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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
PRE-APPLICATIONS FOR CLINICAL TRIALS FOR MRNA RSV AND
MRNA SHINGLES/HERPES ZOSTER VACCINES OF AIM VACCINE
SUBMITTED TO FDA

This announcement is made by AIM Vaccine 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 developments of the Group.

Following the established corporate strategy, the Group proactively advances the development of the vaccine product pipelines, and leverages the advantages of the mRNA technology platform to accelerate the research and development of mRNA vaccine series products through on-going technological innovation. In August 2024, the Group has submitted pre-applications for clinical trials for mRNA RSV (respiratory syncytial virus) vaccines and mRNA shingles/herpes zoster vaccines to the U.S. Food and Drug Administration (“**FDA**”).

In June 2024, pre-applications for clinical trials for the above two mRNA vaccines were submitted to the Center for Drug Evaluation (CDE) of National Medical Products Administration.

The submission of pre-applications for clinical trials to the U.S. FDA was based on the Group’s internationalization strategy, as well as the favorable data demonstrated by the two mRNA vaccines in animal tests as compared with commercially available control vaccines. The submission not only demonstrated the strength of the Group’s mRNA technology platform, but also marked a solid step forward by the Group in the field of global health.

Should the two mRNA vaccines pass the rigorous review and obtain approval of the FDA, they will not only obtain the endorsement of an authoritative international organization, which will provide stronger proof of their safety and efficacy, but will also receive a permit to accelerate their clinical trials in a number of countries and regions around the world. This move will greatly facilitate the globalization of the Group’s products and enable the Group to rapidly respond to global public health needs.

Currently, no mRNA shingles/herpes zoster vaccine has been approved for marketing in the world and no RSV vaccine has been approved for marketing in China. The Group has now smoothed the whole life cycle process such as the research, development and production of mRNA vaccines. After obtaining clinical approvals, we can quickly industrialize the mRNA vaccine products and accelerate the commercialization process of the vaccine products, which will help to further realize our mission to develop and manufacture top quality vaccines to safeguard the health of the world.

1. About mRNA RSV Vaccine

RSV, a common respiratory tract infection pathogen, is highly contagious and widely prevalent worldwide. RSV infection is an important cause of death in infants under one year old and also an important factor in the death of respiratory tract infections in the elderly. Meanwhile, people who have been infected with RSV previously are still at risk of being reinfected with RSV. At present, there is no approved antiviral drug specifically for RSV that is available for clinical use worldwide. Therefore, the prevention of RSV has become an important strategy to resist the health threat from RSV, and vaccination for active immune prophylaxis is an effective means to avoid severe RSV infection. No RSV vaccine has been approved for marketing in China, and now there are two RSV vaccines from GlaxoSmithKline and Pfizer on the global market. In 2023, the global sales of RSV vaccines reached US\$2.46 billion. According to the forecast of China Insights Industry Consultancy Limited, an industry consultant, it is expected that the global market size of RSV vaccines will reach approximately US\$16.7 billion by 2030. Furthermore, Moderna also announced that its mRNA RSV vaccine (mRESVIA) had obtained approval for marketing from the FDA recently, which was the second commercialized mRNA vaccine in the world and further promoted the application of mRNA technologies in the research and development of non-COVID-19 vaccines. Also, RSV vaccine is expected to become a heavyweight product in the field of mRNA vaccines.

2. About mRNA Shingles/Herpes Zoster Vaccine

The distinctiveness of shingles/herpes zoster virus lies in its lifelong latency after primary infection and absolute immune protection mediated by T cells. The shingles/herpes zoster vaccines mainly reduce the risk of shingles/herpes zoster by increasing the level of specific T-cell-mediated immune response, preventing the reactivation of the virus and controlling the intracellular infection of the virus. This matches with the advantages of the mRNA vaccine, i.e., the ability to effectively induce T-cell responses without the addition of adjuvants and without the safety risks associated with adjuvants. Currently, the vaccination rate of shingles/herpes zoster vaccines in the target population is only about 0.1%, and no mRNA shingles/herpes zoster vaccines have been approved for marketing in China, leaving much room for improvement. According to the forecast of China Insights Industry Consultancy Limited, an industry consultant, it is expected that the market size of shingles/herpes zoster vaccines in China will reach approximately RMB20.0 billion and the global market size will reach approximately US\$23.9 billion by 2030.

3. About the Group's mRNA Technology Platform

The Group is one of the enterprises that take the lead in developing mRNA vaccine products in China, and also one of the first batch of domestic vaccine enterprises that have obtained an independent patent for mRNA technology. The Group has a mature mRNA vaccine research and development system and has developed several mRNA vaccine candidates (including but not limited to mRNA rabies vaccine, mRNA RSV vaccine and mRNA shingles/herpes zoster vaccine, etc.). Meantime, the Group has established a sound quality management system for mRNA vaccines and a commercial-scale production workshop in line with GMP standards, and vaccines produced on the Group's mRNA technology platform have also been verified by clinical trials. The Group has now smoothened the whole life cycle process such as the research, development and production of mRNA vaccines, allowing for rapid achievement of the industrialization of mRNA vaccine products after obtaining clinical approval and accelerating the commercialization process of vaccine products. In the future, the Group will continue to focus on the key technologies of the mRNA platform, and on this basis, rapidly advance the research and development and registration of new products. The Group will focus on addressing the unmet clinical needs in core disease areas and continue boosting the Company's innovation capabilities, core competitiveness, and overall strength.

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

*Chairman of the Board, Executive Director
and Chief Executive Officer*

Hong Kong, August 29, 2024

As at the date of this announcement, the Board of Directors 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.