and *the Regulations on the Administration of Drug Clinical Trial Institution* (《藥物臨床試驗機構管理規定》) jointly promulgated by NMPA and NHC on November 29, 2019 and effective from December 1, 2019, drug clinical trial institutions shall be under filing administration. Entities that only conduct analysis of biological samples related to clinical trials of drugs do not need to be filed.

New Drug Application (NDA) and Approval

Upon completion of clinical trials, a sponsor may submit clinical trial data to support marketing approval for the drug.

The Registration *Category of Biological Products and the Data Requirements for Declaration* (《生物製品註冊分類及申報資料要求》), issued by NMPA on June 29, 2020, and took effect from July 1, 2020, which replaced the former category of therapeutic biological products and stipulated that the therapeutic biological products should be classified into three

Categories, and Category I refers to therapeutic biological products that have not been marketed anywhere in the world. Category II refers to improved therapeutic biological products and Category III refers to therapeutic biological products that have been marketed in China or abroad.

NDA sponsors must submit data derived from domestically manufactured drugs in support of a drug approval. According to the DRR, the applicant may apply for drug marketing registration to CDE upon completion of relevant search on pharmacy, pharmacology, toxicology and drug clinical trials, determination of the quality standards of the drug, validation of commercial-scale production processes and preparation for acceptance of verification and inspection conducted by professional technical institution designated by competent NMPA. The CDE will organize pharmaceutical, medial, and other technicians to conduct comprehensive review of the safety, efficacy, and quality controllability, among others, of the drug according to the application materials submitted by the applicant, the results of the verification and inspection conducted by professional technical institutions, etc. If the comprehensive review conclusion is affirmative, the drug shall be approved for marketing and a drug registration certification will be issued containing the information of the drug approval number, the marketing authorization holder and the manufacturer, which is effectively the marketing approval allowing the holder to market/commercialize the drug in China.

On September 29, 2021, the NMPA released the *Announcement on the Implementation of the Application for Electronic Common Technical Documents for Drugs* (《國家藥監局關於實施藥品電子通用技術文檔申報的公告》), stipulating that from December 29, 2021, applications for marketing authorization of Class 1 and Class 5.1 of the registration classification of chemical drugs, Class 1 biological products for therapeutic use and Class 1 biological products for preventive use may be filed in accordance with eCTD.

Other Related Regulations in the PRC Pharmaceutical Industry

Price Controls

In China, governmental pricing controls on drugs (other than narcotic and certain psychiatric drugs) have been lifted since May 2015 when the *Opinions on Advancing Drug Price Reform* (《推進藥品價格改革意見》) came into effect. Instead of direct governmental controls, the government exercises control over the drugs through establishing a centralized tender process or centralized procurement mechanism, revising the National Reimbursement Drug List or provincial medical insurance drug catalogues and strengthening regulation of medical and pricing practices. Also, according to the *Opinions on the Reform of Review and Approval System for Drugs and Medical Devices* (《關於改革藥品醫療器械審評審批制度的意見》) promulgated by the State Council in August 2015, enterprises which apply for the registration of new drugs should promise that the prices of their products on the PRC market should not be higher than the comparable market prices in original countries or the surrounding area of the PRC.

Drug Centralized Procurement

On November 15, 2018, the Joint Procurement Office published the *Papers on Drug Centralized Procurement in "4+7 Cities"* (《4+7城市藥品集中採購文件》, the "Paper"), which launched the national pilot scheme for drugs centralized tendering with minimum procurement quantities. The pilot scheme will be carried out in 11 cities, including Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu and Xian (the "4+7 cities").

