"Xianrui Plan" for Cell and Gene Therapy Medicinal Products (Draft for Comments)[1]

Issuing Authority: Center for Drug Evaluation (CDE), National Medical Products Administration (NMPA)

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I. Background

Cell and gene therapy medicinal products employ cutting-edge technologies in the field of biopharmaceuticals and provide revolutionary therapeutic approaches for many intractable diseases that pose serious threats to human health. However, such medicinal products are characterized by a high degree of innovation, complexity and individualized nature, with multiple targets, novel mechanisms of action, rapidly evolving technologies and numerous change requirements. Throughout their development lifecycle, they present numerous technical challenges in areas including pharmaceutical research, non-clinical studies and clinical trials. Given the lack of mature development and regulatory experience globally, these products pose significant challenges both to sponsors in conducting research and development and to regulatory authorities in conducting regulatory review and approval.

Pursuant to the *Opinions of the General Office of the State Council on Comprehensively Deepening the Reform of Drug and Medical Device Regulation and Promoting the High-Quality Development of the Pharmaceutical Industry* (Guobanfa [2024] No. 53), as well as the relevant requirements articulated at the National Conference on Drug Administration concerning the optimization of review and approval measures for cell and gene therapy medicinal products, the Center for Drug Evaluation, under the direction and guidance of the National Medical Products Administration, has launched the "Xianrui Plan" for Cell and Gene Therapy Medicinal Products in accordance with the principles of early engagement, tailored policies for individual enterprises, end-to-end guidance, and coordinated development and review.

II. Work Objectives

To optimize the review and approval model for cell and gene therapy medicinal products, strengthen support for research and development, improve the quality and efficiency of research and development, facilitate the early marketing of cell and gene therapy medicinal

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products, and provide review and approval support throughout the entire development process.

III. Scope of Products

(1) Scope and Classification of Cell and Gene Therapy Medicinal Products

See the *Technical Guidelines for the Scope and Classification of Cell Therapy Medicinal Products (2026 Edition)* and the *Technical Guidelines for the Scope and Classification of Gene Therapy Medicinal Products (2026 Edition)*.

(2) Scope of Application of the "Xianrui Plan"

1. Innovative medicinal products featuring novel targets or novel mechanisms of action, intended for the prevention or treatment of life-threatening diseases, major chronic diseases (including cardiovascular and cerebrovascular diseases, respiratory diseases, neurodegenerative diseases, metabolic diseases and immune system diseases), or genetic diseases, for which no effective means of prevention or treatment are currently available, or which demonstrate clinical value compared with existing therapeutic options.

Medicinal products featuring a novel target are those that exert a preventive or therapeutic effect against a disease through a target different from that of medicinal products already marketed.

Medicinal products featuring a novel mechanism of action are those that exert a preventive or therapeutic effect against a disease through a mechanism of action different from that of medicinal products already marketed. Examples include achieving more precise targeting, acting through novel signaling pathways, innovatively acting on multiple key targets, and innovatively regulating gene expression through epigenetic mechanisms.

"Clinical value" refers to the presence, prior to submission of a clinical trial application or during the early stages of clinical trials, of data indicating potential clinical benefit; or, where a pivotal registration clinical trial has been completed, data demonstrating a clear clinical advantage.

2. Major changes involving optimization of the manufacturing process of marketed medicinal products.

IV. Organization and Implementation

(1) Application

Applicants may submit an application to join the "Xianrui Plan" through the Applicant Portal by applying for a Type I meeting through the communication and exchange process. The relevant discipline shall be selected from pharmaceutical sciences, pharmacology and toxicology, clinical

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medicine, statistics, and clinical pharmacology. Under the "Meeting Purpose" field, applicants shall enter "Xianrui Plan Application". No other consultation matters shall be combined with the application.

In addition to the general requirements for the submission of materials for communication and exchange meetings under the *Administrative Measures for Communication and Exchange in Drug Research and Development and Technical Review*, applicants shall also submit the *" ianrui Plan" Application Form* (Annex 1) and the *Cell and Gene Therapy Medicinal Product Development Plan* (Annex 2).

(2) Inclusion

The CDE review team shall conduct a comprehensive assessment of applications for the "Xianrui Plan" and, where necessary, convene a communication and exchange meeting and/or an expert consultation meeting. Where, following assessment, the medicinal product falls within the scope of products eligible for the "Xianrui Plan", and the submitted *Cell and Gene Therapy Medicinal Product Development Plan* is considered reasonable, scientifically sound and feasible, the medicinal product shall be included in the Plan.

For medicinal products proposed for inclusion following assessment, the CDE shall publish the relevant information for a public notice period of five working days. The public notice shall include the medicinal product name, applicant, indication, and category (novel target, novel mechanism of action, or major change involving optimization of the manufacturing process of a marketed medicinal product).

Medicinal products for which no objections are raised during the public notice period shall be included in the "Xianrui Plan".

A maximum of 15 medicinal products may be included in the Plan each year.

Where the same medicinal product applies for inclusion in the Plan multiple times under the category of "major change involving optimization of the manufacturing process of a marketed medicinal product", it shall be counted as one medicinal product.

(3) Implementation

The management pathway for medicinal products included in the Plan shall follow the applicable laws and regulations and current working procedures. In addition, the following support measures shall be provided:

1. Communication and Exchange

For medicinal products included in the Plan, the CDE shall continuously monitor their development progress, proactively address their needs, and provide technical support throughout the entire development process. At key stages, including prior to the submission

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of a clinical trial application, prior to a confirmatory clinical trial, and prior to the submission of a marketing authorization application, applicants may apply for communication and exchange through a Type I meeting.

2. Early Acceptance Support

Applicants for medicinal products included in the Plan may apply to the CDE or a sub-center for early acceptance support in relation to application acceptance.

3. Review Timeline for Post-Marketing Changes

For a supplemental application involving a "major change involving optimization of the manufacturing process of a marketed medicinal product" that has been included in the Plan, the explanatory letter accompanying the submission dossier shall specify the relevant details of its inclusion in the Plan, including the communication and exchange meeting number, the date of the public notice of inclusion in the Plan, and the outcome thereof.

The review timeline shall be governed by the *NMPA Announcement on Matters Concerning the Optimization of the Review and Approval of Cell and Gene Therapy Medicinal Products*.

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