



**Organon and ObsEva Enter Global License Agreement to Develop and Commercialize Ebopiprant (OBE022), an Investigational Agent Being Evaluated as a First-in-Class Treatment for Preterm Labor**

*Every year, an estimated 15 million babies are born preterm (before 37 completed weeks of gestation)<sup>1</sup>; agent is being studied in an area of significant unmet need*

Ad hoc announcement pursuant to Art. 53 LR of the SIX Swiss Exchange

Jersey City, N.J., Geneva, Switzerland, July 27, 2021 - Organon (NYSE: OGN), a global women's health company and ObsEva (NASDAQ: OBSV) (SIX: OBSN), a biopharmaceutical company dedicated to improving women's reproductive health, today announced that the companies have entered into an agreement whereby Organon will license the global development, manufacturing and commercial rights to ebopiprant (OBE022). Ebopiprant is an investigational, orally active, selective prostaglandin F2 $\alpha$  (PGF2 $\alpha$ ) receptor antagonist being evaluated as a potential treatment for preterm labor by reducing inflammation and uterine contractions. If approved, it has potential to be a first-in-class innovation for this common and serious condition with no approved therapies for acute treatment of preterm labor in the United States.

"This development-stage asset is being studied in one of the most crucial unmet needs for women globally. As we build Organon's women's health research and development portfolio, the agreement strengthens our path to long term growth," said Kevin Ali, Organon's Chief Executive Officer. "Organon and ObsEva share a commitment to improve the lives of women around the world. Through Organon's strong development, scientific and medical capabilities, our goal is to change the future for millions of mothers and babies."

Organon intends to work with the scientific and medical communities and regulatory authorities in major markets, including the United States, to advance the clinical development and registration of ebopiprant.

Brian O'Callaghan, CEO of ObsEva, commented, "Organon is the ideal partner for the development and commercialization of ebopiprant and we see this agreement as an important

step in advancing this investigational agent. Although preterm birth rates are on the rise, there are currently no other known compounds in development. That is why we are focused on evaluating this agent in an important area of unmet need. Together with the data generated to date, this agreement underscores the value of our program, and we look forward to executing on our shared vision."

Under the terms of the agreement, Organon will gain exclusive worldwide rights to develop and commercialize ebopiprant. ObsEva is entitled to receive tiered double-digit royalties on commercial sales as well as up to \$500 million in upfront and milestone payments including \$25 million to be paid at signing, up to \$90 million in development and regulatory milestones and up to \$385 million sales based milestones. Goldman Sachs acted as exclusive financial advisor to ObsEva.

### **About Ebopiprant**

In November 2020, ObsEva announced positive results from PROLONG, the Phase 2a proof-of-concept, randomized, double-blind, placebo-controlled trial of ebopiprant in preterm labor. In this study, 113 women with spontaneous preterm labor (gestational age between 24 and 34 weeks) were randomized and treated with atosiban (ex-U.S. standard of care) plus ebopiprant or atosiban plus placebo for 7 days. There were 83 (73%) women with singleton pregnancies and 30 (27%) with twin pregnancies. One hundred and forty-one neonates were born.

In the PROLONG study, ebopiprant reduced delivery in singleton pregnancies at 48 hours after the start of dosing by 55% compared to atosiban alone. Overall, 7/56 (12.5%) of women receiving ebopiprant delivered within 48 hours of starting treatment compared to 12/55 (21.8%) receiving placebo (OR 90% CI: 0.52 (0.22, 1.23)). In singleton pregnancies, 5/40 (12.5%) of women receiving ebopiprant delivered within 48 hours compared to 11/41 (26.8%) receiving placebo (OR 90% CI: 0.39 (0.15, 1.04)). A modest effect on delivery at 7 days was seen in the singletons.

The incidence of maternal, fetal and neonatal adverse events were comparable between subjects in the ebopiprant group and the placebo group.

Ebopiprant (OBE022) was licensed from Merck KGaA, Darmstadt, Germany, in 2015.

