Oramed Completes Patient Enrollment in Pivotal Phase 3 Oral Insulin Study ORA-D-013-1

May 3, 2022 at 8:10 AM EDT

- ***ORMD-0801 positioned to potentially be the first FDA approved oral insulin for the treatment of diabetes***
- ***Completed enrollment of 710 patients for the Phase 3 ORA-D-013-1 study***
- ***Top line data expected in January 2023***

NEW YORK, May 3, 2022 /PRNewswire/ -- Oramed Pharmaceuticals Inc. (NASDAQ: ORMP) (TASE: ORMP), a clinical-stage pharmaceutical company focused on the development of oral drug delivery platforms, today announced it has completed patient enrollment for its Phase 3 ORA-D-013-1 study of its oral insulin capsule ORMD-0801 for the treatment of type 2 diabetes (T2D), surpassing its target of 675 patients with 710 patients enrolled.

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.

"We are thrilled to announce that the world's first Phase 3 oral insulin study, conducted under an FDA protocol, has achieved a significant milestone with the completion of enrollment. Following the last patient's six months of treatment, we anticipate announcing topline results in January 2023," said Oramed CEO Nadav Kidron. "We are very excited about the prospect of an oral insulin option for people living with diabetes. Being delivered orally, oral insulin mimics endogenous insulin regulation before reaching the bloodstream, providing better blood glucose control and potentially reducing risks and complications associated with injectable insulin, including weight gain and hypoglycemia, while also being easier to administer. I would like to thank all of the patients, investigators and partners involved in this clinical trial, all with the common goal of bringing forth a breakthrough in diabetes therapy."

About the Study

The ORA-D-013-1 study initially aimed to enroll 675 patients and has now completed its enrollment oversubscribed with a total of 710 patients. The enrolled patients are currently on 2 or 3 oral glucose-lowering agents through 96 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. More information can be found here: ORA-D-013-1.

About Oramed Pharmaceuticals

Oramed Pharmaceuticals (Nasdaq/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 trials 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 expected timing of topline results of the Phase 3 study or 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.

Video - https://www.youtube.com/watch?v=t_emiPyO6Ik
Logo - https://mma.prnewswire.com/media/1724339/Oramed_Logo.jpg

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