On January 1, 2019, the General Office of the State Council also published the *Notice of Issuing Pilot Program of the Centralized Procurement and Use of Drugs Organized by the State* (《國務院辦公廳關於印發國家組織藥品集中採購和使用試點方案的通知》), which provides the detailed measures in the implementation of the national pilot scheme for drugs centralized tendering with minimum procurement quantities in the 4+7 cities. According to the *Implementing Opinions on Expanding the Pilot Program for Conducting Centralized Procurement and Use of Drugs by the State to Wider Area*s (《關於國家組織藥品集中採購和使用試點擴大區域範圍的實施意見》) promulgated and came into effect September, 25, 2019, together with the *Documents on National Centralized Drug Procurement (GY-YD2021-1)* (《全國藥品集中採購文件》) issued by the Joint Procurement Office on January 15, 2021, the model of centralized procurement with target quantity in the pilot program for conducting centralized procurement and use of drugs by the State will be promoted nationwide and all manufacturers of drugs within the scope of centralized procurement marketed in Mainland China, with the approval of the medical products administration, may participate in the pilot program.

National Reimbursement Drug List

The National Drug Catalog for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (《國家基本醫療保險、工傷保險和生育保險藥品目錄》), or the National Reimbursement Drug List, or the NRDL, sets forth the payment standard for pharmaceutical products under the basic medical insurance, work-related injury insurance and maternity insurance funds. Medicines listed in the NRDL are divided into two parts, List A and List B. List A drugs are widely used clinical treatments with good efficacy and lower prices compared to similar drugs, while List B drugs are clinical treatments with good efficacy and slightly higher prices compared to List A drugs. The NRDL must be adjusted every two years in principle, and the Provincial Reimbursement Drug List, or the PRDL must be adjusted based on the adjustment of the NRDL. The NRDL is permitted to be expanded for new drugs once every year, while provincial governments are not permitted to expand the PRDL for new drugs.

Drug Advertisements

Insert Sheet, Labels and Packaging of Pharmaceutical Products

Pursuant to the Measures for the Administration of the *Insert Sheets and Labels of Drugs* (《藥品說明書和標籤管理規定》) which came effective on June 1, 2006, the insert sheets and

labels of drugs should be reviewed and approved by the CFDA. A drug insert sheet should include the important scientific data, conclusions and information concerning drug safety and efficacy in order to direct the safe and rational use of drugs. The inner label of a drug should bear such information as the drug's name, indication or function, strength, dose and usage, production date, batch number, expiry date and drug manufacturer, and the outer label of a drug should indicate such information as the drug's name, ingredients, description, indication or function, strength, dose and usage, adverse reaction, contraindications, precautions, storage, production date, batch number, expiry date, approval number and drug manufacturer.

Pursuant to the *Measures for the Administration of Pharmaceutical Packaging* (《藥品包裝管理辦法》) which came effective on September 1, 1988, pharmaceutical packaging must comply with the national and professional standards. If no national or professional standards are available, the enterprise can formulate its standards and put into implementation after obtaining the approval of the drug regulatory authorities or bureau of standards at provincial level. The enterprise shall reapply with the relevant authorities if it needs to change its packaging standard. Drugs without packing standards must not be sold or traded (except for drugs for the military).

Pursuant to the *PRC Physicians Law* (《中華人民共和國醫師法》) promulgated by the Standing Committee of the National People's Congress on August 20, 2021 and will come into effect from March 1, 2022, physicians shall adhere to the principle of using medicine in a safe, effective, economical and reasonable manner, follow the drug clinical application guidelines, clinical diagnosis and treatment guide and drug instructions in the use of drugs in an appropriate manner. Under special circumstances where no effective or better treatment is available, the physicians may, upon obtaining the explicit and informed consent of the patients, adopt the drug usage that is not specified in the insert sheets and labels but backed by medical evidence.

LAWS AND REGULATIONS RELATING TO INTELLECTUALPROPERTY PROTECTIONS

Patents

Pursuant to the *PRC Patent Law* (《中華人民共和國專利法》), most recently amended in October 17, 2020 and taking effect from June 1, 2021, and its implementation rules, most recently amended in January 2010, patents in China fall into three categories: invention, utility model and design. Under the currently effective PRC Patent Law, the term of patent protection starts from the date of application. Patents relating to invention are effective for twenty years, and utility model and design patents are effective for ten years from the date of application. The PRC Patent Law adopts the principle of "first-to-file" system, which provides that where more than one person files a patent application for the same invention, a patent will be granted to the person who first files the application.

