AyuVis' Lead Drug Candidate – AVR-48 -- Granted Rare Pediatric Disease Drug Designation

FORT WORTH, TX. (2-8-2021) – AyuVis Research, Inc.'s proprietary small molecule drug AVR-48, which last month was granted Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA), additionally has been granted Rare Pediatric Disease Drug Designation for use in prevention of bronchopulmonary dysplasia in at-risk premature infants.

Bronchopulmonary dysplasia (BPD) is a chronic lung disease that develops in prematurely born babies, and can lead to death or long-term respiratory issues and developmental delays. These babies require mechanical ventilation (MV) or other positive pressure delivery of supplemental oxygen in order for them to survive, but the MV and high oxygen also damages their underdeveloped lungs and releases inflammatory substances, causing inflammation and tissue damage. A damaged lung no longer can supply sufficient oxygen to other organs in the body, including the brain, and as affected infants and children grow, they may be at a greater risk than the general population of developing asthma, respiratory infections, or viral pneumonia.

AVR-48 works to modulate the immune system by decreasing the inflammatory response to MV and oxygen toxicity, as demonstrated by preventing the development of BPD in pre-clinical animal models. Preventing BPD by administering AVR-48 to babies in the neonatal intensive care unit (NICU) is anticipated to result in lives being saved, improvement in the quality of life of survivors, and reduced hospital costs.

Rare Pediatric Disease Drug Designation (RPDD) is given to drugs and biologics that are defined for the treatment, prevention or diagnosis of a rare pediatric disease or condition, one that affects fewer than 200,000 people in the U.S. The disease must be serious or life-threatening -- primarily affecting individuals from birth to 18 years. Earning the RPDD allows AyuVis to apply for FDA grant funding to be used for clinical trials. During 2019, the FDA awarded 12 companies with RPDD programs a sum of more than $15M to partially fund Phase 1 and 2 clinical trials.

The RPDD also opens the opportunity for AyuVis, a TechFW client, to apply for a Priority Review Voucher (PRV) when submitting a New Drug Application (NDA). PRVs are highly valuable because they shorten the FDA's drug submission review time from 10 months to six. They can be used on any future NDA and any subsequent application would not have to meet the usual requirements for a priority review.

"The FDA granting the Rare Pediatric Disease Drug Designation to our lead candidate for BPD is highly encouraging to our team and a strong step forward toward developing the first FDA-approved therapy for BPD," said David Riley, MD, MBA, a board certified neonatologist and AyuVis' Chief Medical Officer.

"This is a meticulous regulatory strategy we planned from the beginning and I am very happy to say that we are making steady progress," said Suchismita Acharya, PhD, the CEO and founder of AyuVis.

AyuVis has plans for its first-in-human Phase 1 clinical trial in 2021. To reach the marketplace, AyuVis will complete GMP manufacturing of AVR-48 for clinical trials, finish the remaining IND-enabling pre-clinical studies, and conduct Phases 1, 2a and 2b clinical trials. With positive clinical results, there is the opportunity to be considered for Accelerated Approval from the FDA, which could preclude a phase 3 trial.

About the company: AyuVis Research, Inc. is a pre-clinical stage pharmaceutical company focused on the discovery and development of novel, multi-functional small molecules that boost the body's natural ability to fight disorders associated with inflammation, immune modulation and microbial infection. Its lead candidate is completing pre-clinical-IND enabling studies for the prevention of Bronchopulmonary dysplasia, a pediatric orphan indication of severe lung injury. It also has pre-clinical assets for *Pseudomonas aeruginosa* lung and skin infection and systemic inflammatory response syndrome.

AyuVis Research, Inc. was founded by Suchismita Acharya, PhD, CEO in 2014. Before AyuVis, she spent 11 years in various leadership roles with Alcon Labs (Novartis) and led projects from early discovery stage to pre-clinical and clinical stages of development in different disease areas, including glaucoma, age-related macular degeneration (AMD) and viral conjunctivitis.

The AyuVis team members are: David Riley, MD, MBA, Chief Medical Officer; Keith Bryant, MBA, CBO; Dale Christensen, PhD, Director of Early Development; William Dean, PhD, Head of CMC; Russell Bromley, Director of Operations; Stella Robertson, PhD, Drug Development Advisor; Ranjan Misra, Business Advisor; and Darlene Boudreaux, MBA, CPA, former Executive Director of TechFW, as CFO.

Ayuvis is a client company of TechFW, a nonprofit technology business incubator and accelerator in Fort Worth, and portfolio company of the Cowtown Angels, an angel investor network that is a program of TechFW.

For more information contact:
Sarah Spain
Operations Manager
AyuVis Research, Inc.
sarah@ayuvis.com

(214) 507-3144
www.ayuvis.com