



Traws Pharma Completes First Cohort Dosed in Phase 1 Trial for COVID Therapy

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Investigational travatrelvir demonstrated preclinical activity against multiple SARS-CoV-2 variants

Orally administered novel protease inhibitor does not require ritonavir co-administration

First-in-Human study to evaluate safety, tolerability and pharmacokinetics in healthy volunteers

Topline Phase 1 data and Phase 2 initiation expected in H2 2024

NEWTOWN, Pa., May 07, 2024 (GLOBE NEWSWIRE) -- Traws Pharma, Inc. ("Traws" or "Traws Pharma"), a clinical stage biopharmaceutical company developing oral small molecules for respiratory viral diseases and cancer, today announced that it completed dosing in the first cohort of the first-in-human Phase 1 study to evaluate travatrelvir (TRX01), an orally-available protease inhibitor, in development for treatment of COVID19. There have been no safety observations reported.

"COVID-19 remains a significant global health concern, with SARS-CoV-2 infections posing a leading cause of mortality, especially among individuals aged 65 and above," stated Werner Cautreels, Ph.D., Chief Executive Officer of Traws Pharma. "Our mission at Traws is to develop novel agents to treat respiratory viral diseases. Subject to future study results, we believe that travatrelvir may represent a major potential advance in the treatment of SARS-CoV-2 and are thrilled to advance this program into the first human clinical studies. We expect to report topline data from the Phase 1 study in H2 2024, followed by the initiation of an international Phase 2 safety and efficacy study."

Robert R. Redfield, M.D., Chief Medical Officer of Traws Pharma and former director of the US Centers for Disease Control (CDC) added, "Travatrelvir has an exciting and unique profile. In preclinical trials, it is active against multiple SARS-CoV-2 variants, does not require ritonavir co-administration and has a pharmacokinetic profile that may enable a dosing regimen that reduces the likelihood of viral rebound. These qualities may enable travatrelvir to overcome some of the limitations reported with other treatments and position travatrelvir as a potential best-in-class agent. We are grateful for the collaboration of the clinical investigators, human volunteers, and study sites and hope that travatrelvir will represent a new treatment option for this deadly viral disease."

About Travatrelvir, the Phase 1 Program and Planned Next Steps

Travatrelvir was designed as an inhibitor of the SARS-CoV-2 Mpro (3CL protease). It has demonstrated *in vitro* activity against the original strain of the virus as well as the delta and omicron variants and is more active than nirmatrelvir (Pfizer's Mpro inhibitor) in preclinical studies. Also in preclinical studies, travatrelvir did not require co-administration with a human cytochrome P450 (CYP) inhibitor, such as ritonavir, and so it is expected to avoid associated drug:drug interactions, potentially permitting wider patient use. The drug candidate's pharmacokinetic (PK) profile may enable a once daily, 10-day treatment regimen to reduce the likelihood of viral rebound. GLP toxicology studies did not identify adverse events (AEs) in animals at the doses being studied in the Phase 1 clinical trial.

The Phase 1 study will evaluate single and multiple ascending doses of travatrelvir in a double-blinded, placebo-controlled study to assess safety, tolerability, and pharmacokinetics. Subjects will be randomized 3:1 in five fasted and one fed single ascending dosing (SAD) cohorts and two multiple ascending dosing (MAD) cohorts. Topline data from the study, which is being conducted in Australia (ACTRN12624000220561p), and the initiation of an international Phase 2 study in subjects with moderate to severe COVID19, are expected to take place in H2 2024.

About Traws Pharma, Inc.

Traws Pharma is a clinical stage biopharmaceutical company developing oral small molecule therapies for the treatment of respiratory viral diseases and cancer. The viral respiratory disease program includes an oral inhibitor of the SARS-CoV-2 Mpro (3CL protease), and a new oral antiviral drug candidate for influenza which targets the influenza cap-dependent endonuclease and has shown activity in cell-based assays against drug resistant viruses as well as against avian flu.

In the cancer program, Traws is developing the novel, proprietary multi-kinase CDK2/4/6 inhibitor narazaciclilb for refractory endometrial cancer and potentially other cancers. Narazaciclilb targets pathways involved in the development of resistance to CDK inhibitors.

Traws Pharma is committed to delivering novel compounds for unmet medical needs using state-of-the-art drug development technology. With a focus on product safety and a commitment to patients in need or that are specifically vulnerable, we build solutions for important medical challenges, aiming to alleviate the burden of viral infections and cancer.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, and involve risks and uncertainties including statements regarding the Phase 1 study of travatrelvir in Australia and its design, timing and potential results and the timing of a planned Phase 2 study. Traws has attempted to identify forward-looking statements by terminology including "believes", "estimates", "anticipates", "expects", "plans", "intends", "may", "could", "might", "will", "should", "preliminary", "encouraging", "approximately" or other words that convey uncertainty of future events or outcomes. Although Traws believes that the expectations reflected in such forward-looking statements are reasonable

as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including the success and timing of Traws' clinical trials, collaborations, market conditions and those discussed under the heading "Risk Factors" in Traws' filings with the Securities and Exchange Commission. Any forward-looking statements contained in this release speak only as of its date. Traws undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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