The newly amended PRC Patent Law introduces patent extensions to patents of new drugs that launched in the PRC, and stipulates that the Patent Administration Department under the

State Council shall, upon request of the patentee, extend the patent term of relevant invention patents of the new drug that is approved to be listed on the market in China, to compensate for the time spent for the review and examination and approval of the listing of a new drug on the market. The compensated extension shall not exceed five years, and the total valid patent term after the new drug is approved for the market shall not exceed 14 years. Such newly adopted patent term extension rule benefits the Company through providing longer protection terms of patents applied or registered in the PRC and related to our product candidates. This rule needs to be further elaborated by the competent authority, and the benefits we could enjoy are subject to the relevant clarifications and explanations.

Moreover, the NMPA and the China National Intellectual Property Administration issued and put into effect the *Implementation Measures for Early Resolution Mechanism of Pharmaceutical Patent Disputes (Trial)* (《藥品專利糾紛早期解決機制實施辦法(試行)》) on July 4, 2021, which sets forth details of how such patent linkage system would be implemented. The system aims to link the marketing approval procedure for generic drugs to the patent protection of brand name drugs to offer relevant parties a way to resolve patent disputes during the marketing review and approval of related drugs. The Measures make provisions on patent information platform construction and information disclosure system, patent right registration system, generic drug patent declaration system, judicial linkage and administrative linkage system, approval waiting period system, drug review and approval classification system and market exclusivity period system for first generic chemical drug, etc.

Trade Secrets

According to the *PRC Anti-Unfair Competition Law* (《中華人民共和國反不正當競爭法》), the term "trade secrets" refers to technical and business information that is unknown to the public, has utility and may create business interests or profits for its legal owners or holders, and is maintained as a secret by its legal owners or holders. Trade secret requirements under the current framework in China is still under development and not robust.

Under the PRC Anti-Unfair Competition Law, which was promulgated on September 2, 1993 and was latest amended on April 23, 2019, business persons are prohibited from infringing others' trade secrets by: (1) acquiring a trade secret from the right holder by theft, bribery, fraud, coercion, electronic intrusion, or any other illicit means; (2) disclosing, using, or allowing another person to use a trade secret acquired from the right holder by any means as specified in the item (1) above; (3) disclosing, using, or allowing another person to use a trade secret in its possession, in violation of its confidentiality obligation or the requirements of the right holder for keeping the trade secret confidential; (4) abetting a person, or tempting, or aiding a person into or in acquiring, disclosing, using, or allowing another person to use the trade secret of the right holder in violation of his or her non-disclosure obligation or the requirements of the right holder for keeping the trade secret confidential. If a third party knows or should have known that an employee or former employee of the right owner of trade secrets or any other entity or individual conducts any of the illegal acts listed above, but still

accepts, publishes, uses or allows any other to use such secrets, this practice will be deemed as an infringement of trade secrets. A party whose trade secrets are being misappropriated may petition for administrative corrections, and regulatory authorities may stop any illegal activities and fine infringing parties in the amount of RMB100,000 to RMB1,000,000, and where the circumstance is serious, the fine will be RMB500,000 to RMB5,000,000. Alternatively, persons whose trade secrets are being misappropriated may file lawsuits in a Chinese court for loss and damages incurred due to the misappropriation.

The measures to protect trade secrets include oral or written non-disclosure agreements or other reasonable measures to require the employees of, or persons in business contact with, legal owners or holders to keep trade secrets confidential. Once the legal owners or holders have asked others to keep trade secrets confidential and have adopted reasonable protection measures, the requested persons bear the responsibility for keeping the trade secrets confidential.

