**TIANJIN PHARMACEUTICAL DA REN TANG GROUP CORPORATION LIMITED**
(Formerly known as Tianjin Zhong Xin Pharmaceutical Group Corporation Limited)
(Incorporated in the People's Republic of China)
(Company Registration No.: 91120000103100784F)

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**ANNOUNCEMENT ON RECEIPT OF DRUG REGISTRATION CERTIFICATE BY XINXIN PHARMACEUTICAL PLANT (新新制药厂) OF THE COMPANY**

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***The board of directors (the "Board") and every individual director of Tianjin Pharmaceutical Da Ren Tang Group Corporation Limited (formerly known as Tianjin Zhong Xin Pharmaceutical Group Corporation Limited) (the "Company") hereby confirm that they will individually and collectively accept full responsibility for the accuracy of the information given in this announcement, and confirm, having made all reasonable enquiries, that to the best of their knowledge and belief, the facts stated in this announcement are fair and accurate in all material respects as at the date of this announcement, and that there are no material facts the omission of which would make any statement in this announcement misleading.***

## 1. INTRODUCTION

The Board wishes to announce that Xinxin Pharmaceutical Plant (新新制药厂), a branch of the Company, has recently received a Drug Registration Certificate (《药品注册证书》) (the "**Drug Registration Certificate**") issued by the National Medical Products Administration of the People's Republic of China (国家药品监督管理局) in respect of Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (I) (沙格列汀二甲双胍缓释片（Ⅰ）) (the "**Drug**"). The key details of the Drug Registration Certificate and the other relevant information relating to the Drug are set out in **Appendix A** to this announcement.

## 2. IMPACT ON THE COMPANY

The Company places great emphasis on pharmaceutical research and development ("**R&D**") and exercises strict quality and safety controls throughout the R&D, production and sale of pharmaceutical products. The Drug was submitted for registration as a Category 4 chemical drug. Upon approval, the Drug is deemed to have passed the quality and efficacy consistency evaluation. The approval for registration of the Drug, which signifies that it meets the relevant requirements for drug registration, is not expected to have a material impact on the Company's short-term financial performance.

## 3. CAUTION IN TRADING

**There may be uncertainties during the period from the marketing approval of the Drug to its actual production and sale. Factors such as national policies and market conditions may affect the scale of future production and sales of the Drug.**

**Shareholders and potential investors are advised to exercise caution when trading in the shares of the Company.**

**By Order of the Board**

Jiao Yan
Secretary to the Board of Directors
7 August 2026

**APPENDIX A**

## 1. Key Details of the Drug Registration Certificate
## 一、药品注册证书的主要内容

| | | |
|---|---|---|
| Drug Name<br>药品名称 | : | Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (I)<br>沙格列汀二甲双胍缓释片（Ⅰ） |
| Dosage Form<br>剂型 | : | Tablets<br>片剂 |
| Specification<br>规格 | : | Each tablet contains 5 mg of Saxagliptin and 1,000 mg of Metformin Hydrochloride<br>每片含沙格列汀 5mg 与盐酸二甲双胍 1000mg |
| Registration Classification<br>注册分类 | : | Class 4 Chemical Drug<br>化学药品 4 类 |
| Application Number<br>受理号 | : | CYHS2403931; CYHB2600835 |
| Certificate Number<br>证书编号 | : | 2026S02599 |
| Marketing Authorisation Holder<br>上市许可持有人 | : | Xinxin Pharmaceutical Plant of Tianjin Pharmaceutical Da Ren Tang Group Corporation Limited<br>津药达仁堂集团股份有限公司新新制药厂 |
| Manufacturer<br>生产企业 | : | Jiangsu Yongan Pharmaceutical Co., Ltd.<br>江苏永安制药有限公司 |
| Drug Registration Standard Number<br>药品注册标准编号 | : | YBH20772026 |
| Application Type<br>申请事项 | : | Drug Registration (Domestic Manufacture)<br>药品注册 (境内生产) |
| Drug Approval Number<br>药品批准文号 | : | National Medical Products Administration Approval No. (known as “Guo Yao Zhun Zi” in Chinese regulatory terminology) H20265242<br>国药准字 H20265242 |
| Validity Period of the Drug Approval Number | : | Until 20 July 2031<br>至 2031 年 7 月 20 日 |



