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News Release

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Organon Completes Agreement to License MIUDELLA®, Sebela Pharmaceuticals' Hormone-Free Intrauterine Device

This transaction strengthens Organon's contraception portfolio and expands long-acting reversible options for women

JERSEY CITY, N.J., June 22, 2026 - Organon (NYSE: OGN), a global healthcare company with a mission to deliver impactful medicines and solutions for a healthier every day, today announced the completion of a global licensing agreement with Sebela Pharmaceuticals, granting Organon exclusive rights to MIUDELLA®, a hormone-free, copper intrauterine device (IUD). Please see our prior announcement for a summary of the transaction terms.

Approved by the U.S. Food and Drug Administration on February 24, 2025, MIUDELLA is the first hormone-free copper IUD to be introduced in the U.S. in over 40 years. Indicated for the prevention of pregnancy for up to three years in females of reproductive potential, MIUDELLA is 99% effective. It features a proprietary SLIMSERT™ technology which consists of a highly-flexible frame and a fully preloaded inserter with a small, tapered insertion tube diameter of 3.7mm.[i]

MIUDELLA is anticipated to be commercially available in late 2026. The MIUDELLA label includes a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy used by the FDA to manage known or potential risks associated with a product. To mitigate complications due to potential improper insertion, MIUDELLA will only be available in the US through the MIUDELLA REMS program. **See additional safety information below.**

"MIUDELLA represents an important hormone-free option in contraception, expanding choices for women seeking long-acting reversible birth control," said Joe Morrissey, Chief Executive Officer of Organon. "By building on our long history in contraception and leveraging our deep expertise and capabilities, this agreement strengthens Organon's ability to deliver contraceptive options that meet the needs of women."

"Developed by Sebela Women's Health, MIUDELLA represents an effective option for pregnancy prevention," said Alan Cooke, Chief Executive Officer and President of Sebela Pharmaceuticals. "We are delighted to complete this global license agreement with Organon. Organon offers the scale, launch readiness and access capabilities needed to bring this

valuable product efficiently into clinical practice and help ensure MIUDELLA reaches more women who are looking for hormone-free contraception options."

Truist Securities, Inc. acted as financial advisor to Sebela Pharmaceuticals.

About MIUDELLA

MIUDELLA was investigated in three clinical trials in the U.S. in 1,904 women aged 17 to 45 years. The Phase 3 prospective, multicenter single-arm open-label study was conducted in 42 centers in the U.S. with a primary endpoint of contraceptive efficacy through 3 years of use as assessed by the Pearl Index (defined as the number of pregnancies per 100 women over one year).[i] In the efficacy cohort of women aged 17 to 35 years from the Phase 3 study (n=1397), the first-year Pearl Index was 0.94 (95% CI, 0.43-1.78) and the cumulative 3-year Pearl Index was 1.05 (95% CI, 0.66-1.60) in other words, 99% effective, with an overall placement success rate of 98.8%. The most common adverse reactions (≥5%) observed in clinical trials were heavy menstrual bleeding, dysmenorrhea, intermenstrual bleeding, pelvic discomfort, procedural pain, pelvic pain, post-procedural hemorrhage, and dyspareunia. In the first year, 8.5% of participants across all three studies discontinued treatment due to bleeding or pain adverse events, which decreased to 3.2% by year 3. Expulsion rates ranged from 1.9% in year 1 to 0.9% in year 3.

Indication

- MIUDELLA® is a copper-containing intrauterine system (IUS) indicated for prevention of pregnancy in females of reproductive potential for up to 3 years.

Selected Safety Information

WARNING: RISK OF COMPLICATIONS DUE TO IMPROPER INSERTION

- **Improper insertion of intrauterine systems, including MIUDELLA, increases the risk of complications**
- **Proper training prior to first use of MIUDELLA can minimize the risk of improper insertion.**
- **MIUDELLA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MIUDELLA REMS program to ensure all healthcare providers are trained on the proper insertion of MIUDELLA prior to first use. Further information is available at miudellarems.com and 1-855-337-0772.**

CONTRAINDICATIONS

- Use of MIUDELLA is contraindicated when 1 or more of the following conditions exist:
    - Pregnancy or suspicion of pregnancy; congenital or acquired abnormalities of the uterus, including leiomyomas, resulting in distortion of the uterine cavity; acute pelvic inflammatory disease (PID); postpartum endometritis or postabortal endometritis in the past 3 months; known or suspected uterine or cervical malignancy; for use as postcoital contraception (emergency contraception); uterine bleeding of unknown etiology; untreated acute cervicitis or vaginitis or other lower genital tract infection; conditions associated with increased susceptibility to pelvic infections; Wilson's disease; a previously placed IUS that

has not been removed; hypersensitivity to any component of MIUDELLA including to polypropylene, copper, nitinol, an alloy of nickel and titanium, or any of the trace elements present in the copper component of MIUDELLA. Persons with allergic reactions to these components may suffer an allergic reaction to this intrauterine system. Prior to placement, patients should be counseled on the materials contained in the IUS, as well as potential for allergy/hypersensitivity to these materials.

