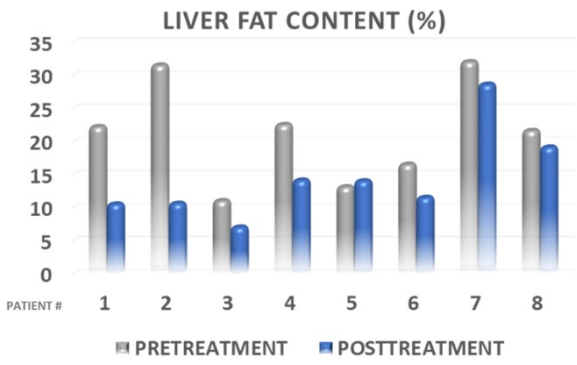
Oramed Announces Positive Initial Clinical Trial Results for Treatment of NASH with Oral Insulin

Data Presented at the American Diabetes Association Scientific Session 2020

NEW YORK, June 15, 2020 – Oramed Pharmaceuticals Inc. (Nasdaq/TASE: ORMP) (www.oramed.com), a clinical-stage pharmaceutical company focused on the development of oral drug delivery systems, today announced that its pilot study of its oral insulin candidate ORMD-0801 in type 2 diabetes patients with non-alcoholic steatohepatitis (NASH), has shown ORMD-0801 to be safe and well tolerated thus far, with an encouraging lowering of fatty liver content, as seen by MRI- derived proton density fat fraction (MRI-PDFF).

The data is being presented in a poster at the 80th American Diabetes Association (ADA) Scientific Sessions, held virtually this year, June 12-16, 2020.

The pilot, open-label study of the first 8 patients of a planned 40-patient multi-center study, aimed to assess the safety, tolerability, and early effects of 16 mg ORMD-0801 (2x8 mg capsules) on liver fat in type 2 diabetes patients with NASH. The 12-week, once-daily treatment had no serious adverse events, and induced an observed mean 6.9±6.8% reduction in liver fat content (sign test p value: 0.035), and the relative reduction was 30%, [see graph] as measured by MRI-PDFF. In parallel, concentrations of gamma-glutamyltransferase (GGT), a key marker of chronic hepatitis, were significantly lower after 12 weeks of treatment as compared to baseline (-14.6±13.1 U/L; sign test p value: 0.008), as were fasting insulin levels (-96.5±206.0 pmol/L; sign test p value: 0.035).



Oramed's CEO, **Nadav Kidron** said, "These preliminary observations suggest a positive effect of oral insulin on NASH in people with type 2 diabetes, as shown by reductions in liver fat content. We look forward to further validating these encouraging findings in the larger population of this study and in large-scale, randomized clinical trials."

In addition to the NASH data, Oramed is presenting two posters illustrating ORMD-0801's impact on type-2 diabetes mellitus (T2DM). Oramed's poster presentations at the ADA include:

- **Oral Insulin (ORMD-0801) Effects on Glucose Parameters in Uncontrolled T2DM on Oral Antibiotic Drugs (OADs),** Presented by **Dr. Julio Rosenstock**, Director of the Dallas Diabetes Research Center and Scientific advisory board member at Oramed Pharmaceuticals
- **Oral Insulin–Induced Reduction in Liver Fat Content in T2DM Patients with Nonalcoholic Steatohepatitis (NASH),** presented by **Dr. Miriam Kidron**, Chief Scientific Officer at Oramed Pharmaceuticals

- **Evening Oral Insulin (ORMD-0801) Glycemic Effects in Uncontrolled T2DM Patients,** presented by **Dr. Julio Rosenstock**

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, with offices in New York and Israel, Oramed has developed a novel Protein Oral Delivery (POD™) technology. Oramed is seeking to revolutionize 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 potential safety and toleration of ORMD-801, the validation of preliminary findings in future trials, the potential of ORMD-0801 to be the first commercial oral insulin capsule for the treatment of diabetes or revolutionizing the treatment of diabetes with our products. 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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