



Adamis Pharmaceuticals Provides Update on Clinical Study Assessing Tempol for the Treatment of COVID-19

July 29, 2022

Interim DSMB review expected in late September

SAN DIEGO, July 29, 2022 (GLOBE NEWSWIRE) -- [Adamis Pharmaceuticals Corporation](#) (NASDAQ: ADMP) today provided an update on 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. The next Data Safety Monitoring Board (DSMB) meeting to review interim data results has been scheduled for late September. 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.

The DSMB is comprised of infectious disease experts who independently review the unblinded trial data and make recommendations. The Company will not have access to unblinded trial data until the trial has concluded. 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. If the DSMB recommendations indicate that the analysis of the clinical and safety data from the trial demonstrates significant efficacy, Adamis would submit a clinical study report to the FDA and request a meeting to discuss the findings and next steps for continued clinical development. If positive trends are observed in favor of the Tempol treatment group, the DSMB may recommend continuing the study along with the enrollment of additional subjects. If no efficacy is demonstrated, then the Company would likely stop the trial.

"We are committed to continue advancing Tempol for the treatment of COVID-19, especially with the recent increase of cases due to new variants," said David J. Marguglio, President and Chief Executive Officer of Adamis Pharmaceuticals. "With more than 200 patients enrolled, we believe this next DSMB data review could provide important additional insights into the safety and treatment effects of Tempol, as well as the future clinical path for Tempol."

About the Trial

Tempol is being evaluated in an ongoing Phase 2/3, adaptive, randomized, double-blind, placebo-controlled study to examine the effects of Tempol in subjects with mild to moderate COVID-19 infection. 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 cytokines and inflammatory markers, hospitalizations, and all cause of mortality. Additional information about the trial can be found on www.clinicaltrials.gov using the identifier NCT04729595.

About Tempol

Tempol (APC100) 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 antiviral, 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. The Phase 2/3 clinical trial examining the safety and efficacy of Tempol in COVID-19 patients early in the infection began in September 2021.

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, 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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