Trademarks

Pursuant to the *Trademark Law of the PRC* (《中華人民共和國商標法》) promulgated by the Standing Committee of the NPC on August 23, 1982 and latest amended on April 23, 2019 and became effective from November 1, 2019, the period of validity for a registered trademark is ten years, commencing from the date of registration. The registrant shall go through the formalities for renewal within twelve months prior to the expiry date of the trademark if continued use is intended. Where the registrant fails to do so, a grace period of six months may be granted. The validity period for each renewal of registration is ten years commencing from the day immediately after the expiry of the preceding period of validity for the trademark. In the absence of a renewal upon expiry, the registered trademark shall be canceled. Industrial and commercial administrative authorities have the authority to investigate any behavior in infringement of the exclusive right under a registered trademark in accordance with the law. In case of a suspected criminal offense, the case shall be timely referred to a judicial authority and decided according to the law.

Domain names

Domain names are regulated under the *Administrative Measures on the Internet Domain Names* (《互聯網域名管理辦法》) issued by the Ministry of Industry and Information Technology, or the MIIT, on August 24, 2017 and effective from November 1, 2017. The MIIT is the main regulatory authority responsible for the administration of PRC internet domain names. Domain name registrations are handled through domain name service agencies established under the relevant regulations, and the applicants become domain name holders upon successful registration.

LAWS AND REGULATIONS RELATING TO FOREIGN INVESTMENT

Foreign Investment

Investment activities in the PRC by foreign investors are principally governed by the *Guidance Catalog of Industries for Foreign Investment* (《外商投資產業指導目錄》), or the Catalog, which was promulgated and is amended from time to time by the Ministry of Commerce, or the MOFCOM and National Development and Reform Commission, or the NDRC. Pursuant to the *Catalog of Industries for Encouraging Foreign Investment (2020)* (《鼓勵外商投資產業目錄(2020年版)》), or the 2020 Catalog, which came to effect from January 27, 2021, *Special Administrative Measures (Negative List) for the Access of Foreign Investment in Pilot Free Trade Zones (2020)* (《自由貿易試驗區外商投資准入特別管理措施(負面清單) (2020年版)》), or the *Negative List in Pilot Free Trade Zones and Special Administrative Measures (Negative List) for the Access of Foreign Investment (2020)* (《外商投資准入特別管理措施(負面清單) (2020年版)》), or the Negative List (2020), all of which shall come into effect on July 23, 2020, industries are divided into two categories: encouraged industries and the industries within the Negative List. The Negative List is further divided into two sub-categories: restricted industries and prohibited industries. Foreign investors are not allowed to invest in industries in the prohibited categories. Investment in restricted fields of investment in the Negative List shall obtain foreign investment access permit. Unless otherwise prescribed by the PRC laws, any industries not falling into any of the encouraged, restricted or prohibited industries set out in the Encouraged Catalog and the Negative List are generally deemed as permitted for foreign investment.

On March 15, 2019, the NPC approved the *Foreign Investment Law of the PRC* (《外商投資法》), or the Foreign Investment Law, which became effective on January 1, 2020 and replaced the three old rules on foreign investment in China, namely, the *PRC Equity Joint Venture Law* (《中外合資經營企業法》), the PRC Cooperation Joint Venture Law (《中外合作經營企業法》) and the *Wholly Foreign-Owned Enterprise Law* (《外資企業法》), together with their implementation rules and ancillary regulations. The Foreign Investment Law establishes the basic framework for the access to, and the promotion, protection, and administration of foreign investments in view of investment protection and fair competition.

On December 26, 2019, the State Council promulgated the *Implementation Rules to the Foreign Investment Law* (《外商投資法實施條例》), which became effective on January 1, 2020. The implementation rules further clarified that the state encourages and promotes foreign investment, protects the lawful rights and interests of foreign investors, regulates foreign investment administration, continues to optimize foreign investment environment, and advances a higher-level opening.

