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Company Name: AnGes Inc.

Presentative: Ei Yamada, President & CEO

AnGes Announces Discontinuation of Development of DNA Vaccine for Original Wuhan Strain of COVID-19 and Start of Research into Improved DNA Vaccine for COVID-19 Variants and Formulation for its Intranasal Delivery

AnGes, Inc. hereby announces that it has decided to discontinue the development of a DNA vaccine for the original Wuhan strain of COVID-19 it had previously been working on ("initial vaccine") and to start researching an improved DNA vaccine that is also effective in treating COVID-19 variants (Omicron BA.5, etc.) as well as a formulation for its intranasal delivery. Details are as follows.

1. Background to the development of DNA vaccine for original Wuhan strain of COVID-19

In March 2020, we decided to use our DNA plasmid technology to develop a DNA vaccine for the original Wuhan strain of COVID-19. We began conducting a non-clinical trial for the initial vaccine from March 2020 and proceeded with its development with a Phase 1/2 Clinical Trial and a Phase 2/3 Clinical Trial. However, in November 2021, we came to the conclusion that the initial vaccine was unlikely to have the expected effect.

Meanwhile, since August 2021, AnGes has also been conducting a Phase 1/2 Clinical Trial using a vaccine with a higher drug concentration than the initial vaccine (hereinafter referred to as the "high-concentration vaccine").

2. Discontinuation of development of DNA vaccine for the original Wuhan strain of COVID-19

We have now completed administration for the Phase 1/2 Clinical Trial using the high-concentration vaccine and are in the process of organizing and analyzing the data.

Whilst further time is needed to determine the final results of the clinical trial of this high-concentration vaccine, but preliminary data from the clinical trial confirm its safety. However, although the high-dose formulation had enhanced immunogenicity compared to the initially developed early vaccine, the primary endpoints of neutralizing activity against SARS-CoV-2 pseudovirus at 12 weeks and SARS-CoV-2 spike (S)-glycoprotein-specific antibody titer at 12 weeks were not reached at the expected levels in either the intramuscular or intradermal vaccination groups. Based on these results, AnGes decided to discontinue development of the initial vaccine including the high-concentration vaccine targeting the original Wuhan strain of COVID-19.

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3. Research into improved DNA vaccine for COVID-19 variants and a formulation for its intranasal delivery

In response to the situation described in 2. above, AnGes decided to leverage the knowledge of research and development gained thus far to review its platform, including improving plasmid expression efficiency and transfer efficiency, and at the same time to start research into an improved DNA vaccine that is also effective against the most recent Omicron strain of COVID-19 (BA.5, etc.) in anticipation of new strains that might emerge in the future.

Furthermore, AnGes decided to start research into an intranasal formulation of the vaccine which will induce a broader immune response, potentially preventing multiplication of the virus and impeding its spread with respect to viral lung diseases. By researching and developing the improved DNA vaccine and a formulation for its intranasal delivery, we aim to deliver a safe preventive DNA vaccine and a method for its administration.

We intend to announce details of our research into an intranasal formulation of the improved DNA vaccine separately.

4. Future outlook

We previously received subsidies for our development of the initial vaccine under the "Drug Discovery Support Promotion Project - Vaccine Development Against Novel Coronavirus Infectious Disease (COVID-19)" and the Vaccine Development Promotion Project implemented by The Japan Agency for Medical Research and Development (AMED) and the Vaccine Production System Urgent Development Project implemented by the Ministry of Health, Labour and Welfare. These subsidies are recorded in "Advances Received" under liabilities on the balance sheet at the time of payment. Advances received as of the end of the second quarter of the fiscal year ending December 2022 amounted to 5,764 million yen. After recording this subsidy as an advance payment, our company reports the details of the expenses used in the development of the vaccine, and the report is investigated every fiscal year, and the vaccine development expenses recognized as appropriate are transferred to the subsidy income of non-operating income. Subsidies for vaccine development to be provided to our company have already been paid, and with regard to subsidies already recorded in advance payments, the costs of vaccine development deemed appropriate based on future declarations and investigations will be recorded as subsidy income for each research year. Following the discontinuation of the initial vaccine development, the joint research on the initial vaccine with Osaka University, Takara Bio Inc., Daicel Corp., EPS Group, FanPep Co., Ltd., Peptide Institute Inc., Shin Nippon Biomedical Laboratories, Ltd., Human Metabolome Technologies Inc., Future Corp., 3D-Matrix, Ltd., AGC Biologics, Cytiva, Shionogi Pharma Co., Ltd., Kaneka Eurogentec and Brikell Biotech will also be terminated.

However, for the time being we plan to use cash on hand to cover the cost of research into the improved vaccine and a formulation for its intranasal delivery, given that this research is in the initial stages, and will consider funding based on an assessment of the progress of our research and

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development.

The impact that discontinuation of development of the initial vaccine and the research on the improved DNA vaccine and its intranasal formulation on our consolidated business results and financial position for the current consolidated fiscal year is difficult to predict at this time because the details, such as the extent to which vaccine development expenses will be recognized during the current fiscal year out of the subsidy recorded as an advance payment as described above, have not yet been determined. The details of the grant, including the extent to which vaccine development expenses will be recognized during the current fiscal year, have not yet been determined, and it is difficult to foresee the impact at this point in time. Based on future progress, we will promptly disclose such information as soon as a reasonable calculation becomes possible.

AnGes, Inc.
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