***Disclaimer:*** *The English version of the key details of the Drug Registration Certificate and other relevant information relating to the Drug set out in this Appendix A has been translated from the original Chinese text for reference only. In the event of any discrepancy, conflict or inconsistency between the English and Chinese versions, the Chinese version shall prevail.*

药品批准文号有效期

| | | |
|---|---|---|
| Approval Conclusion<br>审批结论 | : | Pursuant to the applicable laws and regulations, including the *Drug Administration Law of the People's Republic of China (《中华人民共和国药品管理法》)*, and upon review, this drug meets the relevant requirements for drug registration. Approval is hereby granted for registration. The quality standards, package insert, labeling, and manufacturing process shall be implemented in accordance with the approved versions attached to this certificate. The drug manufacturing enterprise shall comply with Good Manufacturing Practice (GMP) requirements before commencing production and sale.<br>根据《中华人民共和国药品管理法》及有关规定，经审查，本品符合药品注册的有关要求，批准注册，发给药品注册证书。质量标准、说明书、标签及生产工艺照所附执行。药品生产企业应当符合药品生产质量管理规范要求方可生产销售。 |

**2. Other Relevant Information on the Drug**
**二、药品的其他相关情况**

The Drug (i.e. Saxagliptin and Metformin Hydrochloride Sustained-release Tablets (I)) is indicated, as an adjunct to diet and exercise, for the improvement of glycaemic control in adult patients with type 2 diabetes mellitus who are suitable for treatment with saxagliptin and metformin (see the package insert for details). The Drug was jointly developed by Bristol Myers Squibb and AstraZeneca and has broad market potential in the areas of long-term glycaemic control and chronic disease management for patients with type 2 diabetes mellitus. According to data from the Menet database, sales of the Drug in China have recorded significant growth in recent years. Total sales in China amounted to approximately RMB480 million in 2025, representing an increase of approximately 33% as compared with 2024.
沙格列汀二甲双胍缓释片(Ⅰ)，本品配合饮食和运动治疗, 适合使用沙格列汀和二甲双胍治疗的 2 型糖尿病成人患者，以改善此类患者的血糖控制（详见说明书）。本品由百时美施贵宝与阿斯利康合作开发，在 2 型糖尿病长期血糖控制及糖尿病慢病管理领域具有广阔的市场应用前景。根据米内数据库显示，沙格列汀二甲双胍缓释片(Ⅰ)销量近年来始终保持显著增速，2025 年国内总销售额约为 4.8 亿元，同比 2024 年增长约 33%。

The Drug is a compound oral sustained-release formulation involving relatively complex technical requirements, and its research and development involves key technical processes, including the control of the release profiles of multiple active ingredients, the optimisation of formulation and manufacturing processes, and quality control throughout the entire process. Accordingly, the Drug is generally subject to a relatively lengthy regulatory review and approval process. The Company has an established presence in the field of endocrine and metabolic diseases, with traditional Chinese medicine products supported by a solid evidence base, including Jinqi Jiangtang Tablets. The introduction of the Drug, as a sustained-release chemical drug, is expected to complement the Company's existing traditional Chinese medicine products and strengthen its product portfolio comprising evidence-based traditional Chinese medicine products and chemical drugs for targeted glycaemic control. Going forward, the Company intends to leverage its clinical experience in traditional Chinese medicine in the field of endocrine and metabolic diseases and the technical advantages of sustained-release chemical formulations,

explore the clinical value of the combined use of traditional Chinese and Western medicines, and provide more diversified and comprehensive blood glucose management options for clinical use.
沙格列汀二甲双胍缓释片（Ⅰ）属于具有较高技术要求的复方口服缓释制剂，其研发涉及多组分药物释放行为控制、工艺优化攻关及全过程质量控制的关键技术环节，审评审批周期较长。公司在内分泌代谢领域已拥有金芪降糖片等循证基础扎实的中药品种。本次化药缓释制剂的落地，将与公司现有中药产品形成有效互补，构建起“中药循证+化药精准控糖”的产品矩阵。未来，公司将依托在内分泌代谢领域的中药临床积淀，充分发挥化药缓释制剂的技术优势，积极探索中西药联合用药的临床价值，为临床提供多元化的血糖管理综合选择。