On December 30, 2019, the MOFCOM and the SAMR jointly promulgated the *Measures for Information Reporting on Foreign Investment* (《外商投資信息報告辦法》), which became effective on January 1, 2020. Pursuant to the Measures for Information Reporting on Foreign

Investment, where a foreign investor carries out investment activities in China, the foreign investor or the foreign-invested enterprise shall submit the investment information to the competent commerce department online.

M&A Rules

According to the *Provisions on the Merger or Acquisition of Domestic Enterprises by Foreign Investors* (《關於外國投資者併購境內企業的規定》), or the M&A Rules, which was jointly issued by the MOFCOM, the State-owned Assets Supervision and Administration Commission of the State Council, the State Administration of Taxation of the PRC, or the SAT, the State Administration for Industry and Commerce (now known as the SAMR), China Securities Regulatory Commission, or the CSRC and State Administration of Foreign Exchange, or the SAFE, on August 8, 2006 and latest amended by the MOFCOM on June 22, 2009, application shall be made for examination and approval of the acquisition of any company in China affiliating to a domestic company, enterprise or natural person, which is made in the name of an oversea company established or controlled by such domestic company, enterprise or natural person.

LAWS AND REGULATIONS RELATING TO FOREIGN EXCHANGE

The *PRC Foreign Exchange Administration Regulations* (《中華人民共和國外匯管理條例》) promulgated by the State Council on January 29, 1996, which was latest amended on August 5, 2008, are the principal regulations governing foreign currency exchange in China. Under the PRC foreign exchange regulations, payments of current account items, such as profit distributions and trade and service-related foreign exchange transactions, may be made in foreign currencies without prior approval from the SAFE, by complying with certain procedural requirements. In contrast, approval from or registration with appropriate government authorities or designated banks is required when RMB is to be converted into a foreign currency and remitted out of China to pay capital expenses such as the repayment of foreign currency-denominated loans.

Under current regulations, the capital of a foreign-invested enterprise and capital in RMB obtained by the foreign-invested enterprise from foreign exchange settlement must not be used for the following purposes: directly or indirectly used for the payment beyond the business scope of the enterprises or the payment prohibited by relevant laws and regulations; directly or indirectly used for investment in securities, unless otherwise provided by relevant laws and regulations; extending loans to non-related parties, unless permitted by the scope of business; and/or paying the expenses related to the purchase of real estate that is not for self-use, except for the real estate enterprises.

In 2017, new regulations were adopted which, among other things, relax the policy restriction on foreign exchange inflow to further enhance trade and investment facilitation and tighten genuineness and compliance verification of cross-border transactions and cross-border capital flows.

In 2019, SAFE promulgated *Notice by the State Administration of Foreign Exchange of Further Facilitating Cross-border Trade and Investment* (《關於進一步促進跨境貿易投資便利化的通知》), or the SAFE Circular 28, which canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. If a non-investing foreign-funded enterprise makes domestic equity investment with capital funds obtained from foreign exchange settlement, the investee shall undergo registration formalities for accepting domestic reinvestment and open the "capital account—account for settled foreign exchange to be paid" to receive the corresponding funds according to relevant provisions.

SAFE Circular 37

In July 2014, SAFE promulgated the *Notice of the State Administration of Foreign Exchange on Issues concerning Foreign Exchange Administration of the Overseas Investment and Financing and the Round-tripping Investment Made by Domestic Residents through Special-Purpose Companies*《關于境內居民通過特殊目的公司境外投融資及返程投資外匯管理有關問題的通知》), or the SAFE Circular 37, which replaces the *Notice of the State Administration of Foreign Exchange on Relevant Issues concerning Foreign Exchange Administration for Domestic Residents to Engage in Financing and in Return Investment via Overseas Special Purpose Companies* (《關于境內居民通過境外特殊目的公司融資及返程投資外匯管理有關問題的通知》), or the SAFE Circular 75. SAFE Circular 37 requires PRC residents, including PRC individuals and PRC corporate entities, to register with SAFE or its local branches in connection with their direct or indirect offshore investment activities. SAFE Circular 37 is applicable to our Shareholders who are PRC residents and may be applicable to any offshore acquisitions that we may make in the future.

