Adamis Provides Update on the Phase 2/3 Trial of Tempol in COVID-19 Positive High-Risk Subjects

September 21, 2022

- ***Interim data from the Phase 2/3 clinical trial of Tempol did not demonstrate statistical significance of its primary endpoint of clinical resolution of COVID-19 symptoms at day 14 versus placebo***
- ***Independent Data Safety Monitoring Board recommends halting the trial***

SAN DIEGO, Sept. 21, 2022 (GLOBE NEWSWIRE) -- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced that the third planned interim analysis of the Phase 2/3 clinical trial examining the effects of Tempol in high risk subjects with early COVID-19 infection did not achieve its primary endpoint, as measured by comparing the rate of sustained clinical resolution of symptoms of COVID-19 at day 14 of Tempol versus placebo. The independent Data Safety Monitoring Board (DSMB) recommended that the study be halted early due to lack of efficacy. The DSMB did note that no safety concerns were identified in the subjects that received Tempol. Based on the recommendation from the DSMB, the Company has halted the trial and will now evaluate the unblinded data from the trial to determine the next developmental steps for Tempol.

"We are obviously disappointed that the study did not meet its endpoints," said Ron Moss, MD, Chief Medical Officer of Adamis. "Much of the preclinical work on Tempol for COVID-19 examined the effects of the drug on severe illness. This trial did not meet its primary endpoint, but we are exploring the possibility that vaccinations and the less virulent variants (Omicron) during the trial period may have obscured an effect of Tempol. This speculation is based on the lower-than-expected observed hospitalization rate in this trial (less than 1%) compared to other COVID-19 treatment trials. We will continue to analyze the data to determine if we believe Tempol can be utilized in other COVID patient populations including those with more severe illness or immunocompromised. I would like to thank our clinical research partners, the trial investigators and all the trial subjects for their participation."

David J. Marguglio, Adamis' CEO added, "Though we are certainly frustrated with these results, we remain bullish on ZIMHI ® (launched in 2022) and SYMJEPI® and our team is focused on increasing sales and improving manufacturing efficiencies for our commercial products."

Phase 2/3 Trial

The trial "A Phase 2/3, Adaptive, Randomized, Double-Blind, Placebo-Controlled Study to Examine the Effects of Tempol (MBM-02) in Subjects With COVID-19 Infection" was designed to enroll approximately 248 high risk subjects with early COVID-19 infection age 18 years of age and older. Eligible subjects with positive COVID-19 infection within five days of study entry plus at least one co-morbidity were randomized one-to-one to receive either Tempol or placebo. Co-morbidities include age of 65 or older, hypertension, diabetes, obesity, cancer, immunodeficiency and in the opinion of the investigator the risk factor is not acutely life-threatening. Patients randomized to Tempol received 800mg daily in two divided oral doses of 400mg capsules for up to 21 days. Similarly, placebo capsules were administered twice daily to subjects in the placebo group for up to 21 days.

About Adamis Pharmaceuticals

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company primarily focused on developing and commercializing products in various therapeutic areas, including allergy, opioid overdose, respiratory and inflammatory disease. The Company's SYMJEPI® (epinephrine) Injection products are approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis. The Company's ZIMHI ™ (naloxone) Injection product is approved for the treatment of opioid overdose. Tempol is in development for the treatment of patients with COVID-19 and a Phase 2/3 clinical trial has been conducted. For additional information about Adamis Pharmaceuticals, please visit our website and follow us on Twitter and LinkedIn.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include those that express plans, anticipation, intent, contingencies, goals, targets or future development and/or otherwise are not statements of historical fact. These statements relate to future events or future results of operations, including, but not limited to statements concerning the following matters: the next developmental steps for Tempol; possible factors affecting the results of the Phase 2/3 clinical trial for Tempol; possible use of Tempol in other COVID patients including those with more severe illness; the Company's beliefs concerning the mechanisms of action, safety and effectiveness of Tempol; the Company's beliefs concerning the ability of its products and product candidates to compete successfully in the market; and the Company's believes concerning improvement of manufacturing efficiencies for its commercial products. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, which may cause Adamis' actual results to be materially different from the results anticipated by such forward-looking statements. There are no assurances concerning the next developmental steps for Tempol; that vaccinations or less virulent variants of COVID-19 during the trial period affected the results of the Phase 2/3 clinical trial; that the Company will explore the use of Tempol with other categories of COVID patients; or that sales of the Company's commercial products will increase or that manufacturing efficiencies will be achieved. In addition, forward-looking statements concerning our anticipated future activities assume that we have sufficient funding to support such activities and continue our operations and planned activities. You should not place undue reliance on any forward-looking statements. Further, any forward-looking statement speaks only as of the date on which it is made, and except as may be required by applicable law, we undertake no obligation to update or release publicly the results of any revisions to these forward-looking statements or to reflect events or circumstances arising after the date of this press release. Certain of these risks and additional risks, uncertainties, and other factors are described in greater detail in Adamis' filings from time to time with the SEC, including its annual report on Form 10-K for the year ended December 31, 2021, and subsequent filings with the SEC, which Adamis strongly urges you to read and consider, all of which are available free of charge on the SEC's website at http://www.sec.gov.

Contacts

Adamis Investor Relations
Robert Uhl
Managing Director
ICR Westwicke
619.228.5886
robert.uhl@westwicke.com

Source: Adamis Pharmaceuticals Corporation