Oramed Announces Successful Phase IIb Study of Oral Insulin in Type 2 Diabetes

Achieves primary endpoint with statistically significant reduction in A1C versus placebo

Excellent safety profile

Conference call today at 8:30 a.m. ET to review Phase IIb data; Extended review event and conference call scheduled for November 18th

NEW YORK, November 12, 2019 – Oramed Pharmaceuticals Inc. (NASDAQ/TASE: ORMP), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, today announced positive results from the initial cohort of the Phase IIb trial evaluating the efficacy and safety of its lead oral insulin candidate, ORMD-0801, which has the potential to be the first commercial oral insulin capsule for the treatment of diabetes.

The placebo-controlled, double-blinded, randomized, 90-day dose-ranging phase IIb trial in type 2 diabetes (T2D) 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 a dose range.

Patients randomized in the trial to once-daily ORMD-0801 achieved a reduction in mean A1C of 0.60% from baseline, or a reduction of 0.54% adjusted for placebo (p value = 0.036). This 0.54% reduction in A1C is considered clinically meaningful, reflecting an improved glucose control that would result in reduced risk of developing diabetes-related complications.

Treatment with ORMD-0801 demonstrated an excellent safety profile, with no serious drug-related adverse events and with no increased frequency of hypoglycemic episodes. In addition, during this 90-day trial, no weight gain was observed.

Oramed's Chief Executive Officer, Nadav Kidron, said, "These results further demonstrate that ORMD-0801 is a safe and efficacious insulin treatment for improving disease management for the millions of people living with diabetes. As a next step, we look forward to the read-out of data from a second cohort of the trial in the first quarter of 2020 and further discussions with the U.S. FDA about Phase III trials. We are enthusiastic about ORMD-0801's potential as we transition into the final stages of development."

Joel M. Neutel, MD, the Principal Investigator of the Phase IIb trial of ORMD-0801, commented, "This Phase IIb study provides statistically significant efficacy data which, coupled with no reported hypoglycemia, support a unique mechanism of action of Oramed's oral insulin. The intestinal absorption of insulin enables direct delivery of insulin to the liver, mimicking the natural transport of

insulin in the body. The result is a more physiologic replacement of insulin leading to an effective treatment with less risk of hypoglycemia and weight gain. Based on these positive results and the demonstrated meaningful reduction in A1C in T2D patients with inadequate blood glucose control, many of whom were on multiple diabetes medications, I believe the use of ORMD-0801 could be clinically beneficial to patients." Dr. Neutel is the Director of Research at Orange County Research Center in Tustin, California.

A teleconference call will be held today, Tuesday, November 12, 2019, at 8:30 a.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 1288697.

On November 18, 2019, Oramed will host an investor event and an additional teleconference call to further review the data details of its ORMD-0801 Phase IIb trial. The dial-in numbers for the additional conference call are 1-866-966-1396 for domestic callers and +44 (0) 207-192-8000 for international callers. The conference ID is 9469607. To view the slides and hear the presentation connect at
https://webconnect.webex.com/webconnect/onstage/g.php?MTID=ea5e270cfeb418bfbd1fa7b53824a26c7

About ORMD-0801 Phase IIb Study

The Phase IIb study was a 90-day, double-blind, randomized, multi-center trial designed to evaluate the safety and efficacy 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, is a key clinical measure of blood glucose control) at Week 12.

In the initial cohort, 269 U.S.-based patients were enrolled and treated with a dose-increasing approach: 16 mg initial dose, titrated to 24 mg per dose, and then titrated to 32 mg per dose. Patients were randomized into three groups to assess dosing frequency: once-daily (32 mg per day), twice-daily (64 mg per day), thrice-daily (96 mg per day). There was a corresponding placebo for each treatment arm. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). In addition, due to evidence of treatment-by-center interaction, two sites (36 patients (13.4% of enrolled subjects)) were excluded from the statistical analysis.

The once-daily and twice-daily arms achieved statistically significant (p-value 0.036 and 0.042, respectively) reductions from baseline in A1C of 0.60% (0.54% with placebo adjustment) and 0.59%, (0.53% with placebo adjustment) respectively. The thrice-daily arm did not meet statistical significance (p-value 0.093). ORMD-0801 demonstrated an excellent safety profile with no serious drug-related adverse events.

The ongoing second cohort is designed with a sample size of 15 subjects per treatment group to identify the optimal dose of ORMD-0801 for the Phase III trial. In the low-dose second cohort, 75 patients have been 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 twice-daily. Oramed expects to announce the results from the second cohort in Q1 of 2020.

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 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, 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. 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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