



Oramed Completes Patient Enrollment in Phase 2 Oral Insulin NASH Trial

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- **Topline results expected H2 2022**
- **ORMD-0801 is the first oral insulin to be evaluated as a treatment for NASH**
- **Currently no FDA approved therapy exists for NASH**

NEW YORK, March 16, 2022 /PRNewswire/ -- Oramed Pharmaceuticals Inc. (Nasdaq: ORMP), (TASE: ORMP), a clinical-stage pharmaceutical company focused on the development of oral drug delivery platforms, today announced it has completed enrollment of all patients in a Phase 2 trial of its oral insulin capsule ORMD-0801 for the treatment of non-alcoholic steatohepatitis (NASH). An estimated 1.5% to 6.5% of adults in the U.S., or between 4 million and 17 million people, have NASH and about half of these also have diabetes, according to the National Institute of Diabetes and Digestive and Kidney Diseases.



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

"There is currently no drug approved to treat this disease, leaving NASH with a serious unmet medical need. With direct action on the liver, we believe that ORMD-0801 has the potential to address over 50% of people with diabetes who also suffer from NASH, a population with unfortunately increased mortality. We look forward to analyzing and reporting topline data, which we expect will confirm our prior pilot study's efficacy and safety results," said Oramed Chief Executive Officer, Nadav Kidron.

The global market for drugs to treat NASH is expected to reach \$84 billion by 2029, according to a publication by Research and Markets on the Global Non-Alcoholic Steatohepatitis (NASH) Drugs Market.

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 treatment 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 is being evaluated in two pivotal Phase 3 trials and has the potential to be the first commercial oral insulin capsule for the treatment of diabetes. 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 for ORMD-0801 to address over 50% of people with diabetes who also suffer from NASH, the expected timing of topline results of our Phase 2 study and whether it will confirm prior safety and efficacy results 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.

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