### **About ObsEva**

ObsEva is a biopharmaceutical company developing and commercializing novel therapies to improve women's reproductive health and pregnancy. Through strategic in-licensing and disciplined drug development, ObsEva has established a late-stage clinical pipeline with development programs focused on new therapies for the treatment of uterine fibroids,

endometriosis, and preterm labor. ObsEva is listed on the Nasdaq Global Select Market and is traded under the ticker symbol “OBSV” and on the SIX Swiss Exchange where it is traded under the ticker symbol “OBSN”. For more information, please visit [www.ObsEva.com](http://www.ObsEva.com).

### **About Organon**

Organon is a global healthcare company formed through a spinoff from Merck, known as MSD outside of the United States and Canada, to focus on improving the health of women throughout their lives. Here for her health, the company has a portfolio of more than 60 medicines and products across a range of therapeutic areas. Led by the reproductive health portfolio coupled with an expanding biosimilars business and stable franchise of established medicines, Organon’s products produce strong cash flows that will support investments in future growth opportunities in women’s health, including business development like recently acquired Alydia Health, a medical device company focused on postpartum hemorrhage. In addition, Organon is pursuing opportunities to collaborate with biopharmaceutical innovators looking to commercialize their products by leveraging its scale and presence in fast growing international markets.

Organon has a global footprint with significant scale and geographic reach, world-class commercial capabilities, and approximately 9,000 employees with its headquarters located in Jersey City, New Jersey. For more information, visit <http://www.organon.com> and connect with us on [LinkedIn](#) and [Instagram](#).

### **Forward-Looking Statement of Organon & Co.**

Except for historical information herein, this news release of Organon & Co. (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, including, but not limited to, statements about ebopirant as a potential treatment for preterm labor, Organon’s and ObsEva’s ability to improve the lives of women, Organon’s ability to advance the clinical development of ebopirant, and the potential benefits of the license. Forward-looking statements may be identified by words such as “potential,” “expects,” “intends,” “anticipates,” “plans,” “believes,” “seeks,” “estimates,” “will” or words of similar meaning. These statements are based upon the current beliefs and expectations of Organon’s management and are subject to significant risks and uncertainties. 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 the impact of the recent global outbreak of novel coronavirus

disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Organon's ability to accurately predict its future financial results and performance; Organon's ability to accurately predict future market conditions; manufacturing difficulties or delays; dependence on the effectiveness of Organon's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Organon does not undertake any 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 Organon's filings with the Securities and Exchange Commission ("SEC"), including its registration statement on Form 10, available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).

#### **Cautionary Note Regarding Forward Looking Statements of ObsEva SA**

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe", "expect", "may", "plan", "potential", "will", and similar expressions, and are based on ObsEva's current beliefs and expectations. These forward-looking statements include expectations regarding the clinical development of and commercialization plans for ObsEva's product candidates, expectations regarding regulatory and development milestones, including the potential timing of regulatory submissions to the EMA and FDA and ObsEva's ability to obtain and maintain regulatory approvals for its product candidates, and the results of interactions with regulatory authorities. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials and clinical development, including the risk that the results of earlier clinical trials may not be predictive of the results of later stage clinical trials, related interactions with regulators, ObsEva's reliance on third parties over which it may not always have full control, the impact of the ongoing novel coronavirus outbreak, and other risks and uncertainties that are described in the Risk Factors section of ObsEva's Annual Report on Form 20-F for the year ended December 31, 2020 filed with Securities and Exchange Commission (SEC) on March 5, 2021 and other filings ObsEva makes with the SEC. These documents are available on the Investors page of ObsEva's website

at <http://www.ObsEva.com>. Any forward-looking statements speak only as of the date of this press release and are based on information available to ObsEva as of the date of this release, and ObsEva assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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<sup>i</sup> WHO Key Facts, 2018: <https://www.who.int/news-room/fact-sheets/detail/preterm-birth>