Oramed Initiates Second Phase 3 Oral Insulin Study Under the FDA's Approved Dual Concurrent Protocol

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Patients screened in ORA-D-013-2 study which is recruiting 450 patients in 53 sites in the U.S., Europe and Israel

NEW YORK, March 23, 2021 /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, announced today it has screened the first patients in its ORA-D-013-2 study, the second of two concurrent Phase 3 studies of its oral insulin capsule, ORMD-0801, for the treatment of type 2 diabetes (T2D).

The studies are taking place under U.S. Food and Drug Administration (FDA) approved protocols to treat T2D patients who have inadequate glycemic control over a period of 6 to 12 months. [Enrollment for the other Phase 3 study, ORA-D-013-1, is ongoing and has surpassed 25%]. The double-blinded, placebo-controlled, multi-center randomized studies will recruit a total of 1,125 patients to evaluate the efficacy and safety of ORMD-0801. Efficacy data for the studies will become available after all patients have completed the first 6-month treatment period.

"With both concurrent Phase 3 studies now enrolling, we have achieved another world-first milestone, as the only company to conduct two Phase 3 oral insulin studies under an FDA protocol. While ORA-D-013-1 will help us evaluate our oral insulin capsule in patients who are already on two or three glucose-lowering medications, ORA-D-013-2 will help us assess our oral insulin capsule in patients who are on diet control alone or on diet and metformin monotherapy. Evaluating ORMD-0801 in these diverse population groups is expected to yield compelling results for use cases upon potential approval," stated Oramed CEO Nadav Kidron.

About the Study
The ORA-D-013-2 study is recruiting 450 T2D patients with inadequate glycemic control who are managing their condition with either diet alone or with diet and metformin monotherapy. Patients will be recruited through 28 sites in the U.S. and 25 sites in Western Europe and Israel. The double-blind study will randomize patients 1:1 into two cohorts dosed with 8 mg of ORMD-0801 at night and placebo at night. The primary endpoint of the study is to compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c over a 26-week treatment period, with a secondary endpoint of comparing ORMD-0801 to placebo in maintaining glycemic control over a 52-week treatment period.

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 the United States and Israel, Oramed has developed a novel Protein Oral Delivery (POD™) technology. Oramed is seeking to transform 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 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 enrollment for our studies, the potential efficacy, safety and toleration of ORMD-801, the validation of preliminary findings in future trials and the timing of results thereof, 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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