Oramed Reaches 75% Enrollment in Phase 3 Oral Insulin Study

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NEW YORK, Nov. 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 that it has enrolled and randomized over 75% of the 675 patients planned for its Phase 3 ORA-D-013-1 study of its oral insulin capsule ORMD-0801 for the treatment of type 2 diabetes (T2D).

ORA-D-013-1 is the larger of Oramed's two Phase 3 studies being conducted 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. Efficacy data for ORA-D-013-1 will become available after all patients have completed the first 6-month treatment period. The concurrent study, ORA-D-013-2, commenced enrollment in March for a planned 450 patients.

"We are excited to announce that we are nearing the end of enrollment in the world's first Phase 3 oral insulin study conducted under the FDA protocols and we anticipate announcing topline results in 2022," said Oramed CEO Nadav Kidron.

About the Study

ORA-D-013-1 is recruiting 675 patients who are currently on 2 or 3 oral glucose-lowering agents through 75 clinical sites throughout the U.S. The primary endpoint of the study is to compare the efficacy of ORMD-0801 to placebo in improving glycemic control as assessed by A1c, with a secondary endpoint of assessing the change from baseline in fasting plasma glucose at 26 weeks. Efficacy data will become available after all patients have completed the first 6-month treatment period.

The ORA-D-013-1 study is a double blind, double dummy study randomizing patients 1:1:1 for 8 mg ORMD-0801 once-daily at night and placebo 45 minutes before breakfast; or 8 mg ORMD-0801 twice-daily at night and 45 minutes before breakfast; or placebo twice daily at night and 45 minutes before breakfast.

About Oramed Pharmaceuticals

Oramed Pharmaceuticals (Nasdaq: ORMP) (TASE: ORMP) 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 is being evaluated in two pivotal Phase 3 studies and has the potential to be the first commercial oral insulin capsule for the treatment of diabetes. 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 pace of randomization and expected timing of topline results of our Phase 3 studies and the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes. 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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