Adamis Pharmaceuticals Provides Regulatory Update for Its Higher Dose Naloxone Pre-Filled Syringe

November 5, 2019

SAN DIEGO, Nov. 04, 2019 (GLOBE NEWSWIRE) -- Adamis Pharmaceuticals Corporation (NASDAQ: ADMP) ("Adamis") today announced that as of the close of business today, Adamis has not received any notice of action from the U.S. Food and Drug Administration ("FDA") on the company's New Drug Application relating to its ZIMHI™ high-dose naloxone injection product for the treatment of opioid overdose. As Adamis has previously stated, in connection with its acceptance for review of the NDA the FDA previously provided a PDUFA target agency action date of October 31, 2019. However, the FDA's review processes can extend beyond, and in some cases significantly beyond, anticipated or target completion or action dates due to the timing of the FDA's review process, FDA requests for additional data, information, materials or clarification, difficulties scheduling an advisory committee meeting, FDA workload issues, extensions resulting from the submission of additional information or clarification regarding information already in the submission, or other reasons. Adamis intends to make an announcement relating to FDA action concerning the NDA after it receives a notice of action or similar communication from the agency.

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 2017, drug overdoses resulted in approximately 72,000 deaths in the United States – greater than 195 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.

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, and both were fully launched in the U.S. in July 2019. Please refer to www.SYMJEPI.com for additional product information. In addition to its ZIMHI (naloxone) injection product, Adamis is developing other products, including 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 patients, animals, 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. 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 company's beliefs concerning the timing and outcome of the FDA's review of the company's New Drug Application (NDA) relating to the ZIMHI product; the company's beliefs concerning its ability to commercialize ZIMHI and its other products and product candidates; the company's beliefs concerning the ability of its product candidates to compete successfully in the market; the company's beliefs concerning the safety and effectiveness of ZIMHI or its other products and product candidates; the company's beliefs concerning its commercialization strategies; and the company's beliefs concerning the anticipated timing of any commercial launch of its ZIMHI product. 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 these forward-looking statements. There can be no assurances that the FDA will approve our NDA relating to our ZIMHI product or concerning the timing of any future action by the FDA on our NDA, regarding the commercialization options that the company will pursue if our NDA is approved, or that the product will be able to compete successfully in the market if approved and launched. 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 may require additional funding, and there are no assurances that such funding will be available if required. 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, uncertainties, and other factors are described in greater detail in Adamis' filings from time to time 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. Except to the extent required by law, any forward-looking statements in this press release speak only as the date of this press release, and Adamis expressly disclaims any obligation to update any forward-looking statements.

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