Oramed Receives Positive Feedback From End-of-Phase 2 Oral Insulin CMC Meeting With FDA

NEW YORK, March 19, 2020 /PRNewswire/ -- Oramed Pharmaceuticals Inc. (Nasdaq: ORMP) (TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, today announced positive feedback from its initial End-of-Phase 2 (EoP2) meeting with the U.S. Food and Drug Administration (FDA) to discuss Chemistry Manufacturing and Control (CMC) of its lead oral insulin capsule ORMD-0801.

The meeting, held in February, followed the successful completion of Oramed's Phase 2b trial of ORMD-0801 for the treatment of type 2 diabetes (See Press Release dated November 12, 2019), which achieved its primary endpoint, the reduction in HbA1c compared to placebo at week 12.

During this meeting the FDA provided feedback on key issues relating to Drug Product manufacture and supported continuing to Phase 3 clinical development. The Company expects an additional meeting with the FDA following deeper analysis of the data from the Phase 2b trial, during which the Company anticipates receiving the FDA's guidance on the Phase 3 study design.

Oramed's Chief Executive Officer, Nadav Kidron, said, "We are very pleased with the productive and constructive feedback from the FDA as we continue on the path to bring oral insulin to market. We look forward to further discussions with the FDA and to their guidance in regards to our anticipated Phase 3 trial."

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, with offices in New York and Israel, Oramed has developed a novel Protein Oral Delivery (POD™) technology that is based on more than 30 years of research by scientists at Jerusalem's Hadassah Medical Center. Oramed is seeking to revolutionize the treatment of diabetes through its proprietary lead candidate, ORMD-0801, which has the potential to be the first commercial oral insulin capsule for the treatment of type 2 and type 1 diabetes. The Company has completed multiple Phase 2 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 (Glucagon-like peptide-1) analog capsule, ORMD-0901.

For more information, 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 potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes, revolutionizing the treatment of diabetes with our products, the timing of expected clinical development programs and clinical trials and discussions with and guidance from the FDA. In addition, historic results of scientific research and clinical trials do not guarantee that the conclusions of future research or trials will suggest identical or even similar conclusions. 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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