



Oramed Provides Clinical Update with Meaningful Data Expected by Year-End

- Completed recruitment and randomization of all patients in the primary cohort of Phase IIb HbA1c trial for **oral insulin** capsule ORMD-0801, potentially the first commercial oral insulin capsule for the treatment of Type 2 diabetes; results expected in 4Q 2019; following results Oramed plans to initiate end of Phase II meeting with FDA to plan for Phase III
- Initiated second low dose cohort in Phase IIb HbA1c trial for **oral insulin** capsule ORMD-0801 to evaluate potential efficacy of lower doses; results expected in 1Q 2020
- Evaluating results of Phase I PK study of oral **GLP-1 analog** ORMD-0901 to assess options for supplemental studies
- Examination of ORMD-0801 underway for the treatment of nonalcoholic steatohepatitis (**NASH**) patients
- Clinical trial for **oral leptin** capsule for weight loss initiated

NEW YORK, June 18, 2019 - Oramed Pharmaceuticals Inc. (NASDAQ/TASE: ORMP), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, today provided a clinical update regarding four ongoing clinical programs.

"All of our clinical programs continue to advance on-track as planned with no related serious adverse safety issues. We expect to provide meaningful clinical results from these ongoing trials in the coming months," stated Oramed CEO, Nadav Kidron. "We believe we have a unique oral technology platform that has the potential to revolutionize the effective delivery of important medication to improve treatment of diabetes and related conditions."

Oral Insulin:

In mid-May, Oramed completed enrollment and randomization of close to 300 patients in the primary cohort for its 90-day dose-ranging Phase IIb HbA1c clinical study of its oral insulin capsule, ORMD-0801, for Type 2 diabetes.

Over 80% (237 patients) of these patients have completed treatment in the study.

The Phase IIb double-blind, randomized study for Type 2 diabetes is designed to identify the optimal dose to take into Phase III evaluation. The Phase IIb study will assess the primary efficacy endpoint of reduction in HbA1c as well as safety endpoints. Study results for the primary cohort are expected by year-end 2019. Following the results of the primary cohort Oramed plans to initiate an end of Phase II meeting with the FDA to discuss Phase III protocol.

In addition, Oramed initiated a secondary cohort of patients within the 90-day Phase IIb HbA1C clinical study to evaluate potential efficacy of ORMD-0801 at lower doses. The results are expected in 1Q 2020.



GLP-1:

Oramed completed its Phase I pharmacokinetic (PK) study for ORMD-0901, its oral glucagon-like peptide-1 (GLP-1) analog of exenatide capsule for Type 2 diabetes. This is the first study of ORMD-0901 under Oramed's existing FDA Investigational New Drug application (IND). It is a randomized, single-blind, placebo-controlled, crossover study that aims to evaluate the safety, in addition to the pharmacokinetics, of ORMD-0901 compared to placebo and to open-label subcutaneous exenatide (an FDA-approved GLP-1 analog currently on the market) in 16 healthy subjects. Oramed is now assessing the results for future study options. Previous small studies have shown positive trends.

NASH

Oramed is conducting an exploratory clinical trial with ORMD-0801 for the treatment of nonalcoholic steatohepatitis (NASH). Prevalence of NASH is accelerating rapidly and correlates directly with the rising incidence of Type 2 diabetes. The exploratory 3-month NASH study is ongoing, and Oramed expects to conclude the first cohort by 4Q 2019.

Oral Leptin

Oramed is conducting an exploratory trial with an oral leptin capsule to evaluate glucagon reduction in Type 1 diabetes, with a long-term goal of addressing weight loss. Leptin, known as the "obesity hormone," is a protein that regulates hunger. Obesity and diabetes are highly correlated.

Oramed's proof-of-concept, single-dose study examining glucagon reduction, the first in humans, is planned to begin in 3Q 2019. The study will enroll 10 patients with Type 1 diabetes.

Study results are expected in 4Q 2019.

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 that is based on more than 30 years of research by scientists at Jerusalem's Hadassah Medical Center. 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 Type 2 and Type 1 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, which has potential to be the first orally-ingestible GLP-1 analog.

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 timing of expected clinical development programs and clinical trials, including patient enrollment, release of results, recruitment of additional cohorts or revolutionizing the treatment of diabetes with our products. 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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