October 4, 2016

Dipexium Receives European Medicines Agency Designation as a Small and Medium Enterprise

Top-line data from pivotal Phase 3 trials of Locilex in Mild Infections of Diabetic Foot Ulcers expected shortly

NEW YORK, Oct. 4, 2016 /PRNewswire/ -- Dipexium Pharmaceuticals, Inc. (Nasdaq: DPRX) ("Dipexium" or the "Company"), a late-stage pharmaceutical company focused on the development and commercialization of Locilex® (pexiganan cream 0.8%), a novel, broad spectrum, topical antimicrobial peptide, today announced that it has been granted Small and Medium Enterprise (SME) designation by the European Medicines Agency (EMA). The Company recently completed its pivotal Phase 3 clinical trials (OneStep-1 and OneStep-2) with Locilex in mild infections of diabetic foot ulcers in the U.S. under a Special Protocol Assessment (SPA) agreement from FDA. Dipexium expects to have top-line data from these trials available for release shortly as its scientific advisory team is finalizing the database, which currently remains blinded.

The SME designation was established by EMA to promote innovation and the development of new medicinal products by smaller companies. Companies with SME status are eligible to receive financial incentives as well as administrative and regulatory support through national and regional level programs. These benefits include access to dedicated EMA personnel during the clinical development process as well as reductions in fees associated with regulatory procedures such as Scientific Advice, Marketing Authorizations, and inspections.

"We are pleased to have SME designation, which allows us to benefit from financial incentives and support from the EMA as we aim to bring Locilex to the global pharmaceutical marketplace," said David P. Luci, President and Chief Executive Officer of Dipexium.

"With prior guidance from the EMA, the results from our clinical trials conducted in the U.S. will form the basis for the planned Marketing Authorization Application to be submitted shortly after filing our New Drug Application Amendment with the FDA," concluded Mr. Luci.

About Dipexium Pharmaceuticals

Dipexium Pharmaceuticals, Inc. (NASDAQ: DPRX) is a late-stage pharmaceutical company focused on the development and commercialization of Locilex® (pexiganan cream 0.8%), a novel, broad spectrum, topical antimicrobial peptide. Initially, Locilex is targeted for the treatment of mild infections of diabetic foot ulcers. Based on a compilation

of available clinical and microbiology data, Locilex is also considered a promising product candidate to treat other mild and moderate skin and skin structure infections, including infected decubitus ulcers, infected burns, infected surgical wounds, infected animal bites and nasal colonization of methicillin-resistant staphylococcus aureus (MRSA). For more information, visit www.dipexiumpharmaceuticals.com.

About OneStep-1 and OneStep-2 Pivotal Phase 3 Clinical Trials

OneStep-1 and OneStep-2 were identical, double-blind, placebo-controlled clinical trials conducted simultaneously that enrolled a total of 389 patients at 59 separate centers in the United States. The primary objective was to establish the clinical superiority and safety of topical Locilex® plus standard local wound care as compared to placebo cream plus standard local wound care, in the treatment of Mild DFI. Patients were randomized 1:1 to receive either topical Locilex® plus standard local wound care or placebo cream plus standard local wound care for 14 days, with final evaluation at day 28. The primary endpoint of the trials is clinical response, which is defined as infection resolved per the judgment of each treating physician using the 2012 Infectious Disease Society of America (IDSA) Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections. Secondary endpoints include microbiological success, which is defined as complete microbiological response, as well as the incidence and severity of adverse events. Other clinical endpoints include several measurements with respect to the timing to, and the extent of, wound healing. The FDA has agreed to a Special Protocol Assessment (SPA) with Dipexium for Locilex®'s pivotal Phase 3 clinical trial program in Mild DFI.

Forward-Looking Statements

This press release may contain, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include statements relating to our anticipated clinical and regulatory development; European Development, I.V. formulation, cash position; cash flows; business strategies and initiatives; and other matters. We have based these forward-looking statements on the assumptions, expectations and projections about future events that we hold at the time the statements are made. We use words like "believe," "anticipate," "intend," "estimate," "expect," "project" and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these words. These forward-looking statements are necessarily estimates reflecting the best judgment of our senior management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements.

Investors should consider the information contained in our filings with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K, especially in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" sections, our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Other unknown or unpredictable factors also could have material adverse effects on our future results, performance or achievements. In light of these risks, uncertainties, assumptions

and factors, the forward-looking events discussed in this press release may not occur. You are cautioned not to place undue reliance on these forward-looking statements, which reflect our beliefs at the time the statements are made.

We do not undertake any obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, nor any other information provided in a conference call, webcast, news release, SEC filing or website.

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