Tellus Therapeutics Awarded NINDS SBIR Funding for Development of TT-20 for Treatment of Neonatal Brain Injury

$696,000 Phase I award will support drug product formulation and in vivo pharmacokinetic study to enable an IND application for First-in-Neonate clinical trial

DURHAM, NC, UNITED STATES, December 7, 2020 /EINPresswire.com/ -- Tellus Therapeutics, a neonatal care company developing safe and effective treatments for unmet needs of newborns in the neonatal intensive care unit (NICU), today announced the award of a Phase 1 Small Business Innovation Research (SBIR) grant from the National Institute of Neurological Diseases and Stroke (NINDS) of $696,000 to fund further preclinical development of the Company's lead product candidate, TT-20, for the treatment of diffuse white matter injury in premature infants who are at risk for neurodevelopmental impairment, including cerebral palsy.

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> *Dr. Jason Kralic, chief executive officer and co-founder of Tellus*

"With this award, the NINDS recognizes the therapeutic potential of TT-20 to address a significant unmet medical need in premature infants at risk for brain injury," said Dr. Jason Kralic, Tellus' chief executive officer and co-founder. "We are harnessing the same pathway used by the newborn brain for development to repair damage and improve neurodevelopmental outcomes in patients. Tellus is grateful to the NINDS for its support in advancing the development of TT-20. "

The SBIR funding will be used develop a drug product formulation amenable for use in the NICU setting and study the dosing and pharmacokinetics of TT-20 – in its proposed clinical formulation

– following IV infusion in animals. The Company anticipates completing an FDA pre-IND meeting in 2021 to support a First-in-Neonate Phase 1b trial in premature infants at risk for brain injury.


Preterm Infant in the Neonatal Intensive Care Unit

The SBIR program was created by the U.S. Congress to strengthen the role of small, innovative companies in federally supported research and development. It is one of the largest sources of early-stage technology financing in the U.S. The NINDS is the nation's leading funder of research on the brain and nervous system and a component of the National Institutes of Health (NIH). The content in this press release is solely the responsibility of Tellus Therapeutics and does not necessarily represent the official view of NINDS or the NIH. This award was granted by the National Institutes of Health under Award Number R43NS117230.

About Tellus Therapeutics
Founded in 2018, Tellus is a mission-driven R&D company dedicated to developing safe and effective treatments for unmet needs in newborns. One in ten babies is born premature and at significant risk for diffuse white matter (myelin) injury and subsequent life-long cognitive and neurological impairments. Tellus is developing novel small molecules derived from human maternal breast milk demonstrated to induce regeneration of myelin-producing oligodendrocytes and reverse white matter injury in animal models of perinatal brain injury and is pursuing a First-in-Neonate regulatory path to evaluate safety and efficacy in newborns with brain injury for whom no treatments are available.

About Diffuse White Matter Injury
Diffuse white matter injury (DWMI) is the most prevalent form of preterm neonatal cerebral injury and is a strong predictor of poor neurologic outcomes in preterm neonates, leading to adverse neurodevelopmental events including cerebral palsy, intellectual disability, and neurosensory impairments. DWMI is characterized by diffuse, subtle changes in the white matter (myelin) microenvironment due to global hypomyelination. This disease process is driven by a reduction in the number of oligodendrocyte progenitor cells (OPCs) in the third trimester that can result from postnatal infections that induce systemic inflammation, including necrotizing enterocolitis or spontaneous intestinal perforations. There are currently no FDA-approved treatments for DWMI.

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