



Chinese Regulatory Authority [NMPA] Approves IND Application of Oramed's Oral Insulin Capsules

NEW YORK, March 26, 2019 - Oramed Pharmaceuticals Inc. (NASDAQ/TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, announced today that its Chinese partner, Hefei Tianhui Incubator of Technologies Co., Ltd. ("HTIT"), has reached the significant regulatory milestone of approval of an investigational new drug application ("IND") for two doses of its oral insulin (ORMD-0801). The approval of the IND by the Center For Drug Evaluation of the China National Medical Products Administration ("NMPA", formerly the CFDA) of the oral insulin paves the way for the start of clinical trials in China.

"We are pleased that the Chinese regulatory authorities have approved the IND, as it sets a clear path forward for approval of oral insulin in China, bringing oral insulin closer to becoming a reality in the Chinese market," stated Oramed CEO Nadav Kidron.

About Oramed Pharmaceuticals

Oramed Pharmaceuticals is a platform technology pioneer in the field of oral delivery solutions for drugs currently delivered via injection. Established in 2006, Oramed's Protein Oral Delivery (POD™) technology is based on over 30 years of research by scientists at Jerusalem's Hadassah Medical Center. Oramed is seeking to revolutionize the treatment of diabetes through its proprietary flagship product, an orally ingestible insulin capsule ([ORMD-0801](#)). The Company completed multiple Phase II clinical trials under an Investigational New Drug application with the U.S. Food and Drug Administration. In addition, Oramed is developing an oral GLP-1 analog capsule ([ORMD-0901](#)).

For more information, the content of which is not part of this press release, please visit www.oramed.com

Forward-looking statements: This press release contains forward-looking statements. For example, we are using forward-looking statements when we discuss the timing of expected clinical development programs and clinical trials or revolutionizing the treatment of diabetes with our products. These forward-looking statements are based on the current expectations of the management of Oramed only, and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements, including the risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; difficulties or delays in obtaining regulatory approval or patent protection for our product candidates; competition from other pharmaceutical or biotechnology companies; and our ability to obtain additional funding required to conduct our research, development and commercialization activities. In addition, the following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: changes in technology and market requirements; delays or obstacles in launching our clinical trials; changes in legislation; inability to timely develop and introduce new technologies,



products and applications; lack of validation of our technology as we progress further and lack of acceptance of our methods by the scientific community; inability to retain or attract key employees whose knowledge is essential to the development of our products; unforeseen scientific difficulties that may develop with our process; greater cost of final product than anticipated; loss of market share and pressure on pricing resulting from competition; laboratory results that do not translate to equally good results in real settings; our patents may not be sufficient; and finally that products may harm recipients, all of which could cause the actual results or performance of Oramed to differ materially from those contemplated in such forward-looking statements. Except as otherwise required by law, Oramed undertakes no obligation to publicly release any revisions to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. For a more detailed description of the risks and uncertainties affecting Oramed, reference is made to Oramed's reports filed from time to time with the Securities and Exchange Commission.

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