WARNINGS AND PRECAUTIONS

- Risk of Complications Due to Improper Insertion: Improper insertion of IUSs, including MIUDELLA, increases the risk of perforation, infection, undiagnosed abnormal bleeding, pregnancy loss (if pregnancy occurs with IUS in situ), and expulsion. Proper training prior to first use of MIUDELLA can minimize the risk of improper insertion. MIUDELLA is available only through a restricted program under a REMS.

- MIUDELLA REMS: MIUDELLA is only available through a restricted program under a REMS called MIUDELLA REMS Program to ensure healthcare providers are trained prior to first use. Notable requirements include the following:
    - Healthcare providers must be certified with the program by enrolling and completing training on the proper insertion of MIUDELLA prior to first use.
    - Pharmacies and healthcare settings that dispense MIUDELLA must be certified by enrolling in the REMS and must only dispense MIUDELLA to certified healthcare providers.

  Further information is available at www.miudellarems.com and 1-855-337-0772.

- Ectopic Pregnancy: Promptly evaluate females who become pregnant for ectopic pregnancy while using MIUDELLA. Ectopic pregnancy may require surgery and may result in loss of fertility.

- Intrauterine Pregnancy: Increased risk of spontaneous abortion, septic abortion, premature delivery, sepsis, septic shock, and death if pregnancy occurs. Remove MIUDELLA if pregnancy occurs with MIUDELLA in place and the thread ends are visible or can be retrieved from the cervical canal.

- Sepsis: Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following insertion of other IUSs; strict aseptic technique is essential during insertion.

- Pelvic Infection: Promptly examine users with complaints of lower abdominal or pelvic pain, odorous discharge, unexplained bleeding, fever, genital lesions or sores after insertion of MIUDELLA. IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. Remove MIUDELLA in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.
  Subclinical PID: PID may be asymptomatic but still result in tubal damage and its sequelae.

- Perforation: Partial or total perforation of the uterine wall or cervix may occur during insertions, although the perforation may not be detected until sometime later. Perforation may also occur at any time during IUS use. Perforation that results in embedment or

translocation may reduce contraceptive efficacy and result in pregnancy. Risk is increased if inserted in postpartum and lactating females and may be increased if inserted in females with fixed, retroverted uteri or noninvoluted uteri. If perforation is suspected or if known perforation occurs during placement, the IUS should be removed as soon as possible. Surgery may be required. Delayed detection or removal of MIUDELLA in cases of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal penetration, intestinal obstruction, abscesses and/or damage to adjacent organs.

- Expulsion: Partial or complete expulsion of MIUDELLA has been reported, resulting in the loss of contraceptive protection. MIUDELLA should be placed no earlier than 4 weeks post-pregnancy to mitigate the risk of expulsion that may be increased when the uterus is not completely involuted at the time of insertion. Remove a partially expelled MIUDELLA and do not attempt to push a partially expelled MIUDELLA into the uterus.

- Wilson's Disease: MIUDELLA may exacerbate Wilson's disease, a rare genetic disease affecting copper excretion; therefore, the use of MIUDELLA is contraindicated in females with Wilson's disease.

- Bleeding Pattern Alterations: Menstrual bleeding may be altered and result in heavier and longer bleeding with spotting. Females complaining of heavy vaginal bleeding should be evaluated and treated, and may need to discontinue MIUDELLA.

- Magnetic Resonance Imaging (MRI) Safety Information: Patients using MIUDELLA can be safely scanned with MRI only under certain conditions.

- Medical Diathermy: Medical equipment that contains high levels of Radiofrequency (RF) energy such as diathermy may cause health effects (by heating tissue) in females with a metal-containing IUS including MIUDELLA. Avoid using high medical RF transmitter devices in females with MIUDELLA.

ADVERSE REACTIONS

- Most common adverse reactions (≥5%) observed in clinical trials were heavy menstrual bleeding, dysmenorrhea, intermenstrual bleeding, pelvic discomfort, procedural pain, pelvic pain, post-procedural hemorrhage, and dyspareunia.

Before prescribing MIUDELLA®, please read the full Prescribing Information, including Boxed Warning.