Employee Stock Incentive Plan

On February 15, 2012, the SAFE promulgated the *Notice of the State Administration of Foreign Exchange on Issues concerning the Foreign Exchange Administration of Domestic Individuals' Participation in Equity Incentive Plans of Overseas Listed Companies* (《國家外匯管理局關于境內個人參與境外上市公司股權激勵計劃外匯管理有關問題的通知》), or the SAFE Circular 7. In accordance with the SAFE Circular 7 and relevant rules and regulations, PRC citizens or non-PRC citizens residing in China for a continuous period of not less than one year, who participate in any stock incentive plan of an overseas publicly listed company, subject to a few exceptions, are required to register with the SAFE through a domestic qualified agent, which could be a PRC subsidiary of such overseas listed company, and complete certain procedures. We and our employees who are PRC citizens or who reside in China for a continuous period of not less than one year and who participate in our stock incentive plan will be subject to such regulation. In addition, the State Taxation Administration, or the STA has issued circulars concerning employee share options or restricted shares. Under these circulars, employees working in the PRC who exercise share options, or whose restricted shares vest, will be subject to PRC individual income tax, or the IIT. The PRC subsidiaries of an overseas listed company have obligations to file documents

related to employee share options or restricted shares with relevant tax authorities and to withhold IIT of those employees related to their share options or restricted shares. If the employees fail to pay, or the PRC subsidiaries fail to withhold, their IIT according to relevant laws, rules and regulations, the PRC subsidiaries may face sanctions imposed by the tax authorities or other PRC government authorities.

LAWS AND REGULATIONS RELATING TO EMPLOYMENT, SOCIAL SECURITY AND HOUSE FUNDS

Labor Protection

Pursuant to the *PRC Labor Law* (《中華人民共和國勞動法》) promulgated by the Standing Committee of the NPC on July 5, 1994 and latest amended on December 29, 2018 and the *PRC Labor Contract Law* (《中華人民共和國勞動合同法》) promulgated by the Standing Committee of the NPC on June 29, 2007 and latest amended on December 28, 2012, employers shall execute written labor contracts with full-time employees. All employers shall comply with local minimum wage standards. Employers shall establish a comprehensive management system to protect the rights of their employees, including a system governing occupational health and safety to provide employees with occupational training to prevent occupational injury, and employers are required to truthfully inform prospective employees of the job description, working conditions, working location, occupational hazards, and status of safe production as well as remuneration and other conditions. Violations of the PRC Labor Contract Law and the PRC Labor Law may result in the imposition of fines and other administrative and criminal liability in the case of serious violations.

Social Insurance and Housing Provident Funds

In addition, according to the *PRC Social Insurance Law* (《中華人民共和國社會保險法 》) promulgated on October 28, 2010 by the Standing Committee of the NPC and latest amended on December 29, 2018, the *Interim Regulations on the Collection and Payment of Social Security Funds* (《社會保險費徵繳暫行條例》) promulgated by the State Council on January 22, 1999 and latest amended on March 24, 2019, and the *Regulations on the Administration of Housing Provident Funds* (《住房公積金管理條例》) promulgated by the State Council on April 3, 1999 and latest amended on March 24, 2019, employers like our PRC subsidiaries in the PRC shall provide employees with welfare schemes covering pension insurance, unemployment insurance, maternity insurance, work-related injury insurance, medical insurance and housing funds. These payments are made to local administrative authorities, and any employer who fails to contribute may be fined and ordered to pay the deficit amount within a stipulated time limit.

