Grand Pharmaceutical Group Limited
遠大醫藥集團有限公司*
(Incorporated in Bermuda with limited liability)
(Stock Code: 00512)

VOLUNTARY ANNOUNCEMENT

THE INVESTIGATIONAL NEW DRUG APPLICATION IN CHINA OF THE GROUP'S GLOBAL INNOVATIVE THERAPEUTIC TUMOR VACCINE ARC01 WAS APPROVED BY NMPA

This announcement is made by the board of directors (the "**Board**") of Grand Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis.

The Board is pleased to announce that the Investigational New Drug ("**IND**") application of ARC01 (A002), a therapeutic tumor vaccine of the Group's subsidiary Nanjing AuroRNA Biotech Co., Ltd. ("**AuroRNA Biotech**") for human papillomavirus type 16 ("**HPV-16**")-positive late-stage unresectable or recurrent/metastatic solid tumors, has been approved by the National Medical Products Administration of the People's Republic of China ("**NMPA**"). The study is an open-label, dose-escalating Phase I clinical study, planning to enroll no more than 42 subjects to evaluate the safety, tolerability, immunogenicity, pharmacokinetic characteristics and effectiveness of ARC01 in the treatment of Chinese subjects with HPV-16-positive late-stage unresectable or recurrent/metastatic solid tumors.

ARC01 is the first mRNA therapeutic tumor vaccine that has been approved to conduct clinical trials in China, and its drug registration classification is Class 1 therapeutic biological products. Through liposome nanoparticle ("**LNP**") delivery technology, the mRNA of E6 and E7 antigens in encoding HPV-16 is transfected in autologous cells, and the corresponding antigens are translated. Under the combined action of immune adjuvants TriMix®, the body is stimulated to produce specific humoral immunity and cellular immunity, thereby achieving the anti-tumor effect. Among them, LNP delivery technology and TriMix® adjuvant technology are exclusive patented technologies that can significantly enhance the body's immune response, thereby improving the immunotherapy effect of the vaccine.

HPV is an epitheliotropic non-enveloped double-stranded circular DNA virus, and can cause proliferative lesions of human skin and mucous membranes. Among which, persistent infection with high-risk HPV can cause precancerous lesions in the cervix, vagina, vulva, anus, penis, head and neck and other parts of the body, and the lesions can eventually develop into invasive cancer. According to statistics, 5% of current cancers in the world are directly or indirectly related to HPV infection. Among them, almost 100% of cervical cancer, 88% of anal cancer, 78% of vaginal cancer, 50% of penile cancer and other tumors are related to high-risk HPV infection. While among all cancers caused by HPV, HPV-16 infection predominates. The global HPV infection rate among healthy people is about 11.7%, with HPV-16 infection rate ranking the first. In recent years, although preventive HPV vaccines have brought a lot of help to the prevention and treatment of HPV-related diseases, but it is still unable to cure confirmed infections. For cancer caused by HPV infection, current clinical treatments mainly include surgery, radiotherapy and chemotherapy. However, traditional treatment methods have the disadvantages of being harmful to patients and prone to recurrence. mRNA therapeutic tumor vaccines are expected to provide doctors and patients with a new and better treatment method.

AuroRNA Biotech is the Group's global innovative mRNA technology platform. Relying on mature mRNA production technology, stable and efficient LNP delivery technology and safe TriMix® adjuvant technology, it has established a widely applicable and scalable R&D platform for the research and development of tumor immunotherapy and infectious disease vaccines related products. The approval of the IND for ARC01 is a significant progress for the Group in the field of mRNA tumor treatment.

The Group always puts focus on the R&D of innovative products and advanced technologies. Adhering to a patient-centered and innovation-driven approach, the Group will continue to increase its investment in world-class innovative products and advanced technologies to meet unmet clinical needs and enrich its product pipeline and improve supply chain. The Group adopts the strategy of "global expansion and dual-cycle operation", forming a new pattern of domestic and international cycles that synergize with each other. In this way, the Group can make full use of its industrial advantages and R&D capabilities, to accelerate the commercialization process for innovative products and provide patients with more advanced and diverse treatment options globally.

Warning:

The aforementioned product is still in the R&D stage. The approval of commercialization, manufacturing and sale of such product is subject to various factors with uncertainty. Shareholders and prospective investors of the Company are advised to exercise caution when dealing in the securities of the Company.

By order of the Board
Grand Pharmaceutical Group Limited
Chairman
Dr. Tang Weikun

Hong Kong, 24 January 2024

As at the date of this announcement, the Board comprises four executive directors, namely, Dr. Tang Weikun, Mr. Zhou Chao, Dr. Shi Lin and Mr. Yang Guang, and three independent nonexecutive directors, namely, Ms. So Tosi Wan, Winnie, Dr. Pei Geng and Mr. Hu Yebi.

** For identification purpose only*