# Organon Enters into Global License Agreement to Commercialize Daré Bioscience's XACIATO™ (clindamycin phosphate vaginal gel, 2%), FDA-Approved Treatment for Females 12 and Older with Bacterial Vaginosis (BV)

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*An estimated 21 million American women experience BV*

JERSEY CITY, N.J. & SAN DIEGO--(BUSINESS WIRE)--Mar. 31, 2022-- Organon (NYSE: OGN), a global women's healthcare company, and Daré Bioscience, Inc. (NASDAQ: DARE), a leader in women's health innovation, today announced they have entered into an agreement whereby Organon will license global rights to XACIATO (clindamycin phosphate vaginal gel, 2%). XACIATO is an FDA-approved medication for the treatment of bacterial vaginosis (BV) in females 12 years of age and older. XACIATO received both Qualified Infectious Disease Product (QIDP) and Fast Track designations from the FDA for the treatment of bacterial vaginosis.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20220331005242/en/

"Our agreement with Daré aligns well with our long-term growth strategy focused on delivering new options for women where therapeutic gaps exist," said Kevin Ali, Organon's Chief Executive Officer. "Organon will bring its commercial expertise to this collaboration so that we can deliver this option to women, specifically in a condition like bacterial vaginosis where more treatment choices are needed."

BV is the most common cause of vaginitis worldwide and is estimated to affect approximately 21 million women in the U.S. The condition results from an overgrowth of bacteria, which upsets the balance of the natural vaginal microbiome and can lead to symptoms of odor and discharge.

Sabrina Martucci Johnson, Daré's President and Chief Executive Officer, commented, "Organon shares our commitment to advance critically needed innovations in women's health. We are excited to be collaborating with one of the premier companies in women's health as we believe that Organon's commercial capabilities will ensure that XACIATO reaches the women most impacted by this condition."

Daré will receive a $10 million upfront payment from Organon. Daré is eligible to receive potential milestone payments of up to $182.5 million and tiered double-digit royalties based on net sales. XACIATO is expected to be available commercially in the U.S. in Q4 2022. Completion of the transaction is subject to review under the Hart-Scott-Rodino Antitrust Improvements Act and other customary conditions. The transaction is expected to close in Q2 2022.

**About Organon**

Organon is a global healthcare company formed through a spin-off from Merck & Co., Inc., Rahway, NJ, USA, (NYSE: MRK) known as MSD outside of the United States and Canada, to focus on improving the health of women throughout their lives. Organon has a portfolio of more than 60 medicines and products across a range of therapeutic areas. Led by the women's 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 innovation and future growth opportunities in women's health. 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 9,300 employees with headquarters located in Jersey City, New Jersey.

For more information, visit http://www.organon.com and connect with us on LinkedIn and Instagram.

**About Daré Bioscience**

Daré Bioscience is a biopharmaceutical company committed to advancing innovative products for women's health. The company's mission is to identify, develop and bring to market a diverse portfolio of differentiated therapies that prioritize women's health and well-being, expand treatment options, and improve outcomes, primarily in the areas of contraception, fertility, and vaginal and

sexual health.

For more information, visit http://www.darebioscience.com, and follow these Twitter accounts: @SabrinaDareCEO and @DareBioscience.

**Forward-Looking Statement of Organon**

Except for historical information herein, this news release 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 XACIATO as a potential treatment for BV, Organon’s and Daré’s ability to improve the lives of women, Organon’s ability to deliver new therapeutic options for women, and the potential benefits of the licensing agreement with Daré. Forward-looking statements may be identified by words such as “expects,” “intends,” “anticipates,” “plans,” “believes,” “seeks,” “estimates,” “will” or words of similar meaning. Such statements are based upon the current beliefs and expectations of the 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; the impact of the ongoing COVID-19 pandemic and emergence of variant strains; 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 approvals; the 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; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; 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.

Organon 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 Organon’s filings with the Securities and Exchange Commission (SEC), including its Annual Report on Form 10-K, filed on March 21, 2022, available at the SEC’s Internet site ( www.sec.gov).

**Forward-Looking Statements of Daré Bioscience**

Daré cautions you that all statements, other than statements of historical facts, contained in this press release, are forward-looking statements. Forward-looking statements, in some cases, can be identified by terms such as “will,” “estimate,” “believe,” “expect,” “eligible,” “anticipate,” “plan,” “seek,” “potential,” or the negative version of these words and similar expressions. In this press release, forward-looking statements include, but are not limited to, statements relating to Daré’s expectations about its agreement with Organon, including commercial distribution and sale of XACIATO and receipt of payments from Organon, and the expected timing of commercial availability of XACIATO in the United States. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements in this press release, including, without limitation: the risks that closing conditions required for the agreement with Organon to become fully effective may not be satisfied or waived and that the agreement may not become fully effective or may be terminated early and the upfront payment may not become payable; the risk that none of the milestones under the agreement with Organon may be achieved and none of potential milestone payments become payable; the potential for royalty payments to be subject to reductions and offsets; dependence on Organon to commercialize the licensed products and on other third parties for commercial supplies of licensed products and components and Daré’s lack of control over the efforts and resources expended by those third parties; general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the ongoing COVID-19 pandemic and emergence of variant strains; 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; Daré’s ability to accurately predict its future financial condition, operating results and performance; Daré’s or its licensor’s ability to accurately predict future market conditions; third-party manufacturing difficulties or delays; financial instability of international economies and sovereign risk; difficulties developing and sustaining relationships with commercial counterparties; dependence on the effectiveness of patents owned or licensed by Daré and other protections for innovative products; and the exposure of Daré, its commercial counterparties and other third parties on which it relies to litigation, including patent litigation, and/or regulatory actions. Daré’s forward-looking statements are based upon its current expectations and involve assumptions that may never materialize or may prove to be incorrect. All forward-looking statements are expressly qualified in their entirety by these cautionary statements. For a detailed description of Daré’s risks and uncertainties, you are encouraged to review its documents filed with the SEC including Daré’s recent filings on Form 8-K, Form 10-K and Form 10- Q. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Daré undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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