LAWS AND REGULATIONS RELATING TO PRC TAXATION

Enterprise Income Tax

Pursuant to the *PRC Enterprise Income Tax Law* (《中華人民共和國企業所得税法》) effective as of January 1, 2008 and latest amended on December 29, 2018, the income tax rate for both domestic and foreign-invested enterprises is 25% with certain exceptions. As for enterprises qualified as "high and new technological enterprises", the applicable income tax rate shall be reduced to 15%. To clarify certain provisions in the PRC Enterprise Income Tax Law, the State Council promulgated the *Implementation Rules of the Enterprise Income Tax Law* (《中華人民共和國企業所得税法實施條例》) on December 6, 2007, it was later amended and the amendment became effective on April 23, 2019. Under the PRC Enterprise Income Tax Law and the Implementation Rules of the PRC Enterprise Income Tax Law, enterprises are classified as either "resident enterprises" or "non-resident enterprises." Aside from enterprises established within the PRC, enterprises established outside of China whose "de facto management bodies" are located in China are considered "resident enterprises" and are subject to the uniform 25% enterprise income tax rate for their global income. In addition, the PRC Enterprise Income Tax Law provides that a non-resident enterprise refers to an entity established under foreign law whose "de facto management bodies" are not within the PRC, but has an establishment or place of business in the PRC, or does not have an establishment or place of business in the PRC but has income sourced within the PRC.

According to the *Notice of the State Administration of Taxation on Delivering the Table of Negotiated Dividends and Interest Rates to Lower Levels* (《關於下發協定股息税率情況一覽表的通知》) issued on January 29, 2008, latest revised on February 29, 2008, and the *Arrangement between Mainland China and the Hong Kong Special Administrative Region for the Avoidance of Double Taxation and Prevention of Fiscal Evasion with Respect to Taxes on Income* (《內地和香港特別行政區關于對所得避免雙重徵税和防止偷漏税的安排》), or Double Tax Avoidance Arrangement, the withholding tax rate in respect of the payment of dividends by a PRC enterprise to a Hong Kong enterprise may be reduced to 5% from a standard rate of 10% if the Hong Kong enterprise directly holds at least 25% of the PRC enterprise and certain other conditions are met, including: (i) the Hong Kong enterprise must directly own the required percentage of equity interests and voting rights in the PRC resident enterprise; and (ii) the Hong Kong enterprise must have directly owned such required percentage in the PRC resident enterprise throughout the 12 months prior to receiving the dividends. However, based on the *Circular on Certain Issues with Respect to the Enforcement of Dividend Provisions in Tax Treaties* (《關於執行税收協定股息條款有關問題的通知》) issued on February 20, 2009 by the SAT, if the relevant PRC tax authorities determine, in their discretion, that a company benefits from such reduced income tax rate due to a structure or arrangement that is primarily tax-driven, such PRC tax authorities may adjust the preferential tax treatment; and based on the *Announcement on Certain Issues with Respect to the "Beneficial Owner" in Tax Treaties* (《關於税收協定中"受益所有人"有關問題的公告》) issued by the SAT on February 3, 2018 and effective from April 1, 2018, if an applicant's business activities do not constitute substantive business activities, it could result in the negative determination of the applicant's status as a

"beneficial owner", and consequently, the applicant could be precluded from enjoying the above-mentioned reduced income tax rate of 5% under the Double Tax Avoidance Arrangement.

According to the EIT Law, the enterprise income tax for key advanced and new technology enterprises supported by the State shall be at a reduced tax rate of 15%.

LAWS AND REGULATIONS RELATING TO ENVIRONMENT PROTECTION AND SAFETY SUPERVISION

Environmental Assessment and Acceptance of Environmental Protection Facilities

Pursuant to the Law of Environmental Impact Assessment of the PRC (《中華人民共和國環境影響評價法》) (Order No. 77 of the PRC President, effective on September 1, 2003 and amended on July 2, 2016, and December 29, 2018 respectively), *Regulations on Environmental Protection Management for Construction Projects* (《建設項目環境保護管理條例》) (Order No. 253 of the State Council, effective on November 29, 1998 and amended on July 16, 2017), where effects may be exerted on the environment after the completion of construction projects, the construction enterprise shall submit an environmental impact report (form) or environmental impact registration form to the relevant environmental protection department. The project that is required to prepare the environmental impact report (form) in accordance with the law shall obtain the approval from the relevant environmental protection department for its environmental impact assessment documents; otherwise it shall not start the construction. After the construction project is completed, the construction enterprise shall apply for environmental protection acceptance of the construction project and make acceptance report pursuant to the standard and formality set by the environmental protection authority.

