



NEWS RELEASE

Merck and Orion Announce Global Collaboration for the Development and Commercialization of ODM-208, an Investigational Steroid Synthesis Inhibitor for the Treatment of Metastatic Castration-Resistant Prostate Cancer

7/13/2022

Orion to receive an upfront payment of USD 290 million

Agreement strengthens and complements Merck's oncology pipeline

RAHWAY, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, and Orion Corporation ("Orion") today announced a global development and commercialization agreement for Orion's investigational candidate ODM-208 and other drugs targeting cytochrome P450 11A1 (CYP11A1), an enzyme important in steroid production. ODM-208 is an oral, non-steroidal inhibitor of CYP11A1 currently being evaluated in a Phase 2 clinical trial for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20220713005037/en/>

Under the terms of the agreement, Orion and Merck, acting through its subsidiary, Merck Sharp & Dohme LLC, will co-develop and co-commercialize ODM-208. Merck will make an upfront payment to Orion of USD 290 million, which will be expensed by Merck in the third quarter of 2022 and included in non-GAAP results. Of this upfront payment, Orion recognizes approximately EUR 220 million as income at the time of signing and approximately EUR

60 million is reserved to cover Orion's share of ODM-208 development cost to be accrued in the future. Orion will be responsible for the manufacture of clinical and commercial supply of ODM-208.

In addition, the contract provides both parties with an option to convert the initial co-development and co-commercialization agreement into a global exclusive license to Merck. If the option is exercised, Merck would assume full responsibility for all accrued and future development and commercialization expenses associated with the program. Orion would be eligible to receive milestone payments associated with progress in the development and commercialization of ODM-208 as well as tiered double-digit royalties on sales if the product is approved. The total amount potentially accrued from multiple regulatory and sales milestone events represents a substantial opportunity for Orion.

"Targeting CYP11A1 provides a compelling approach to suppressing the production of steroid hormones, a key driver of prostate cancer," said Dr. Dean Y. Li, president, Merck Research Laboratories. "We believe ODM-208 has the potential to complement our existing program in prostate cancer and look forward to working with the team at Orion."

"We are delighted to enter this collaboration with Merck, which is committed to extend and improve the lives of patients with cancer and has a strong commercial presence globally," said Timo Lappalainen, president and chief executive officer, Orion. "This agreement positions Orion to harness the potential of ODM-208 for the good of patients while continuing to invest in our other programs without compromising our financial targets."

About ODM-208

ODM-208 is an oral, non-steroidal and selective inhibitor of the CYP11A1 enzyme discovered and developed by Orion for the treatment of hormone-dependent cancers, such as prostate cancer. By inhibiting CYP11A1 enzyme activity, ODM-208 is designed to suppress the production of all steroid hormones and their precursors that may activate the androgen receptor signaling pathway.

About Metastatic Castration-Resistant Prostate Cancer

Globally, prostate cancer is the second most common cancer in people assigned male at birth, with an estimated 1.4 million patients diagnosed worldwide in 2020. Approximately 10-20% of patients with advanced prostate cancer are estimated to develop CRPC within five years, and at least 84% of these patients may develop metastases at the time of CRPC diagnosis. Patients with advanced prostate cancer have a particularly poor prognosis, and the five-year survival rate remains low.

About Orion

Orion is a globally operating Finnish pharmaceutical company – a builder of well-being. Orion develops, manufactures and markets human and veterinary pharmaceuticals and active pharmaceutical ingredients. The company is continuously developing new drugs and treatment methods. The core therapy areas of Orion's pharmaceutical R&D are oncology and pain. Orion's net sales in 2021 amounted to EUR 1,041 million and the company had about 3,350 employees at the end of the year. Orion's A and B shares are listed on Nasdaq Helsinki.

About Merck

At Merck, known as MSD outside of the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable and healthy future for all people and communities. For more information, visit www.merck.com and connect with us on **Twitter**, **Facebook**, **Instagram**, **YouTube** and **LinkedIn**.

Forward-Looking Statement of Merck & Co., Inc., Rahway, N.J., USA

This news release of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's Annual Report on Form 10-K for the year ended December 31, 2021 and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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