TrippBio Announces Clearance of Investigational New Drug Application for PanCytoVir™ Treatment of Influenza

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

TrippBio, Inc.

JACKSONVILLE, FL, UNITED STATES, September 21, 2023 / EINPresswire.com/ -- TrippBio, Inc. (TrippBio), a clinical development-stage biopharmaceutical company developing antiviral treatments, announces that it has received clearance from the U.S. Food and Drug Administration (FDA) for the Investigational New Drug (IND) application for the use of PanCytoVir™ Suspension (100mg/mL) as a treatment of acute, uncomplicated influenza disease. Clinical studies to evaluate the effect of PanCytoVir™ in patients with acute, uncomplicated influenza disease can now commence with the first study scheduled to evaluate the effect of food on the pharmacokinetics of the novel PanCytoVir™ suspension (NCT06025318).

> We look forward to generating data with our new formulation and advancing another option for the treatment of influenza disease."
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> *Dr. David E. Martin*

David E. Martin, PharmD, and CEO of TrippBio, Inc., stated, "We are pleased to announce that the FDA has cleared our IND for the use of our innovative oral dosage formulation, a PanCytoVir™ suspension. We look forward to initiating our second clinical program and advancing therapeutic options for the treatment of respiratory tract infections."

PanCytoVir™

PanCytoVir™, which is based on probenecid, 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. PanCytoVir™ 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 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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