TrippBio Announces Results of a Phase 2 Study of PanCytoVir™ in Patients with Mild-to-Moderate COVID-19

• Potent antiviral efficacy observed
• Treatment with PanCytoVir™ resulted in a significant increase in the proportion of patients completely free of symptoms

TrippBio, Inc.

JACKSONVILLE, FL, USA, July 6, 2023 /EINPresswire.com/ -- TrippBio, Inc. (TrippBio), a clinical development-stage biopharmaceutical company developing antiviral treatments announces publication of the results from a recently completed Phase 2, dose-range finding study with PanCytoVir™ in non-hospitalized patients with symptomatic, mild-to-moderate COVID-19 (NCT05442983). The manuscript entitled "Oral Probenecid for Non-hospitalized Adults with Symptomatic, Mild-to-Moderate COVID-19" (https://www.mdpi.com/1999-4915/15/7/1508) was published in a special issue of Viruses (Novel and Repurposed Antiviral Agents , https://www.mdpi.com/journal/viruses/special_issues/antiviral_agents).

> These data confirm the antiviral mechanism of action and demonstrate a significant clinical effect of PanCytoVir™ treatment in patients with symptomatic, mild-to-moderate COVID-19."
>
> *Dr. David E. Martin*

The study enrolled 75 non-hospitalized patients with symptomatic, mild-to-moderate COVID-19 infection with patients randomly assigned (1:1:1) to one of three treatment groups: 500 mg twice daily, 1000 mg twice daily, or matching-placebo twice daily and treated for 5 days. COVID-19 viral load, COVID-19-related symptoms, hospitalization or death from any cause through day 28, and safety were evaluated. COVID-19-related symptoms were assessed at baseline, and on Days 3, 5, 10, 15, and 28.

All patients completed the study as planned and there were no hospitalizations or deaths reported. The median time to virologic clearance was significantly shorter for the PanCytoVir™ 1000 mg group than for placebo (7 days vs. 11 days, respectively; P<0.0001), and for the

PanCytoVir™ 500 mg group versus placebo (9 days vs. 11 days, respectively; P<0.0001). In addition, the median time to virologic clearance was significantly shorter for PanCytoVir™ 1000 mg than for PanCytoVir™ 500 mg (7 days vs. 9 days, respectively; P<0.0001). All patients reported at least one COVID-19 related symptom at Day 3 and 5; however, at Day 10, a significantly greater proportion of patients receiving PanCytoVir™ 1000 mg reported complete resolution of symptoms versus placebo (68% vs. 20%, respectively; P=0.0006) and PanCytoVir™ 500 mg versus placebo (56% vs. 20%, respectively, P=0.0087). There was a dose-dependent and statistically significant decrease in viral load versus placebo throughout the sampling window. The maximum difference from placebo for PanCytoVir™ 1000 mg was at Day 7, with an adjusted mean difference of -2.39 log10 copies/mL. The maximum difference from placebo for PanCytoVir™ 500 mg was at Day 9, with an adjusted mean difference of -1.34 log10 copies/mL. The incidence of adverse events that emerged during treatment was similar across all groups, were mild with no serious adverse events reported and no discontinuations due to an adverse event.

David E. Martin, PharmD, and CEO of TrippBio, Inc., stated, "We are extremely pleased to announce these results from our dose-range finding study for PanCytoVir™ in COVID-19. These data not only confirm the potent antiviral effects but also demonstrate a significant impact on symptom resolution with nearly 3.5 times more patients treated with PanCytoVir™ 1000 mg twice daily resolving symptoms by Day 10 versus patients receiving placebo. These data support the continued development of PanCytoVir™ and we are working with FDA to finalize plans for our phase 3 clinical study."

Dr. Fred D. Sancilio, Research Professor at Florida Atlantic University, co-founder and Board Member of TrippBio, said "I am anxiously awaiting the start of the upcoming Phase 3 clinical program targeting COVID-19 and the Phase 2 trials for influenza and RSV. All studies will make use of our innovative oral dosage form, a PanCytoVir™ suspension, which will facilitate the testing of doses across a broad range of concentrations." He further elaborated, stating, "This new and enhanced formulation is specifically designed to allow the utilization of a single product across a wide range of doses, enabling us to potentially treat all three respiratory viruses: Influenza, RSV, and COVID-19 with one product."

PanCytoVir™

PanCytoVir™ is currently approved by the FDA for the treatment of the hyperuricemia associated with gout and can be used as an adjuvant to therapy with penicillin or with ampicillin, methicillin, oxacillin, cloxacillin, or nafcillin 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-21, influenza2, and RSV3 in vitro and in animal models of infection. 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 plans are underway to begin phase 2 studies in

influenza and RSV in the near future. 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).
3. Murray J, Bergeron H, Shepard J, et al. Probenecid Inhibits Respiratory Syncytial Virus (RSV) Replication. Viruses 2022, 14, 912.

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 common shareholder of TrippBio, Inc.

David Martin
TrippBio, Inc.
+1 301-538-1878
davidmartin@trippbio.com
Visit us on social media:
LinkedIn