Oramed's Phase 2 Oral Insulin NASH Trial Reaches Over 50% Enrollment

September 15, 2021 at 8:10 AM EDT

NEW YORK, Sept. 15, 2021 /PRNewswire/ -- Oramed Pharmaceuticals Inc. (Nasdaq: ORMP) (TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery platforms, announced today that it has enrolled over 50% of patients planned for its Phase 2 trial of its oral insulin capsule ORMD-0801 for the treatment of non-alcoholic steatohepatitis (NASH). Patients continue to be screened at sites in the U.S. and Israel.

The double-blind, multi-center trial is assessing the safety and potential efficacy of ORMD-0801 in Type 2 diabetes patients with NASH. Efficacy endpoints including percentage change in liver fat content, liver fibrosis, and liver steatosis from baseline will be measured via MRI-PDFF following 12 weeks of dosing.

"With more than half of NASH patients having diabetes, ORMD-0801 has the potential to improve outcomes for patients in both conditions. NASH is a disease with a significant unmet medical need, as no drugs are currently approved to treat this condition, which is a leading cause of liver transplants in the U.S. We are excited to build upon our pilot study's results which showed a reduction in liver fat content to demonstrate the potential for ORMD-0801 to help patients living with NASH," said Oramed Chief Executive Officer, Nadav Kidron.

The global market for drugs to treat NASH is expected to reach $84 billion by 2029.

About NASH

Non-alcoholic steatohepatitis (NASH) is a serious, progressive liver disease caused by a buildup of fat in the liver and accompanied by inflammation, liver cell damage, and in some cases, scarring of the liver. Over time, NASH may progress to cirrhosis, liver cancer, liver failure, and even death. Currently, no pharmacotherapy is globally approved for the treatment of NASH, and people with NASH are left with very few management options.

About Oramed Pharmaceuticals

Oramed Pharmaceuticals (Nasdaq/TASE: ORMP) is a platform technology pioneer in the field of oral delivery solutions for drugs currently delivered via injection. Established in 2006, with offices in the United States and Israel, Oramed has developed a novel Protein Oral Delivery (POD™) technology. Oramed is seeking to transform 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 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.

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 safety and potential efficacy of ORMD-0801, the potential of ORMD-0801 to improve outcomes for patients in both NASH and diabetes or the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes. 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.

Company Contact
Josh Hexter
+1-844-9-ORAMED
josh@oramed.com