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Hangzhou Diagens Biotechnology Co., Ltd.

杭州德適生物科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2526)

VOLUNTARY ANNOUNCEMENT

THE COMPANY'S CORE PRODUCT, AI AUTOVISION®, RECEIVED CLASS III MEDICAL DEVICE REGISTRATION CERTIFICATE FROM NATIONAL MEDICAL PRODUCTS ADMINISTRATION

This announcement is made by Hangzhou Diagens Biotechnology Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company of the latest business updates of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that on May 20, 2026, AI AutoVision®, the Company's Core Product, received the Class III Medical Device Registration Certificate from the National Medical Products Administration of China. The approved indications under such certificate cover chromosome karyotype analysis for (i) prenatal diagnosis for birth defects using amniotic fluid samples; and (ii) assisted reproduction using peripheral blood samples.

AI AutoVision® is an intelligent chromosome karyotype analysis product built on iMedImage®, the Group's medical imaging large model. The product is capable of assisting with chromosome segmentation, counting and arrangement, and provides abnormality-recognition alerts to assist physicians in clinical diagnosis.

To the best knowledge of the Board and based on the information currently available to the Company, the aforesaid registration certificate represents the world's first Class III medical device registration certificate for L3 chromosome karyotype analysis with abnormality-recognition capability. It is also the first medical device registration certificate obtained on the basis of large model technology. The Board believes that the receipt of the certificate reflects regulatory authority's recognition of the safety, effectiveness and clinical application value of medical imaging large model technology of iMedImage® in medical devices.

The aforesaid registration certificate marks a significant regulatory milestone for AI AutoVision® and lays the foundation for commercialization of the Core Product within the approved indications. The Group believes that the approval will further strengthen its leading position in AI-powered medical imaging and intelligent chromosome analysis, and will support the Group in accelerating market access, hospital deployment and clinical adoption in compliance with applicable laws and regulations.

Shareholders and potential investors of the Company are advised to exercise caution when dealing in the securities of the Company.

By Order of the Board
Hangzhou Diagens Biotechnology Co., Ltd.
Dr. Song Ning

Chairman of the Board, Executive Director and General Manager

Hangzhou, PRC, May 22, 2026

As of the date of this announcement, the Board comprises: (i) Dr. Song Ning and Mr. Weng Chih-Hsin (alias Robin Weng) as executive Directors; (ii) Dr. Xu Chen, Dr. Wu Lingqian and Mr. Yang Zehao as non-executive Directors; and (iii) Mr. Cha Yang (alias Stanley Cha), Ms. Zhang Jing and Mr. Wang Kaifeng as independent non-executive Directors.