TrippBio Submits an Investigational New Drug Application to the U.S. FDA for PanCytoVir™ Treatment of Influenza

First study will evaluate the pharmacokinetics of a novel oral PanCytoVir suspension

TrippBio, Inc.

JACKSONVILLE, FLORIDA, UNITED STATES, August 22, 2023 /EINPresswire.com/ -- TrippBio, Inc. (TrippBio), a clinical development-stage biopharmaceutical company developing antiviral treatments, announces that it has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for the use of PanCytoVir™ as a treatment of acute, uncomplicated influenza disease.

David E. Martin, PharmD, and CEO of TrippBio, Inc., stated, "We are pleased to announce the start of our second clinical development program and the first to use our innovative oral dosage formulation, a PanCytoVir™ suspension. We recently announced the positive results with PanCytoVir™ in a dose-range finding study in patients with mild-to-moderate COVID-19 and are looking forward to rapidly moving into our Phase 2 program for influenza."

> This filing marks a significant milestone with the start of our second development program for the treatment of viral respiratory diseases."
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> *Dr. David E. Martin*

Ralph A. Tripp, PhD, Professor & Georgia Research Alliance Chair in Vaccine and Therapeutic Development, University of Georgia and co-founder commented, "Antiviral drugs have limitations due to toxicity and resistance development when fighting mutating influenza viruses. Further, new vaccines must be developed to keep up with the different strains. PanCytoVir™ can bridge these gaps and immediately fill an important need."

PanCytoVir™

PanCytoVir™ (based on probenecid which is approved by the FDA for the treatment of the hyperuricemia associated with gout and can be used as an adjuvant to therapy with penicillin-derived antibiotics for prolonging drug plasma levels) is a favorable antiviral drug candidate as it is commercially available and has high plasma concentrations with a benign clinical safety profile. It has demonstrated potent activity against SARS-CoV-2[1], influenza[2], and RSV[3] in vitro and in preclinical infection models. The antiviral activity of PanCytoVir™ against influenza is more potent, in vitro, than Tamiflu® against contemporary influenza A and B strains, H7N9 avian influenza A and H5N1, a highly pathogenic influenza A virus. The potency difference was also observed in vivo with both A and B strains. Recent data in patients with symptomatic, mild-to-moderate COVID-19 showed that PanCytoVir™ treatment significantly reduced SARS-CoV-2 viral load, and significantly more treated patients had complete resolution of COVID-19-related symptoms by Study Day 10 versus placebo[4]. This is important as the antiviral mechanism of action against SARS-CoV-2 is shared with influenza, suggesting an increased probability of success in clinical studies. PanCytoVir™ was granted a US patent (#11,116,737) on 14 September 2021 for "Methods of Using Probenecid for Treatment of Coronavirus Infections" with additional international filings ongoing. A Phase 3 clinical trial for COVID-19 is currently being developed, and the clinical program for influenza is expected to start in 3Q2023, with planning underway for an IND filing for RSV soon. A novel oral suspension is being developed to enable flexible dosing across the different patient populations impacted by these three respiratory viruses with a single product.

1. Murray J, Hogan RJ, Martin DE, et al. Probenecid potently inhibits SARS-CoV-2 replication in vivo and in vitro. Scientific Reports 2021:11;18085 (https://doi.org/10.1038/s41598-021-97658-w).
2. Perwitasari O, Yan X, Johnson S et al. Targeting organic anion transporter 3 with probenecid as a novel anti-influenza a virus strategy. Antimicrob Agents Chemother 57(1), 475-483 (2013). (https://doi.org/10.1128%2FAAC.01532-12)
3. Murray J, Bergeron H, Shepard J, et al. Probenecid Inhibits Respiratory Syncytial Virus (RSV) Replication. Viruses 2022, 14, 912. (https://doi.org/10.3390/v14050912)
4. Martin DE, Pandey N, Chavda P, Singh G, Sutariya R, Sancilio F, and Tripp RA. Oral Probenecid for Nonhospitalized Adults with Symptomatic, Mild-to-Moderate COVID-19. Viruses 2023:15;1508. (https://doi.org/10.3390/v15071508)

About TrippBio, Inc.

TrippBio, Inc. is a Jacksonville, Florida-based, clinical development-stage biopharmaceutical company dedicated to commercializing new applications of therapeutics to fight infectious diseases with an emphasis on viral diseases with current efforts focused on the identification of drugs to combat infections such as the SARS-CoV-2 virus that causes COVID-19. TrippBio is founded on the scientific research of Ralph Tripp, Ph.D., Georgia Research Alliance Chair and Professor at the University of Georgia. The University of Georgia Research Foundation is a major

shareholder of TrippBio, Inc.

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