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ASIA EDITION

Singapore approves clinical trial application for LUNAR-COV19 vaccine

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Differentiated STARRÃ¢â??Â¢ mRNA vaccine expected to produce humoral and cellular immunity at very low doses; preclinical data demonstrate neutralizing antibody titers continue to increase for 50 days after a single administration



US based Arcturus Therapeutics Holdings Inc., a leading clinical-stage messenger RNA medicines company focused on the discovery, development and commercialization of therapeutics for rare diseases and vaccines, and Duke-NUS Medical School, Singapore's flagship research-intensive graduate entry medical school, have announced that the Clinical Trial Application for COVID-19 vaccine candidate LUNAR-COV19 has been approved to proceed by the Singapore Health Sciences Authority.

Arcturus and Duke-NUS partnered to develop a coronavirus vaccine using Arcturus' STARR™ technology and a unique platform developed at Duke-NUS allowing rapid screening of vaccines for potential effectiveness and safety.

Arcturus and Duke-NUS will initiate human dosing of LUNAR-COV19 as soon as possible. The healthy volunteer study will evaluate several dose levels of LUNAR-COV19 in up to 108 adults, including older adults. Follow-up will be conducted to evaluate safety, tolerability and the extent and duration of the humoral and cellular immune response.

"Based on our preclinical data, we believe that our self-replicating mRNA-based approach may produce high rates of seroconversion and robust T-cell induction with a potential single administration, at very low doses. The LUNAR-COV19 profile is meaningfully differentiated and may facilitate the mass vaccine campaigns necessary to target hundreds of millions of individuals globally," said Joseph Payne, President and CEO of Arcturus.

Professor Ooi Eng Eong, Deputy Director of the Emerging Infectious Diseases Program at DukeNUS, said, "Preclinical studies on LUNAR-COV19 have shown very promising findings, including the possibility that a single dose of this vaccine may be sufficient to trigger robust and durable immune responses against SARS-CoV-2."

The STARR™ Technology platform employed in LUNAR-COV19 combines self-replicating mRNA with LUNAR®, a proprietary nanoparticle delivery system optimized for mRNA molecules. The efficiency and self-replicating nature of the

approach were designed to enable very low doses, and a potential single vaccine administration. Prior animal data has demonstrated robust humoral and cellular immunity elicited at doses as low as 0.2 µg of LUNAR-COV19. Additionally, Arcturus demonstrated 100% seroconversion for anti-SARS-CoV-2 neutralizing antibodies with a very low single dose (2.0 µg).

New preclinical data demonstrate that neutralizing antibody levels in response to a single administration of LUNAR-COV19 (0.2, 2.0, 10.0 µg) continue to increase over 50 days. The increasing antibody levels are attributed to the self-replicating mRNA of LUNAR-COV19. These results were obtained using a Luminex bead assay. A 1/2000 serum dilution was assayed for neutralizing IgG antibodies in the mouse serum every 10 days for 60 days post vaccination.