Oramed Reports Positive First in Human Data from Oral Leptin Study

Leptin capsule may have a role in helping control and reduce obesity rates which are highly correlated with diabetes

NEW YORK, December 23, 2020 – Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, announced today results from a proof-of-concept study approved by Israel's Ministry of Health for its oral leptin drug candidate. The single dose study evaluated oral leptin's safety and pharmacodynamics (glucagon and glucose reduction) in type 1 diabetic (T1DM) patients.

Ten patients were enrolled, with 7 randomized to receive one capsule of leptin and 3 randomized to receive a placebo. Patients who received leptin on average had a decrease in glucose as compared to the placebo group during the first 30-180 minutes following dosing. At different time periods, the leptin treated patients on average had glucagon values that were either lower than, or similar to, those in the placebo group.

"These results are quite exciting and encouraging. With this data, we plan to move into a larger double-blind, placebo-controlled study with an estimated 30 patients. An oral leptin capsule, as a weight loss treatment, may have a key role in addressing increasing diabetes rates and is a synergistic fit with our current pipeline," said Oramed CEO Nadav Kidron.

Leptin, also known as the "obesity hormone", is a protein that regulates hunger. According to Grand View Research, the overall obesity market is expected to reach $15.6 billion in 2024.

About Leptin

Leptin, sometimes called the obesity, fat or satiety hormone, is a protein that is produced in fat cells located in adipose tissues and sends signals to the hypothalamus in the brain. Leptin helps to regulate and alter long-term food intake and energy expenditure. Leptin helps to inhibit hunger and regulate energy balance. Although leptin reduces appetite, obese individuals generally exhibit a higher concentration of leptin in their blood than average weight individuals. These people show resistance to leptin, similar to resistance of insulin in type 2 diabetes. Leptin has additionally been shown to suppress glucagon secretion and improve glucose levels in type 1 diabetes.

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 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 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 potential safety and pharmacodynamics of oral leptin, the potential role of oral leptin in addressing diabetes, the timing of clinical trials, 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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