GeneOne Life Science Receives Approval for Phase I/IIa MERS-CoV Vaccine Trial in Korea

GeneOne Life Science Receives Approval of IND by the Korean Ministry of Food and Drug Safety (KMFDS) of MERS-CoV Plasmid DNA vaccine, GLS-5300, for a Phase I/IIa Clinical Trial in Korea

Seoul (PRWEB) September 17, 2017 -- GeneOne Life Science, Inc. announces that it has received approval from the South Korean Ministry of Food and Drug Safety (KMFDS) for an Investigational New Drug application for a Phase I/IIa study of its investigational vaccine, GLS-5300, against the Middle East Respiratory Syndrome coronavirus (MERS-CoV). The study in Korea represents the second clinical trial for GLS-5300.

A US clinical trial of GLS-5300 at the Walter Reed Army Institute of Research (NCT02670187, www.ClinicalTrials.Gov) has completed all study visits. GLS-5300 was well tolerated and induced high levels of antibodies and T-cell responses when administered intramuscularly (IM) and followed by electroporation (EP) using the CELLECTRA® device. All dose levels, 0.67 mg, 2 mg, and 6 mg were equally immunogenic. GLS-5300 has been shown to be fully protective in pre-clinical studies in non-human primates. The trial in Korea will assess the responses of GLS-5300 given intradermally (ID) and followed by EP at doses of 0.3 and 0.6 mg.

MERS-CoV causes a severe rapidly progressive respiratory illness. Since 2012, more than 2000 cases of MERS-CoV have been reported from 27 countries. Greater than 35% of those infected died - a mortality rate similar to the recent West African Ebola epidemic. (http://www.who.int/mediacentre/factsheets/fs103/en/) In 2015, South Korea experienced a large outbreak of MERS-CoV emanating from a single traveler returning from a MERS-endemic country. Of the 186 people with MERS-CoV infection in Korea, 36 (19.4%) died(https://www.medicalnewstoday.com/articles/262538.php), and 3 additional deaths reported after the epidemic. Healthcare workers, especially physicians and nurses, unfortunately represented a disproportionate number of those infected. In 2017, the Korean CDC has designated MERS-CoV as one of 10 infectious diseases with significant potential to be imported into South Korea.

“GeneOne has been honored to have participated in the response to this deadly viral illness” states Mr. Young K. Park, CEO of GeneOne. “Regulatory approval for this Phase I/IIa clinical trial will enable GeneOne to bring the GLS-5300 MERS-CoV vaccine into Korea, a country whose citizens suffered significantly from this highly fatal infection in 2015. GeneOne is pleased to have developed a collaborative relationship with the International Vaccine Institute (IVI) that has been instrumental in bringing this clinical trial to Korea. GeneOne has maintained a focus on international infectious disease threats, including SFTS, that have affected many in Asia and Korea. GeneOne was able to respond to the MERS-CoV outbreak by bringing forward the GLS-5300 vaccine into clinical trial in 9 months. GeneOne is committed to working on the development of GLS-5300 so that it is available to Korea in the event of a future MERS outbreak.”

GLS-5300 is the only MERS-CoV vaccine that has entered into human clinical trials to date. Through a Collaboration Agreement with IVI, funding is provided for clinical trial costs. The GLS-5300 DNA cGMP vaccine was manufactured at VGXI. GLS-5300 is being co-developed with Inovio Pharmaceuticals, Inc.

About VGXI, Inc.
With over 15 years of experience, VGXI, Inc. is a leading provider of plasmid DNA manufacturing and development services for DNA vaccine and gene therapy research. The company has an outstanding track record of success in manufacturing plasmid products under cGMP conditions for clinical trials in the US, EU, Asia and Australia, and its cGMP and non-GMP products have passed rigorous reviews by several international regulatory agencies. VGXI’s ability to work with unique requirements and create custom manufacturing solutions is based on its patented manufacturing process, flexible cGMP production facility, and experienced development team. VGXI, Inc. is a wholly-owned subsidiary CMO of GeneOne Life Science, Inc. To learn more about VGXI's services, visit https://www.vgxii.com/.

About GeneOne Life Science

GeneOne Life Science, Inc. is an international developer of DNA vaccines and DNA-based therapeutics. GeneOne has sponsored clinical trials for vaccines against MERS-CoV and Zika virus. It researches and develops DNA vaccines to prevent and treat incurable diseases as well as hematologic diseases, metabolic diseases, and cancers. The company is headquartered in Seoul, South Korea. VGXI, Inc., GeneOne's wholly-owned manufacturing subsidiary, VGXI, located in Texas, is the largest pure-play cGMP DNA plasmid manufacturing facility in the world. For more information, visit http://www.genels.com/en or contact James Kim, 82-10-6202-1396, jikim@genels.com.

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