About Organon

Organon (NYSE: OGN) is a global healthcare company with a mission to deliver impactful medicines and solutions for a healthier every day. With a portfolio of over 70 products across Women's Health and General Medicines, which includes biosimilars, Organon focuses on addressing health needs that uniquely, disproportionately or differently affect women, while expanding access to essential treatments in over 140 markets.

Headquartered in Jersey City, New Jersey, Organon is committed to advancing access, affordability, and innovation in healthcare. Learn more at www.organon.com and follow us on LinkedIn, Instagram, X, YouTube, TikTok and Facebook.

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, this press 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 the potential benefits of Organon’s exclusive license of global rights to MIUDELLA® and expectations regarding the timing of commercialization thereof. Forward-looking statements may be identified by words such as “anticipated, “may”, “will”, and “expected,” among others. These statements are based upon the current beliefs and expectations of the company’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, weakening of economic conditions that could adversely affect the level of demand for MIUDELLA®; pricing pressures globally, including rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to or affecting Medicare, Medicaid and healthcare reform, pharmaceutical pricing and reimbursement, access to the company’s products, international reference pricing, including most-favored-nation drug pricing, and other pricing related initiatives and policy efforts; the impact of tariffs and other trade restrictions or domestic sourcing requirements; expanded brand and class competition in the markets in which the company operates; the failure of any supplier to provide substances, materials, or services as agreed, or otherwise meet their obligations to the company; the increased cost of supply, manufacturing, packaging, and operations; difficulties developing and sustaining relationships with commercial counterparties, including Sebela Pharmaceuticals; the impact of higher selling and promotional costs; efficacy, safety or other quality concerns with respect to the company’s marketed products, whether or not scientifically justified, leading to product recalls, withdrawals, labeling changes or declining sales; future actions of third parties, including significant changes in customer relationships or changes in the behavior and spending patterns of purchasers of healthcare products and services, including delaying medical procedures, rationing prescription medications, reducing the frequency of physician visits and forgoing healthcare insurance coverage; the failure by the company or its third party collaborators and/or their suppliers to fulfill their or their regulatory or quality obligations; and volatility of commodity prices, fuel, and shipping rates that impact the costs and/or ability to supply the company’s products. 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 filings with the SEC, including the company’s most recent Annual Report on Form 10-K and subsequent SEC filings, available at the SEC’s Internet site (www.sec.gov). References and links to websites have been provided for convenience, and the information contained on any such website is not a part of, or incorporated by reference into, this press release. Organon is not responsible for the contents of third-party websites.

About Sebela Pharmaceuticals

At Sebela Pharmaceuticals, we are building a leading gastroenterology company in the US and developing innovative products in women’s health. Braintree Laboratories, Inc., a part of Sebela

Pharmaceuticals, has been innovating, developing, manufacturing, and commercializing gastroenterology products for over 40 years. Tegoprazan is Braintree's lead program in GERD, and in 2025 Sebela Women's Health obtained FDA approval for Miudella (copper-containing intrauterine system), the first non-hormonal intra-uterine device (IUD) for contraception approved in over 40 years. Sebela Pharmaceuticals has operations in Roswell, GA; Braintree, MA; and Dublin, Ireland.

For more information, visit www.sebelapharma.com.

Sebela Forward-Looking Statement

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sebela Pharmaceuticals, Sebela Women's Health and Braintree Laboratories under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995 and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. These statements may be identified by the use of forward-looking words such as "anticipate," "planned," "believe," "may", "will", "forecast," "estimated," "expected," and "intend," among others. There are several factors that could cause actual events to differ materially from those indicated by such forward looking statements. These factors include, but are not limited to, risks related to the development, launch, introduction and commercial potential of Miudella; growth and opportunity, including peak sales and the potential demand for Miudella, as well as its potential impact on applicable markets; market size; substantial competition; our ability to continue as a going concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third-party payer reimbursement; dependence upon third parties; our financial performance and results, including the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; and risks related to noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development and commercialization of new products. There are no guarantees that Miudella will prove to be commercially successful. While the list of factors presented here is considered representative, no such list should be considered a complete statement of all potential risks and uncertainties. Unlisted factors may present significant additional obstacles to the realization of forward-looking statements. Forward-looking statements included herein are made as of the date hereof, and neither Sebela Pharmaceuticals, Sebela Women's Health nor Braintree Laboratories agree to undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

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[i] Creinin MD, Gawron LM, Roe AH, et al. Three-year efficacy, safety, and tolerability outcomes from a phase 3 study of a low-dose copper intrauterine device. Contraception. 2025;143:110771. doi:10.1016/j.contraception.2024.110771