Oramed Reports Positive End of Phase 2 Meeting With the FDA for Oral Insulin

NEW YORK, July 15, 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 that the FDA provided positive feedback during the company's End of Phase 2 (EOP2) meeting for Oramed's oral insulin (ORMD-0801). Based on the FDA's feedback, Oramed intends to initiate two Phase 3 clinical trials following FDA review of those Phase 3 protocols, and nonclinical documents. The FDA outlined its expectations for design of the ORMD-0801 Phase 3 trials as well as submission of the Biologics License Application (BLA) that would follow successful trials. Oramed plans to conduct the two Phase 3 trials concurrently.

Oramed's Chief Executive Nadav Kidron said, "We are very pleased with the results of our meeting with the FDA and look forward to submitting our finalized protocols for the Phase 3 trials to the FDA. Following successful Phase 3 trials, we would submit the BLA, which when approved would grant a full 12 years of marketing exclusivity for ORMD-0801. Based on our science and clinical trial results to date, we strongly believe our oral insulin product will address unmet needs among people with diabetes. Oramed is proud to be the global leader in bringing an oral insulin capsule towards commercial availability."

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. 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 diabetes. The Company has 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 (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 initiation of Phase 3 trials, the potential submission and approval of a BLA, the validation of preliminary findings in future trials, the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes or revolutionizing the treatment of diabetes with our products. 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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