Oramed Announces Successful Meeting with FDA for Oral Insulin

JERUSALEM September 5, 2017 — 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 successfully concluded its meeting with the U.S. Food and Drug Administration (FDA) regarding ORMD-0801, the Company's novel oral insulin formulation.

At the meeting, the FDA gave clear guidance that the regulatory pathway for submission of ORMD-0801, would be a Biologics License Application (BLA). Such a pathway would grant a full 12 years of marketing exclusivity for ORMD-0801 if approved. On top of this, an additional six months of exclusivity can be granted if the product also receives approval for use in pediatric patients.

The FDA confirmed that the approach to nonclinical toxicology, CMC and qualification of excipients would be driven by their published guidance documents, consistent with the Company's expectations. They also made specific recommendations for clinical trials designed to provide pivotal data prior to registration. Since oral insulin may have a positive more physiologic first-pass effect on the liver with less systemic insulin exposure compared to traditional injectable insulin, at the suggestion of the FDA, Oramed also plans to initiate a three-month trial in patients with type 2 diabetes to evaluate the effect of ORMD-0801 on HbA1c, the main FDA registrational endpoint, later this year. In addition, the FDA confirmed the Company's ability to use insulin from different suppliers like HTBT (Hefei Tianmai Biotechnology Development Co., Ltd., Hefei, China) in the Phase 3 study.

"We are very pleased with the outcome and constructive advice received from the FDA during our meeting. We plan on implementing the FDA's feedback in the coming months which will facilitate the confirmatory Phase 3 study and registration of ORMD-0801." said Nadav Kidron, CEO of Oramed. "Additionally, the FDA's classification of ORMD-0801 as a BLA pathway and its significant commercial implications certainly is an additional exciting outcome for us."

About Oramed Pharmaceuticals

Oramed Pharmaceuticals is a 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 top 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 expected pathway for ORMD-0801 and related timing and potential benefits of that pathway and related trials and studies, our expected clinical development programs and clinical trials 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 final 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 U.S. Securities and Exchange Commission.

Company Contact

Oramed Pharmaceuticals
Josh Hexter
Office: +972-2-566-0001 ext. 2
US: 1 844 9 ORAMED ext. 2
Email: josh@oramed.com