Adamis Pharmaceuticals Resubmits ZIMHI New Drug Application to FDA

May 18, 2020

SAN DIEGO, May 18, 2020 (GLOBE NEWSWIRE) -- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) today announced the resubmission of the Company's New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for its ZIMHI ™ (naloxone HCl Injection, USP) 5mg/0.5mL product candidate for the treatment of opioid overdose. The resubmission follows the company's meeting with the agency in February and is intended to address the issues raised by the FDA in the agency's November 2019 Complete Response Letter ("CRL").

Adamis previously announced that it entered into an exclusive distribution and commercialization agreement with US WorldMeds, LLC ("USWM") for commercial rights for the ZIMHI product candidate. Under the terms of the agreement, USWM obtained U.S. rights to commercialize and distribute the ZIMHI, if approved by the FDA, in exchange for an upfront payment and potential regulatory and commercial milestones totaling up to $26 million. Additionally, Adamis and USWM will share equally in the net profits, as defined in the agreement. Adamis has retained rights to commercialize the ZIMHI product outside the U.S. and may also continue to develop its injection platform for additional product candidates. Additional information concerning the agreement and the transaction is contained in a report on Form 8-K that has been filed by the company with the Securities and Exchange Commission.

Dr. Dennis J. Carlo, President and CEO of Adamis, stated, "We have been encouraged by our interactions with the FDA following our CRL and are pleased to resubmit our ZIMHI NDA. Based on the feedback from our Type A meeting in February, we conducted additional product testing with the goal of addressing the Chemistry, Manufacturing and Controls deficiencies discussed in the CRL. I feel the additional data addresses all the issues raised in the November CRL and we hope the FDA can expedite its review. With the rapid increase in synthetic opioid related deaths and the persistence of widespread opioid addiction, we believe that there remains a need for a higher dose treatment option to help combat this crisis."

About ZIMHI
ZIMHI is a high-dose naloxone injection product candidate intended for the treatment of opioid overdose. Naloxone is an opioid antagonist and is generally considered the drug of choice for immediate administration for opioid overdose. It works by blocking or reversing the effects of the opioid, including extreme drowsiness, slowed breathing, or loss of consciousness. Common opioids include morphine, heroin, tramadol, oxycodone, hydrocodone and fentanyl. According to statistics published by the Centers for Disease Control and Prevention (CDC) in 2018, drug overdoses resulted in approximately 67,000 deaths in the United States – greater than 185 deaths per day. Drug overdoses are now the leading cause of death for Americans under 50, and more powerful synthetic opioids, like fentanyl and its analogues, are responsible for the largest number of deaths from opioid overdoses. On May 11, 2020, Adamis announced it entered into an exclusive distribution and commercialization agreement with USWM for U.S. commercial rights for the ZIMHI product.

About Adamis Pharmaceuticals

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company primarily focused on developing and commercializing products in various therapeutic areas, including respiratory disease, allergy and opioid overdose. The company's SYMJEPI (epinephrine) Injection 0.3mg and SYMJEPI (epinephrine) Injection 0.15mg products were approved by the FDA for use in the emergency treatment of acute allergic reactions, including anaphylaxis. Please refer to www.SYMJEPI.com for additional product information. Adamis is developing additional products, including a naloxone injection product candidate, ZIMHI, for the treatment of opioid overdose, and a metered dose inhaler and dry powder inhaler product candidates for the treatment of asthma and COPD. The company's subsidiary, U.S. Compounding, Inc., compounds sterile prescription drugs, and certain nonsterile drugs for use by hospitals, clinics and surgery centers throughout most of the United States.

Adamis Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future results of operations, including, but not limited to the following matters: the timing or outcome of the FDA's review of the company's resubmitted NDA relating to its naloxone product candidate and whether the FDA will approve the resubmitted NDA; the company's beliefs concerning its ability to commercialize the naloxone product candidate if approved and commercialized; the company's beliefs concerning the size of the markets in which the product candidate will compete if approved; the company's beliefs concerning the safety and effectiveness of its products and product candidates; the Company's beliefs concerning its exclusive distribution and commercialization agreement with USWM, LLC for U.S. commercial rights for the ZIMHI product and whether milestone payments and net profit share payments will be made pursuant to that agreement; and other statements concerning our future operations and activities. 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 are only predictions, are not guarantees, involve known and unknown risks, uncertainties and other factors, and concern matters that could subsequently differ materially from those described in this press release, which may cause Adamis' actual results to be materially different from those contemplated by these forward-looking statements. The timing and outcome of the FDA's review of our NDA is uncertain. There is no assurance that the FDA will approve the NDA relating to our naloxone product candidate (or any other NDA that we file) or that other matters or events relating to the submission and regulatory review process under Section 505(b)(2) of the Food, Drug & Cosmetic Act will not differ from our expectations or result in delays in the regulatory approval process. There are no assurances that the FDA will regard our resubmitted NDA as satisfactorily responding to the matters raised in the earlier CRL or in our Type A meeting with the FDA in February 2020. The FDA could issue another CRL, require additional studies or information, or take other actions other than approval of our resubmitted NDA. Receipt of an additional CRL or other adverse action by the FDA concerning our NDA could result in significant additional time and expense before our ZIMHI NDA is approved, if approved at all, and marketing of ZIMHI could commence. There are no assurances concerning the amount of milestone payments or net profit share payments that we may receive in the future pursuant to our agreement with USWM. In addition, forward-looking statements concerning our anticipated future activities assume that we are able to obtain sufficient funding to support such activities and continue our operations and planned activities. As discussed in our filings with the Securities and Exchange Commission, we will require additional funding, and there are no assurances that such funding will be available if

required. 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 our filings from time to time with the SEC, including our annual report on Form 10-K for the year ended December 31, 2019, and our 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.

Contacts:

Mark Flather
Senior Director, Investor Relations
& Corporate Communications
Adamis Pharmaceuticals Corporation
(858) 412-7951
mflather@adamispharma.com

Source: Adamis Pharmaceuticals Corporation