

Adamis Pharmaceuticals Receives Complete Response Letter From FDA For Its Epinephrine Pre-Filled Syringe NDA

SAN DIEGO, CA--(March 27, 2015) - [Adamis Pharmaceuticals Corporation](#)

(NASDAQ: ADMP) (“Company”) announced that today it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) Epinephrine Injection USP 1:1000 0.3mg Pre-filled Single Dose Syringe (PFS) product, for the emergency treatment of acute anaphylaxis, which is a severe allergic reaction. On May 28, 2014, Adamis submitted an NDA to the FDA pursuant to Section 505(b)(2) of the Food, Drug & Cosmetic Act, as amended, for approval of the Epinephrine PFS product.

A CRL is issued by the FDA's Center for Drug Evaluation and Research when it has completed its review of a file and questions remain that preclude the approval of the NDA in its current form. The questions raised by the FDA pertain only to Chemistry, Manufacturing and Controls (CMC) relating to the volume of dose delivered by the syringe, including the ability to deliver volume within the levels contained in the labeling claim and as required by the FDA. No other safety or efficacy issues were raised, and the New Drug Application will remain open until the CMC issues are resolved.

Dr. Dennis J. Carlo, President and CEO of Adamis, stated, “We are reviewing the CRL and plan to request a meeting with the FDA to discuss the letter, including clarifying the product delivery volume specifications. Although we expect to have more clarity with respect to timing, we believe we can satisfy all of the requests in the CRL and will work closely with the FDA to address the items raised in the CRL and finalize its review of our NDA. Adamis remains committed to bringing the epinephrine PFS to market.”

About Adamis Pharmaceuticals Corporation

Adamis Pharmaceuticals Corporation is a specialty biopharmaceutical company focused on developing and commercializing products in the therapeutic areas of respiratory disease, allergy, oncology and immunology. The company’s current specialty pharmaceutical product candidates include the Epinephrine Injection PFS syringe product for use in the emergency treatment of anaphylaxis, APC-1000 and APC-5000 for the treatment of asthma and chronic obstructive pulmonary disease, and APC-3000, an HFA inhaled nasal steroid product for the treatment of allergic rhinitis. The company's vaccine product candidates and cancer drug product candidates include TeloB-VAX, a cell-based therapeutic cancer vaccine and three drugs, APC-100, APC-200, and APC-300, for the treatment of prostate cancer.

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 our 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 NDA relating to its Epinephrine PFS product candidate and the company's ability to satisfactorily respond to the matters raised in the FDA's CRL relating to the Epinephrine PFS product; 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 its product candidates; the results of any future clinical trials that the company may conduct relating to its product candidates; the ability to fund future product development; future revenues expected from any of its product candidates, assuming that they are developed and approved for marketing by the FDA and other regulatory authorities; and the intellectual property protection that may be afforded by any patents or patent applications relating to its products and product candidates. Statements in this press release concerning future events depend on several factors beyond the company's control, including receipt of adequate funding to support these activities, the absence of unexpected developments or delays, market conditions, and the regulatory approval process. 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. 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, Adamis expressly disclaims any obligation to update any forward-looking statements.

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