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European Medicines Agency Accepts Design of NeuroDerm's ND0612 Phase III iNDiGO Efficacy Trial

REHOVOT, Israel – June 6, 2017 – NeuroDerm Ltd. (Nasdaq: NDRM), a clinical stage pharmaceutical company developing drug-device combinations for central nervous system (CNS) disorders, today announced that it has received a Scientific Advice Letter from the Scientific Advice Working Party of the European Medicines Agency (EMA). The letter accepts the main design elements suggested by NeuroDerm for the amended iNDiGO phase III efficacy trial (trial 007), including study population and primary and secondary endpoints, as well as the suggested statistical analysis approach. The EMA suggested that NeuroDerm's planned clinical and regulatory development program may be adequate to support a benefit-risk evaluation of ND0612 for the treatment of Parkinson's disease patients on levodopa with motor fluctuations.

At any stage of development of a product candidate, developers can request Scientific Advice from the EMA, which provides a mechanism for the EMA to give developers advice on the appropriate tests and studies in the development of a product candidate. This process is designed to facilitate the development and availability of high-quality, effective and acceptably safe medicines, for the benefit of patients.

NeuroDerm recently requested Scientific Advice from the EMA focused on the amended ND0612 iNDiGO trial protocol. The goal of this request was to reach agreement with the Agency on the content of this protocol, which is now being conducted as a pivotal efficacy and safety trial to support registration of ND0612 in the EU, and to confirm completeness of the development program intended to support the submission of a Marketing Authorisation Application (MAA).

“The acceptance of the main design elements for the iNDiGO trial protocol provided in the Scientific Advice Letter reaffirms NeuroDerm's regulatory development strategy and constitutes a significant step forward for the development of ND0612 in Europe and the associated MAA submission,” said Oded S. Lieberman, PhD, CEO of NeuroDerm. “The guidance provided in the letter allows us to move forward towards our goal to submit regulatory applications for ND0612 in Europe by the end of 2018.”

About NeuroDerm

NeuroDerm is a clinical-stage pharmaceutical company developing central nervous system (CNS) product candidates that are designed to overcome major deficiencies of current treatments and achieve enhanced clinical efficacy through continuous, controlled administration. NeuroDerm's main focus is in Parkinson's disease, where it has three clinical stage product candidates in development which offer a solution for almost every Parkinson's disease patient, from moderate to the very severe stage of the disease. The primary product candidates are a line of levodopa and carbidopa (LD/CD) products administered through small belt pumps that deliver a continuous, controlled dose of LD/CD. The LD/CD product candidates, ND0612L and ND0612H, are aimed at the treatment of moderate and advanced Parkinson's disease patients, respectively, and are delivered subcutaneously. NeuroDerm is also designing a patch pump for future use. In addition, NeuroDerm is developing ND0701, a novel subcutaneously delivered apomorphine formulation for patients who suffer from moderate to severe Parkinson's disease and who do not respond well to LD/CD. NeuroDerm is headquartered in the Weizmann Science Park in Rehovot, Israel.

Forward-Looking Statements



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This press release contains forward-looking statements, within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended that involve risks and uncertainties. Such forward-looking statements may include projections regarding our future performance and may be identified by words like "anticipate," "assume," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "future," "will," "seek" and similar terms or phrases. The forward-looking statements contained in this press release are based on management's current expectations and projections about future events. There are important factors that could cause our actual results, levels of activity, performance or achievements to differ materially from the results, levels of activity, performance or achievements expressed or implied by the forward-looking statements. In particular, you should consider the risks provided under "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2016 filed with the Securities and Exchange Commission. Any forward-looking statement made by us in this press release speaks only as of the date hereof. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

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