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人工》 艾美疫苗

AIM Vaccine Co., Ltd. 艾美疫苗股份有限公司

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

(Stock Code: 06660)

VOLUNTARY ANNOUNCEMENT UNBLINDING OF DATA FROM PHASE III CLINICAL TRIAL OF ITERATIVE SERUM-FREE RABIES VACCINE: PRE-DEFINED CLINICAL OBJECTIVES MET WITH GOOD IMMUNOGENICITY AND SAFETY

This announcement is made by AIM Vaccine Co., Ltd. (the "Company", together with its subsidiaries, the "Group") on a voluntary basis to inform shareholders and potential investors of the Company of the latest business developments of the Group.

The board of directors of the Company (the "Board") is pleased to announce that the Group has recently received a notice from the National Institutes for Food and Drug Control of the PRC (中國食品藥品檢定研究院) on the serum antibodies test results of Phase III clinical trial of iterative serum-free rabies vaccine. To date, the unblinding and statistical analysis work for data of Phase III clinical trial of the iterative serum-free rabies vaccine of the Group has been completed. The research results showed that the iterative serum-free rabies vaccine developed by the Group has good immunogenicity and safety and has met the pre-defined clinical objectives.

Completely unlike the existing Vero cell rabies vaccine containing serum and human diploid rabies vaccine containing serum, the iterative serum-free rabies vaccine is an iterative upgraded product. Animal serum residues in vaccine products are one of the important factors leading to adverse reactions such as allergies in vaccinated populations, and the iterative serum-free rabies vaccine developed by the Group does not contain animal serum, which significantly improves safety and reduces the probability of adverse reactions. To date, there is no serum-free rabies vaccine that has been approved for launch in the global market, and this product is expected to be the first one on the market.

The Group has completed the construction of the workshops for iterative serum-free rabies vaccine, which have sufficient production capacity and meet international standards. As the second largest supplier of rabies vaccines globally, the Group spearheads the in-depth technological iteration of rabies vaccines in the world, and will offer rabies vaccine products with better quality and higher safety in the market after the iterative serum-free rabies vaccines are marketed, so that new quality productivity will be achieved in the industry.

Currently, the Group has completed the preliminary work for marketing registration and has conducted process validation in the GMP workshop that meets the scale and quality requirements for marketing. The results of pre-testing for drug registration also met quality standards. The Group is actively working on obtaining the clinical summary report. According to the relevant national regulations relating to the drug registration administration, after obtaining the clinical study summary report of the vaccine and carrying out the process validation in a GMP workshop in compliance with the scale and quality requirements for marketing, enterprises may submit the application for drug marketing registration to the National Medical Products Administration (NMPA). The Group will submit the application for marketing registration as soon as possible.

By order of the Board
AIM Vaccine Co., Ltd.
Mr. Yan ZHOU

Chairman of the Board, Executive Director and Chief Executive Officer

Hong Kong, October 6, 2024

As at the date of this announcement, the Board of the Company comprises Mr. Yan ZHOU, Mr. Xin ZHOU, Mr. Wen GUAN, Mr. Shaojun JIA and Mr. Jie ZHOU as executive directors; Mr. Jichen ZHAO and Ms. Aijun WANG as non-executive directors; and Professor Ker Wei PEI, Mr. Hui OUYANG, Ms. Jie WEN and Mr. Xiaoguang GUO as independent non-executive directors.