Oramed Reports Positive Results in the Final Cohort of its Phase 2b Oral Insulin Trial

Primary endpoints successfully met

Results confirm significant clinical benefits of ORMD-0801 at lower dose treatment

0.95% (0.81% placebo adjusted) A1C reduction in patients treated once daily at 8mg

Excellent safety profile

Paves the way for FDA discussions on Phase 3 Study

Conference Call to Review Results Today at 2:00 p.m. ET

NEW YORK, NY, February 26, 2020 – Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, today announced positive topline data from the second and final cohort of its Phase 2b trial evaluating the efficacy and safety of its lead oral insulin candidate, ORMD-0801, at lower dose regimens. ORMD-0801 has the potential to be the first commercially available oral insulin capsule for the treatment of diabetes.

The placebo-controlled, double-blinded, randomized, 90-day dose-ranging Phase 2b trial in type 2 diabetes patients with inadequate glycemic control on oral antihyperglycemic agents, assessed the change in A1C, the primary efficacy endpoint, from baseline to week 12, as well as safety endpoints, when ORMD-0801 was given in different regimens across three daily dose ranges (8 mg, 16 mg, 32 mg).

Patients randomized in the trial treated with 8 mg of ORMD-0801 once daily achieved an observed mean reduction of 1.29% from baseline and a least square mean reduction of 0.95% from baseline, or 0.81% adjusted for placebo (p value = 0.028). Patients who had A1C readings above 9% at baseline and received 8 mg of oral insulin once daily experienced a 1.26% reduction in A1C by week 12.

Treatment with ORMD-0801 at all doses demonstrated an excellent safety profile, with no serious drug-related adverse events and no increased frequency of hypoglycemic episodes or weight gain compared to placebo. The topline data from the second cohort represents the conclusion of the Phase 2b trial, and the company believes that the results now pave the way for FDA discussions regarding the initiation of a Phase 3 trial.

A teleconference call will be held today, Wednesday, February 26, 2020 at 2 p.m. ET. The dial-in numbers for the conference call are 1-866-966-1396 for domestic callers and +44 (0) 207 192 8000 for international callers. The conference ID is 6468688. To view the slides and hear the presentation

connect
at https://webconnect.webex.com/webconnect/onstage/g.php?MTID=e6bfa5a6ceeefb49d48caf1a17f6bf4ef

Oramed's Chief Executive Officer, Nadav Kidron, stated, "We believe the strong efficacy shown while treating patients at a lower dose further demonstrates ORMD-0801's potential as a safe, non-invasive, and effective oral insulin solution for the millions of people suffering from diabetes worldwide. Following this conclusion of our Phase 2b trial, we are excited to further discuss with the FDA our planned Phase 3 trial."

Joel M. Neutel, MD, the Principal Investigator of the ORMD-0801 Phase 2b trial, commented, "The statistically significant efficacy data, coupled with a clean safety profile, characterized by no reported weight gain, no increase in serious drug-related adverse events, and no hypoglycemia, further support ORMD 0801's clinical potential. I believe the data demonstrated in this second cohort further validates the clinical potential of Oramed's oral insulin to have a highly beneficial impact on the treatment of diabetes the world over. The combined first and second cohort data for the lower doses illustrates that a lower dose would seem to be the right dosage level for future Phase 3 trials, and that in this case, less is more."

About ORMD-0801 Phase 2b Trial Second Cohort

The second cohort of the Phase 2b trial was a 90-day, double-blind, randomized, multi-center trial designed to evaluate the safety and efficacy and determine an optimal dose of ORMD-0801 as a treatment for patients with type 2 diabetes. The primary efficacy endpoint was a reduction in Hemoglobin A1C (A1C, also known as HbA1C, a key clinical measure of blood glucose control) at week 12.

In this second cohort, 78 U.S.-based patients were enrolled, treated, and randomized into five groups: 8 mg dosed once-daily; 8 mg dosed twice-daily; 16 mg dosed once-daily; 16 mg dosed twice-daily; and placebo dosed once-daily. The same two sites which were excluded from the statistical analysis in the primary cohort due to evidence of treatment-by-center interaction and a statistically significant placebo effect, were excluded in the second cohort, representing a patient population of 13 patients. Of the 65 patients included in the analysis, 57 completed through week 12.

The once-daily and twice-daily arms of patients dosed at 8 mg achieved statistically significant (p-value 0.028 and 0.029, respectively) reductions from baseline in A1C of 0.95% (0.81% with placebo adjustment) and 0.95% (0.82% with placebo adjustment), respectively. Patients dosed once-daily at 16 mg and twice-daily at 16 mg did not show statistically significant reductions in A1C. ORMD-0801 demonstrated an excellent safety profile with no serious drug-related adverse events, hypoglycemia or weight gain.

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 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 the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes, the safety and efficacy of ORMD-0801, the ability of ORMD-0801 to reduce A1C, the clinical potential of Oramed's oral insulin to have a highly beneficial impact on the treatment of diabetes the world over, the timing of expected clinical development programs and clinical trials and discussions with the FDA 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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