Tellus Therapeutics Receives Orphan Drug and Rare Pediatric Disease Designations for Neonatal Brain Injury Program TT-20

With No Approved Treatments for Diffuse White Matter Injury in Preterm Infants, FDA Decision Highlights Significant Unmet Need

DURHAM, NORTH CAROLINA, UNITED STATES, October 21, 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 that the U.S. Food and Drug Administration (FDA) granted Orphan Drug and Rare Pediatric Drug (RPD) designations to TT-20 for prevention of diffuse white matter injury (DWMI) in preterm infants <32 weeks gestational age. “Receipt of the Orphan Drug and RPD designations from the FDA is an important milestone for our TT-20 program and underscores the need to find treatments for DWMI, the predominate form of brain injury among neonates who survive preterm birth,” said Dr. Jason Kralic, chief executive officer and co-founder of Tellus. “With no FDA-approved drugs for DWMI, we look forward to continued collaboration with the FDA as we further define a regulatory path for TT-20 in DWMI and other neonatal conditions.”

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

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.

Preterm Infant in a Neonatal Intensive Care Unit

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.

About Orphan Drug Designation
The FDA grants Orphan Drug designation status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the U.S. at the time of designation. Orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user fee waivers. If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances.

About Rare Pediatric Drug Designation
The FDA grants the RPD designation for serious or life-threatening diseases that primarily affect children 18 years old or younger and fewer than 200,000 people nationwide. With this designation, Tellus will be eligible upon approval of TT-20 for a priority review voucher which can be used to obtain FDA review of a New Drug Application (NDA) for another product in an expedited period of six months.

Funding to achieve these regulatory milestones was provided by the North Carolina Biotechnology Center.

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This press release can be viewed online at: https://www.einpresswire.com/article/528862481

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