



Oramed Provides Update on Oravax: Oral Vaccine Maker Gets IRB Approval for Clinical Trial

- ***Oravax's virus-like particle (VLP) vaccine being tested against COVID-19 variants including Delta***
- ***Oravax signs licensing deal for VLP injectable vaccine technology with Premas Biotech for commercialization in India***

NEW YORK, July 21, 2021 – 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 several updates for its majority-owned company [Oravax Medical Inc.](#)

Oravax capitalizes on Oramed's proprietary protein oral delivery (POD™) technology in the development of oral vaccines that are now only available via injection. Oravax is the exclusive owner of a virus-like particle (VLP) vaccine technology that targets three SARS CoV-2 virus surface proteins, including proteins less susceptible to mutation, thus making the vaccine potentially effective against current and future variants of the COVID-19 virus. The VLP vaccine is being tested in preclinical studies against COVID-19 variants including the Delta variant. Oravax's VLP vaccine technology is highly scalable with a low cost of goods and easily transferable.

Clinical Trial of Oral COVID-19 Vaccine Moving Forward

Oravax is gearing up to commence clinical trials for its oral COVID-19 vaccine, first in Israel, then in additional clinical sites internationally. The study protocol has been approved by the Institutional Review Board (IRB) at Ichilov Hospital in Tel Aviv, Israel and is now pending approval from the Israeli Ministry of Health. GMP manufacturing for the oral vaccine is under way.

The oral VLP COVID-19 vaccine is being developed for use both as a standalone vaccine as well as a booster for people who have been previously vaccinated for COVID-19. Experts including at the [World Health Organization](#) expect booster shots will be needed for both general and at-risk populations. If successful, an oral vaccine would offer enormous logistical, financial, and environmental benefits for the billions of people slated to receive them, particularly in parts of the world where access to healthcare is limited.

"Our vaccine is a particularly strong candidate against the evolving COVID-19 virus due to its unique targeting of three proteins rather than one. With the Delta and other variants proving a challenge to health administrators globally, Oravax's VLP technology could prove even more important in the effort to combat COVID," said Nadav Kidron, CEO of Oramed.



Oravax Holdings

Oramed is currently evaluating several options with respect to its interest in Oravax, including distributing a portion of its holdings to its shareholders. Subject to applicable law, Oramed will keep shareholders advised of developments.

Premas to Develop and Commercialize VLP Injectable Technology in India

Oravax, the exclusive owner of the VLP technology, has out-licensed certain rights in the territory of India to Premas Biotech, the original developer of the novel vaccine. As Oravax maintains its focus on oral vaccines, it has licensed to Premas the right to develop an injectable version of its VLP technology with an aim to address the urgent need for a vaccine which is effective against the Delta variant. Oravax is entitled to royalties upon commercialization of this vaccine in India.

“Oravax’s VLP platform technology can be delivered either via injection or orally. Because Oravax is focused on oral vaccines, we saw a clear benefit to out-licensing rights to the injectable version in India, where there is an urgent need for vaccines,” Kidron added.

Premas plans to manufacture, test, and potentially commercialize the injectable version of the VLP vaccine in India where the COVID-19 vaccine market is anticipated to grow to over \$2.3 billion by 2027. India is currently in a race to speed up the pace of COVID-19 vaccinations for its population of 1.4 billion as the country’s death toll from the pandemic has topped 400,000 with 31 million cases.

About Oravax Medical Inc.

Oravax was established in 2021 by Oramed Pharmaceuticals Inc., the largest shareholder in Oravax, along with Premas Biotech and certain other shareholders with a mission to bring an oral COVID-19 vaccine to the market. Oravax combines cutting-edge vaccine technology acquired from Premas Biotech and the proprietary POD™ oral delivery technology of Oramed Pharmaceuticals. For more information, please visit www.ora-vax.com

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 studies 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.

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 of the Oravax vaccine or booster to be effective against COVID-19 and other potential benefits of an oral COVID-19 vaccine,



future clinical trials and approvals, potential options with respect to Oramed's interest in Oravax, the potential for royalties and other benefits from the license to Premas, 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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