LATITUDE Pharmaceuticals Receives Grant to Develop a Small-volume Injectable Formulation for Remdesivir

SAN DIEGO, CALIFORNIA, US, October 30, 2020 - LATITUDE Pharmaceuticals Inc. (LATITUDE), a specialized drug formulation developer, announced today that it has received a grant from the COVID-19 Therapeutics Accelerator to develop a small-volume injection formulation of the antiviral remdesivir to facilitate its use in lower-resource settings against COVID-19.

The Therapeutics Accelerator was launched in March 2020 by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard, with additional funding from a range of donors to help speed up the discovery and scale up of effective treatments against COVID-19. Remdesivir has been clinically proven to shorten the recovery period of hospitalized COVID-19 patients.

Veklury® (which was recently approved by the FDA for use in adult and pediatric patients 12 years of age and older for the treatment of COVID-19 requiring hospitalization) is administered via intravenous infusion over 30-120 minutes (IV infusion). IV infusion requires trained hospital personnel to administer and the patient to be hospitalized. For a Veklury® patient, that means a 5-10 day hospitalization with daily Veklury® IV infusion.

LATITUDE has applied its proprietary drug solubilizing vehicle (ClearSol™) to dissolve remdesivir to a much higher concentration, which reduces the dose volume to about 1 mL. Such a small-volume formulation (RemSV™) has the potential to be administered with faster and more convenient IV bolus, subcutaneous (SC), or intramuscular (IM) injections in an outpatient setting. This would be particularly valuable in countries where hospital resources are limited during the current COVID-19 crisis. Moreover, the cost of the ClearSol™ components used in RemSV is significantly less than those used in Veklury®.

“LATITUDE is honored to have received support from the COVID-19 Therapeutics Accelerator to develop a potentially valuable pharmaceutical tool in combating the global COVID-19 pandemic,” noted Andrew Chen, LATITUDE’s President. “We believe RemSV™ can significantly improve remdesivir treatment by enabling its use in outpatients and patients at the early stage of COVID-19

infection. The significantly reduced cost of goods of RemSV compared to Veklury® will allow remdesivir treatment to be more affordable to patients in low- and middle-income countries. In our experience, LATITUDE's ClearSol™ technology has been the most broadly applicable, effective and safest solubilizer, suitable for a wide range of highly insoluble drug compounds. We encourage researchers to use it for their insoluble drugs."

About ClearSol™

ClearSol™ is a stable aqueous solubilization vehicle that combines three key FDA-approved injectable excipients in a proprietary composition to provide extraordinary drug-solubilization activity. The vehicle's safety has been established in numerous animal studies and in a US Phase 1 human clinical trial. ClearSol™ has solubilized about 80% of highly insoluble drugs to adequate concentrations for their dosing by injections. In comparison, betadex sulfobutyl ether sodium, a leading commercially available solubilizer, only solubilized about 20% of these same drugs. In a preclinical safety study, after 28 days of daily intravenous dosing in rats, ClearSol™ did not cause any observable histopathological effects on kidney, liver, lung or pancreas, whereas betadex sulfobutyl ether sodium resulted in vacuolation in kidney tubules.

About LATITUDE Pharmaceuticals Inc.

LATITUDE is a leading developer of innovative drug formulations and drug delivery systems for out-licensing to the biotech and pharmaceutical industries. The company is highly regarded for its intellectual property portfolio and innovative approaches to developing pharmaceutical formulations for problematic and/or highly insoluble drug molecules.

About the COVID-19 Therapeutics Accelerator

The COVID-19 Therapeutics Accelerator is an initiative launched by the Bill & Melinda Gates Foundation, Wellcome, and Mastercard to speed up the response to the COVID-19 pandemic by identifying, assessing, developing, and scaling up treatments. Its partners are committed to equitable access, including making products available and affordable in low-resource settings. The COVID-19 Therapeutics Accelerator will play a catalytic role by accelerating and evaluating new and repurposed drugs and biologics to treat patients with COVID-19 in the immediate term, and other viral pathogens in the longer term. For more information, visit www.therapeuticsaccelerator.org

For more information about LATITUDE's remdesivir formulation or the ClearSol™ technology, please contact:

Matthew A. Singer, PhD
VP, Head of Business Development
Tel: 858-546-0924, ext. 103
Email: matthewsinger@latitudepharma.com