Oramed Announces Additional Positive Safety and Efficacy Data from Its Phase 2 Clinical Trial of ORMD-0801 for NASH

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- Achieved primary endpoint of safety and tolerability in participants with Type 2 diabetes with NASH.
- Oral insulin candidate demonstrates consistent trends across key secondary endpoints with reduction of liver fat, liver stiffness and lipids.
- Key opinion leaders' discussion highlights new data and is available on demand.

NEW YORK, Nov. 17, 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 additional positive data from its Phase 2 double-blind, fully randomized, placebo-controlled, multicenter clinical trial (ORA-D-N02) to assess the safety and efficacy of its oral insulin candidate (ORMD-0801), to reduce liver fat content in Type 2 Diabetes patients with non-alcoholic steatohepatitis ("NASH"). The presentation of this new data, including a discussion by key opinion leaders, was featured in a webinar today with a replay available on Oramed's website under Events and Presentations.

Professor Yaron Ilan, M.D., Director of the Department of Medicine at the Hebrew University-Hadassah Medical Center, and principal investigator for the clinical trial, commented, "The clinical data scientific results of ORMD-0801 demonstrated positive safety results on key liver-related endpoints such as reduction of fat and fibrosis. In this patient population, the safety of a potential therapy is of paramount importance."

"We are very encouraged by the detailed data reported today demonstrating a positive safety profile and signs of efficacy for our oral insulin program to treat NASH," said Oramed's Chief Executive Officer, Nadav Kidron. "We also saw consistent trends across key secondary endpoints. This indicates that our oral insulin may be an ideal treatment option for the millions of diabetes and NASH patients, as the global market for drugs to treat NASH is expected to reach $84 billion by 2029[1]. Using oral insulin to treat NASH opens a world of possibilities."

Phase 2 Trial Results
As previously announced, the Phase 2 trial enrolled 32 patients (with 30 patients completing) over a treatment period of 12-weeks. The trial demonstrated that ORMD-0801 was safe and well tolerated at 8 mg twice daily dosing, meeting the primary endpoint of no difference in adverse events for ORMD-0801 compared to placebo. The trial also evaluated the effectiveness of ORMD-0801 in reducing liver fat content over the 12-week treatment period by observing several independent measures. These measurements included MR PDFF (%) as measured by MRI, Steatosis and Fibrosis as measured by Fibroscan, Lipids and HbA1c. All the measurements showed a consistent clinically meaningful trend in favor of ORMD-0801.

Safety Data Summary

- Primary objective of safety met with no serious adverse events and no difference in the incidence rate of adverse events between ORMD-0801 and placebo.

Efficacy Data Summary
Overall, the Phase 2 trial achieved the proof of concept that ORMD-0801 may be a potential candidate for the reduction in liver fat and stiffness and lipids in patients with T2D and NASH.

- Secondary objective of reducing liver fat content in patients with NASH and T2D (Percent Change from Baseline to Week 12 in MR PDFF (%):

- Whole Liver showed a placebo adjusted mean decrease of 0.96 with a placebo adjusted median decrease of 6.0 for ORMD-0801.

- Exploratory objective of median change from baseline in Fibroscan fibrosis levels:
  - Median Change from Baseline to Week 12 in Fibrosis Median (kPa) showed a placebo adjusted median decrease of 1.1 for ORMD-0801.
  - Median change from Baseline to Week 12 in Steatosis Median (dB/m) showed a placebo adjusted median decrease of 29 for ORMD-0801.
- Exploratory objective of change from baseline in Lipid levels:
  - Mean Change from Baseline to Week 12 in Total Cholesterol (mmol/L) showed a placebo adjusted mean decrease of 0.40 for ORMD-0801.
  - Results were similar for LDL, HDL and Triglycerides.

About the Trial

ORA-D-N02 is a Phase 2 double-blind, randomized, placebo-controlled, multicenter trial to assess the safety and efficacy of Oramed's oral insulin candidate, ORMD-0801, to reduce liver fat content in T2D patients with NASH. The trial's primary endpoint was to evaluate the safety of oral insulin in patients with NASH and T2D, with a secondary endpoint to assess, non-statistically, ORMD-0801's efficacy in reducing liver fat content in patients with NASH and T2D. The trial recruited 32 patients with a diagnosis of T2D and of NAFLD by non-invasive determination of hepatic steatosis grade S1, defined as hepatic steatosis > 8% by MRI-PDFF and CAP FibroScan ≥ 238 dB/m. The patients were administered either placebo (n=11) or ORMD-0801 8 mg twice daily (one capsule in the morning, prior to breakfast, and one capsule at night) (n=21) for 12 weeks.

About NASH

Nonalcoholic 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. NASH is the most common chronic liver disease and is associated with Type 2 diabetes in almost 60% of the cases[2]. Currently, no pharmacotherapy is globally approved for the treatment of NASH, and people with NASH are left with very few treatment options.

[1] Source: Research and Markets report on the Global Non-Alcoholic Steatohepatitis (NASH) Drugs Market.
[2]Source: Rev Med Suisse, 2020 Jun 10;16(697):1197-1199.

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 safety and efficacy of ORMD-0801 to treat diabetes and NASH, the expected market for drugs to treat NASH, the potential of ORMD-0801 to be a well-tolerated and convenient oral insulin product for the treatment of patients with diabetes and NASH and 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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