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

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The clinical trial of Tempol has reached the initial planned enrollment of 248 subjects

Independent Data Monitoring Board to review interim data from approximately 200 initial subjects

SAN DIEGO, Sept. 12, 2022 (GLOBE NEWSWIRE) -- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced that the Company's ongoing U.S. Phase 2/3 clinical trial to evaluate the safety and efficacy of Tempol as a treatment for COVID-19 has reached the initial planned enrollment of 248 subjects.

"We are very pleased to reach this trial milestone and eagerly await the next DSMB meeting later this month," David J. Marguglio, Adamis' CEO stated. "This interim meeting is significant as it will mark the first time the DSMB evaluates statistical measures of efficacy for Tempol."

The Data Safety Monitoring Board (DSMB) is comprised of infectious disease experts who independently review the unblinded trial data and make recommendations. The DSMB previously met to evaluate the clinical and safety data from interim analyses in March and June 2022, and both times recommended that the study continue without modification. At the September meeting, the DSMB plans to evaluate the primary efficacy endpoint, the sustained resolution of COVID-19 symptoms, as well as safety in individuals who are at high risk for disease progression for approximately 190 subjects.

If analysis of the interim clinical data showed significant efficacy, the DSMB may recommend stopping the trial because it has already demonstrated statistical significance. If the interim data indicated no efficacy on the primary endpoint, the DSMB would likely recommend stopping the trial for futility. Under that outcome, the Company would begin analyzing the then unblinded data to determine if there were efficacy on the secondary endpoints. If positive efficacy trends are observed on the primary endpoint in favor of Tempol, but statistical significance is not reached, the DSMB may recommend continuing the trial and enrolling additional patients to further power the study.

Ron Moss, M.D., Chief Medical Officer of Adamis added, "If either the interim data or the final clinical data shows positive results, we would submit a clinical study report to the FDA and request a meeting to discuss the findings and the potential for Emergency Use Authorization. The Agency has approved two oral antivirals under EUA for outpatients with COVID-19. Regardless of what form COVID-19 takes going forward, we believe there will always be a medical need and large market for new effective therapeutics."

About 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. The primary endpoint is the rate of sustained clinical resolution between Tempol and the standard of care versus placebo and the standard of care at Day 14. In addition to the primary endpoint, a number of secondary endpoints will be reviewed including, but not limited to, changes in inflammatory markers, hospitalizations, and all cause of mortality. 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. Additional information about the trial can be found on www.clinicaltrials.gov using the identifier NCT04729595.

About Tempol

Tempol is a redox cycling nitroxide that promotes the metabolism of many reactive oxygen species and improves nitric oxide bioavailability. It has been studied extensively in animal models of oxidative stress and inflammation. Preclinical studies of Tempol have shown it to have anti-inflammatory and antioxidant activity. Adamis has licensed exclusive rights under certain patents, patent applications and related know-how relating to Tempol for certain licensed fields including the fields of COVID-19 infection, asthma, respiratory syncytial virus infection, and influenza infection, as well as a therapeutic for radiation-induced dermatitis.

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 is underway. 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 the following

statements: statements concerning the Company's Phase 2/3 clinical trial for Tempol; statements concerning the activities and process of the DSMB and the timing and outcome of that process; the Company's beliefs concerning the mechanisms of action, safety and effectiveness of Tempol and that Tempol addresses an unmet medical need; the timing, progress or results of the Company's Phase 2/3 clinical trial for Tempol or other studies or trials relating to Tempol; the Company's beliefs concerning the ability of its products and product candidates to compete successfully in the market; 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, including those relating to Tempol; the Company's ability to successfully commercialize the products and product candidates, itself or through commercialization partners; 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 are no assurances concerning the timing or outcome of, or recommendations resulting from, any future meeting of the DSMB. 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. 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. Statements in this press release concerning future events depend on several factors beyond the Company's control, including the absence of unexpected developments or delays, market conditions, the availability of sufficient funding, and the regulatory approval process. 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, 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.

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