Pollution Permit

Pursuant to the *Measures for Pollutant Discharge Permitting Administration (for Trial Implementation)*(《排污許可管理辦法(試行)》) (Order No. 48 of the Ministry of Environmental Protection, effective on January 10, 2018 and amended on August 22, 2019), enterprises, institutions and other producers and operators (the "pollutant discharge enterprises") that have been included in the *Classification Administration List of Pollutant Discharge Permitting for Fixed Pollution Sources*（《固定污染源排污許可分類管理名錄》）shall apply for and obtain a discharge permit in accordance with the prescribed time limit. The pollutant discharge enterprises that are not included in the Classification Management List do not need to apply for a pollutant discharge permit. The pollutant discharge enterprise shall hold a pollutant discharge permit in accordance with the law and discharge pollutants in accordance with the discharge permit. Pursuant to the *Notice of the General Office of the State Council on Issuing the Implementation Plan for the Permit System Controlling Pollutant Emission* (《國務院辦公廳關于印發控制污染物排放許可制實施方案的通知》) (No. 81 [2016] of the General Office of State Council, effective on November 10, 2016) and the *Classification Administration List of Pollutant Discharge Permitting for Fixed Pollution Sources (2019 Version)* (《固定污染源排污許可分類管理名錄(2019年版)》) (Order No. 11 of the Ministry of Ecology and Environment,

effective on December 20, 2019), the state implements a focused management, a simplification management and a registration management of emission permits based on the pollutant-discharging enterprises and other manufacturing businesses' amount of pollutants, emissions and the extent of environmental damage.

Safety Management Supervision

Pursuant to the *Law on Work Safety of the PRC* (《中華人民共和國安全生產法》) (Order No. 70 of the PRC President, effective on November 1, 2002 and amended on August 27, 2009 and August 31, 2014 respectively), enterprises engaged in production activities must strengthen safety production management, establish and improve the responsibility system for safe production and ensure a safe production environment. The state establishes and implements a system for the accountability of production safety accidents. If the company fails to comply with the provisions of the Law on Work Safety, the supervisory authority on production safety may issue a rectification order, impose a fine, order the company to cease production and operation, or revoke the relevant permit.

Some chemical materials needed for new drug research and development, such as toluene and hydrochloric acid, are hazardous chemicals. Pursuant to the *Regulations on Safety Management of Hazardous Chemicals* (《危險化學品安全管理條例》) (Order No. 344 of the State Council, effective on March 15, 2002 and amended on March 2, 2011 and December 7, 2013, respectively), the production, storage, use, operation, and transportation of hazardous chemicals must be in accordance with the safety management regulations. The hazardous chemical units shall oblige to the safety conditions required by laws and administrative regulations and state and industry standards, establish and improve safety management rules and post safety responsibility systems, and provide safety education and legal education and occupation technical training for employees. Employees should accept such education and training, and may begin working only after qualifying the relevant assessment. Where it requires employees to have certain qualification to assume a post, an enterprise shall only designated employees having such qualification to assume the post.

Fire Protection

The *Fire Prevention Law of the PRC* (《中華人民共和國消防法》) (the "Fire Prevention Law"), effective in April 1998 and latest amended on April 29, 2021. The Fire Prevention Law provides that fire control design and construction of a construction project shall comply with the State's fire control technical standards for construction projects. Developers, designers, builders, project supervisors, etc shall be responsible for the quality of the fire control design and construction of the construction project pursuant to the law. The construction project fire protection design examination and acceptance system shall be implemented for construction projects which are required to have fire protection design in accordance with the national fire protection technical standards for project construction.