



Oramed Completes Patient Recruitment of Phase IIb HbA1c Trial for Oral Insulin Capsule ORMD-0801

- ORMD-0801 reaches significant milestone on path to potentially be the first commercial oral insulin capsule for the treatment of Type 2 diabetes
- Close to 300 patients have now been enrolled. 70% of patients have already completed treatment in the study
- Top-line data expected in fourth quarter 2019
- Oral insulin delivery offers advantageous treatment for Type 2 diabetes by interacting with the body in a more physiological way

NEW YORK, May 21, 2019 - 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 that it has completed enrollment for its 90-day dose-ranging Phase IIb clinical study of its oral insulin capsule main cohort. Close to 300 patients have now been enrolled. 70% (over 200) of these patients have completed treatment in the study.

The Phase IIb double-blind, randomized study for Type 2 diabetes was designed to identify the optimal dose to take into Phase III studies. A primary efficacy endpoint of reduction in HbA1c as well as safety endpoints are being assessed. A previous 28-day treatment study of 180 patients revealed a statistically significant improvement from baseline in HbA1c levels. Longer term treatment with ORMD-0801 has the potential for a more significant positive impact on HbA1c, a key clinical measure of blood sugar.

"Having completed recruitment of close to 300 patients, we are on track to announce top line data in the fourth quarter this year. We expect to begin our Phase III clinical trial design immediately following the results," stated Oramed CEO, Nadav Kidron.

371 million people with Type 2 diabetes worldwide are in need of treatment, representing an estimated \$39 billion market in 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, Oramed's Protein Oral Delivery (POD™) technology is based on over 30 years of research by scientists at Jerusalem's Hadassah Medical Center. Oramed is seeking to revolutionize the treatment of diabetes through its proprietary flagship product, an orally ingestible insulin capsule ([ORMD-0801](#)). The Company 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 analog capsule ([ORMD-0901](#)).

For more information, the content of which is not part of this press release, 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, recruitment for an extension 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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