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Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

Novel Coronavirus (COVID-19) DNA Vaccine: Results of Phase 1/2 and Phase 2/3 Clinical Trials

November 5, 2021 - AnGes, Inc. (hereafter, AnGes) today announced the results of a series of clinical trials conducted since 2020 on the novel coronavirus (COVID-19) DNA vaccine as follows. In each of the clinical trials, the safety of the vaccine was confirmed. As for the efficacy, although cellular immune response was confirmed to some extent, humoral immune response, a primary endpoint, observed was not as much as expected. AnGes will hereafter focus on a clinical trial of a high-concentration (high-conc.) vaccine, which already started in August 2021, as an effort to further improve efficacy.

<Phase 1/2 Clinical Trial of COVID-19 DNA Vaccine (1) Overview>
Study design: An open-label, non-controlled study to evaluate the safety and immunogenicity of the intramuscular DNA vaccine injection in healthy adult volunteers
Target enrollment: 30 participants
Administration: Intramuscular injection
Results: No safety issues were observed. Although induction of humoral immune response was observed in some subjects as efficacy, it was not as much as expected. AnGes decided to proceed further development with an improved vaccine.

<Phase 1/2 clinical trial of COVID-19 DNA vaccine (2) Overview>
Study design: An open-label, non-controlled study to evaluate the safety and immunogenicity of the intramuscular DNA vaccine injection in healthy adult volunteers
Target enrollment: 30 participants
Administration: Intramuscular injection
Results: There were no safety issues. We confirmed cellular immune response to some extent as efficacy. Although induction of humoral immune response was observed in some subjects, AnGes judged it is necessary to confirm this in a larger-scale trial.

<Phase 2/3 Clinical Trial of COVID-19 DNA Vaccine Overview>
Study design: A randomized, double-blind, placebo-controlled study to evaluate the safety and immunogenicity of the intramuscular DNA vaccine injection in healthy adult volunteers
Target enrollment: 500 participants
Administration: Intramuscular injection
Results: There were no safety issues. We confirmed cellular immune response to some extent as efficacy. Although induction of humoral immune response was observed in some subjects, it was not as much as expected, leading AnGes to address further improvement in efficacy.

In order to enhance efficacy, AnGes started Phase 1/2 clinical trial in August 2021 using the high-conc. DNA vaccine as follows.

<Phase 1/2 Clinical Trial of COVID-19 High-Conc. DNA Vaccine>

Study design: A randomized, open-label study to evaluate the safety and immunogenicity of the high-conc. DNA vaccine in healthy adult volunteers

Target enrollment: 400 participants

Administration	Intramuscular			Intradermal	
Dose	2mg	4mg	8mg	1mg	1mg
Frequency	2 wks. interval 3 times	4 wks. interval 2 times	4 wks. interval 2 times	2 wks. interval 3 times	4 wks. interval 2 times
Total dose	6mg	8mg	16mg	3mg	2mg
Target enrollment	80	80	80	80	80

Number of clinical trial sites: 6 sites in Kansai and Kanto area

This research is supported by the Japan Agency for Medical Research and Development (AMED) under the Vaccine Development Support Project "Clinical Development of DNA Vaccines Targeting Novel Coronavirus (COVID-19)".

＜About the novel coronavirus DNA vaccine>

The novel coronavirus DNA vaccine produces antibodies against pathogens by inoculating circular DNA (plasmid) that encodes a part of the virus protein in the body, and induce the immune-response against target SARS-CoV-2.　By producing antibodies in the body that recognize antigens (foreign substances recognized by the body's immune system) as part of the structure of the virus, resisting power to the virus is created to exert the effect. We are proceeding the research and development of DNA vaccines by based on the experience on the development of HGF gene therapy product using plasmid DNA.

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