News Release

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

MIUDELLA® *is a strategic addition to Organon's portfolio, strengthening its long-term commitment to advancing women's health*

JERSEY CITY, N.J., February 23, 2026 -- Organon (NYSE: OGN), a global healthcare company with a mission to deliver impactful medicines and solutions for a healthier every day, announced today that it has entered into an agreement to exclusively license global rights to MIUDELLA, Sebela Pharmaceuticals' hormone-free copper intrauterine device (IUD) contraceptive. The effectiveness of this transaction is subject to review under the Hart-Scott-Rodino Antitrust Improvements Act and to U.S. Food and Drug Administration (FDA) approval of MIUDELLA's alternate supply chain entities and certain other conditions.

MIUDELLA, the first hormone-free copper IUD approved in the U.S. in the last 40 years, is complementary to Organon's commercial capabilities and would further Organon's commitment to building a portfolio of products that meet women's diverse reproductive health needs. MIUDELLA was approved by the FDA on February 24, 2025, for the prevention of pregnancy in females of reproductive potential for up to three years and is not yet commercially available. MIUDELLA offers an additional option for women seeking long-acting, reversible, hormone-free contraception. MIUDELLA contains a unique flexible frame and a fully preloaded inserter with a small, tapered insertion tube diameter of 3.7mm.[i]

Under the terms of the agreement, Organon will pay $27.5 million at closing, with potential sales-based milestone payments of up to $505 million, as well as tiered double-digit royalties based on net sales.

INDICATION FOR MIUDELLA®

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

IMPORTANT SAFETY INFORMATION

- **WARNING: 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 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 is contraindicated when one 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 post-coital 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 polypropylene, copper, nitinol, an alloy of nickel and titanium, or any trace elements present in the copper components 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 intrauterine systems, including MIUDELLA®, increases the risk of perforation, infection, undiagnosed abnormal bleeding, pregnancy loss (if pregnancy occurs with MIUDELLA® in situ), and expulsion. Proper training prior to first use 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 all 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 miudellarems.com and 1-855-337-0772.
- **Ectopic Pregnancy**: Promptly evaluate females who become pregnant for ectopic pregnancy while using MIUDELLA®.
- **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**: Group A streptococcal infection has been reported following insertion of other IUSs; strict aseptic technique is essential during insertion.
- **Pelvic Infection**: Promptly evaluate patients with complaints of fever or lower abdominal pain after insertion of MIUDELLA®. Remove MIUDELLA® in cases of recurrent pelvic inflammatory disease or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.
- **Perforation**: May reduce contraceptive effectiveness and require surgery. 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 occurs during placement, MIUDELLA® should be removed.
- **Expulsion**: Partial or complete expulsion may occur. Remove a partially expelled MIUDELLA®.
- **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.
- **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%) are: heavy menstrual bleeding, dysmenorrhea, intermenstrual bleeding, pelvic discomfort, procedural pain, pelvic pain, post procedural hemorrhage, dyspareunia.

MIUDELLA® does not protect against human immunodeficiency virus (HIV) or other sexually transmitted infections (STIs).

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®. Forward-looking statements may be identified by words such as "will," "potential," "future," "can," "may," "would," or words of similar meaning. 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, any review under the Hart-Scott-Rodino Antitrust Improvements Act, failure to secure FDA approval of MIUDELLA's supply chain or otherwise satisfy the conditions of the transaction; 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 (including amendments thereto), 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.

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[i] Creinin MD, Gawron LM, Roe AH, et al.; Copper 175mm^2 IUD Phase 3 Clinical Investigator Group. Three-year efficacy, safety, and tolerability outcomes from a phase 3 study of a low-dose copper intrauterine device. Contraception. 2024 Nov 22:110771. doi: 10.1016/j.contraception.2024.110771.