Adamis Pharmaceuticals Doses First Patients in Phase 2/3 Clinical Trial for Tempol in the Treatment of COVID-19

September 2, 2021

SAN DIEGO, Sept. 02, 2021 (GLOBE NEWSWIRE) -- Adamis Pharmaceuticals Corporation (Nasdaq: ADMP) today announced the initiation of patient dosing in the Phase 2/3 clinical trial for Tempol, an oral antiviral product candidate, in adult patients with confirmed COVID-19 infection. In preclinical studies, Tempol has been shown to have antiviral, anti-inflammatory and antioxidant activity. The trial is designed to enroll 248 patients.

Shyam Kottilil, MBBS, Ph.D., Professor of Medicine at the University of Maryland School of Medicine (UMSOM), Chief of the Division of Clinical Care and Research at UMSOM's Institute of Human Virology, and Principal Investigator for the trial, commented: "The timing for this trial could not be more important as the delta variant spreads and breakthrough infections in vaccinated individuals occur in the U.S. and worldwide. Tempol as an oral antiviral and anti-inflammatory may be an important countermeasure if proven safe and effective in this trial."

Dr. Dennis J. Carlo, President and Chief Executive Officer of Adamis, commented: "We are pleased to begin patient dosing in this Phase 2/3 clinical trial for Tempol, which has demonstrated highly encouraging preclinical data in several disease models of infection and inflammation. Worldwide appearance of new variants with increased transmissibility and resistance necessitates the development of new therapeutic agents. The data from Israel should be a wake-up call to the U.S. and the rest of the world. Israel has among the highest levels of vaccination for COVID-19, yet the country is now showing one of the world's highest infection rates (breakthrough). Currently, in Israel, the majority of the hospitalized patients are fully gene vaccinated. If approved, Tempol may not only prove to be a very important drug for the treatment of COVID-19, but it may also play a role in curbing the pandemic."

Recently, the National Institutes of Health (NIH) highlighted Tempol as a potential home treatment for COVID-19 (NIH Study) The NIH news stated that, "This treatment would likely prevent severe disease." Recent studies conducted by NIH researchers suggested that Tempol had potent antiviral activity against the virus that causes COVID-19 in laboratory studies. The NIH news article further describes how Tempol could possibly reduce COVID-19 symptoms by calming inflammation, protecting organs from damage, and decreasing the clumping of platelets.

The Company recently announced (Stanford Study) the results of a published study in collaboration with Stanford University researchers suggesting that Tempol has strong, broad in-vitro anti-cytokine activity. Suppression of inflammatory cytokines with an antioxidant may be a beneficial treatment strategy in early COVID-19 infection.

About the Phase 2/3 Clinical Trial

This Phase 2/3 adaptive, randomized, double-blind, placebo-controlled clinical trial is designed to enroll approximately 248 high risk unvaccinated subjects with early COVID-19 infection age 18 years of age and older. The primary endpoint is the rate of hospitalization for patients receiving Tempol, versus those receiving placebo. Eligible subjects with positive COVID-19 infection within five days of study entry plus at least one co-morbidity will be randomized 1:1 to receive either Tempol or placebo. Co-morbidities include hypertension, diabetes, obesity, cancer, chronic renal disease, and immunodeficiency, and in the opinion of the investigator, the co-morbidity is not acutely life threatening. Patients randomized to Tempol (n=124), will receive 800mg daily in two divided doses of 400mg for up to 21 days. Similarly, placebo capsules will be administered twice daily to subjects in the placebo group (n=124) for up to 21 days.

As part of the initial Phase 2 portion of the study, 50 COVID positive subjects will be enrolled and randomized 1:1 to receive either Tempol or placebo. An interim analysis by the data and safety monitoring board (DSMB) will examine safety and markers of systemic inflammation during a Stage 1 interim analysis. Based on the DSMB analysis, the Phase 3 portion of the trial designed to enroll 198 patients may begin, with a second interim analysis planned after enrollment of 124 patients. A thorough safety assessment will be conducted, and all treatment related adverse events will be recorded, evaluated and compared for the treated and placebo groups.

Adults who are interested in joining this study can visit https://earlycovidstudy.com/.

Adamis licensed exclusive worldwide rights under patents, patent applications and related know-how relating to Tempol for certain licensed fields including the treatment of respiratory diseases including asthma, respiratory syncytial virus infection, influenza and COVID-19.

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 resubmitted New Drug Applications (NDA) for its naloxone injection product candidate, ZIMHI, for the treatment of opioid overdose, is currently under FDA review. Tempol is in development for the treatment of patients with COVID-19 and a Phase 2/3 clinical trial is underway. Adamis is developing additional products, including treatments for acute respiratory diseases, such as COVID-19, influenza, asthma, and COPD. For additional information about Adamis Pharmaceuticals, please visit www.adamispharmaceuticals.com.

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 the following statements: the opinions and beliefs of NIH researchers summarized in the NIH article discussed in this press release concerning the potential of Tempol as a treatment for COVID-19 and the results of previous studies of Tempol; the Company's beliefs concerning the safety and effectiveness of

Tempol or the Company's other product candidates; the timing, progress or results of the Company's Phase 2/3 clinical trial for Tempol or other studies or trials relating to Tempol; funding for clinical trials relating to Tempol and the Company's ability to receive any government funding relating to clinical development, studies or trials relating to Tempol; the Company's ability to commercialize the product candidates described in this press release, itself or through commercialization partners; the Company's beliefs concerning the benefits, enforceability, and extent of intellectual property rights and protection afforded by patents and patent applications that it owns or has licensed; and other statements concerning the Company's future operations and activities. 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 can be no assurances regarding the timing, progress or outcome of trials or studies relating to Tempol, or that Tempol will be found to be safe and effective in the treatment of COVID-19 or any other indication. There are no assurances that the Company will receive any government funding relating to clinical investigations, development or trials relating to Tempol or concerning the timing, amount of, or terms and conditions relating to, any such governmental funding that might be received. In addition, as previously disclosed, each of the Company and its US Compounding Inc. subsidiary has received a subpoena from the U.S. Attorney's Office for the Southern District of New York issued in connection with a criminal investigation. Accordingly, all forward-looking statements are subject to the outcome of this investigation and any related governmental investigations or proceedings, as well as the related internal investigation being conducted by the Company's Audit Committee. We cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. 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, 2020 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 web site at http://www.sec.gov.

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