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COVAXX initiates Ph 1 trial of COVID-19 vaccine in Taiwan

29 September 2020 | News

Taiwan's Ministry of Health and Welfare Approves Up to $15M Grant to Support Phase 1 and 2 of Human Trials

COVAXX, a subsidiary of United Biomedical Inc (UBI) headquartered in the US, has announced the first healthy adult volunteers were safely dosed in the company's Phase 1, open-label, dose-escalation study of the UB-612 vaccine candidate for COVID-19 in Taiwan.

The study is partly supported by a grant from the Ministry of Health and Welfare in Taiwan of up to 430M (NTD) or approximately $15M.

This clinical trial expands the international collaborations of COVAXX after the recently announced agreements with Dasa, the largest diagnostic medicine company in Brazil and Latin America, and with The University of Nebraska Medical Center to conduct large scale human efficacy clinical trials in Brazil and the United States, respectively.

"Administering the initial dose of our vaccine candidate to the first participants not only marks the start of this Phase 1 clinical trial but also represents a significant step forward in the global fight against COVID-19," said Mei Mei Hu, co-Chief Executive Officer of COVAXX.

The Phase 1 open-label trial is designed to evaluate the safety, tolerability, and immunogenicity of UB-612, a multitope peptide-based vaccine candidate against COVID-19 based on a commercially proven platform that allows for the cost-effective production of vaccines at scale.

The design of the vaccine components provides the additional advantage of utilizing existing cold-chain storage and distribution channels as it does not require additional infrastructure such as -80?C freezers or liquid nitrogen tanks to store materials at temperatures beyond -80?C

The trial is currently enrolling 60 healthy male and female adults, from 20-55 years of age, in three groups of 20 subjects. Each subject will receive ascending dose levels of UB-612 in two intramuscular injections spaced 28 days apart. The dose groups will be staggered so that safety can be rapidly assessed before ascending to the next dose level. Since UB-612 is designed to elicit both functional antibodies (B cells) and cellular immune responses (T cells), a wide array of immunological tests will be performed to demonstrate its protective activity. The most important neutralization titer analysis of the data will be performed by Laboratory of Molecular Virology and Viral Immunology at Academia Sinica, the most prestigious research

institute in Taiwan, under the leadership of Dr. Yi-Ling Lin along with other esteemed clinical and biomedical laboratories globally.