FDA Approves MIUDELLA®, the First Hormone-Free Copper Intrauterine System (IUS) in the U.S. in Over 40 Years, from Sebela Women's Health Inc.

ROSWELL, GA, February 24, 2025 – Sebela Women's Health Inc., a part of Sebela Pharmaceuticals, today announced that the U.S. Food and Drug Administration (FDA) granted approval of MIUDELLA® (copper intrauterine system) for the prevention of pregnancy in females of reproductive potential for up to three years. MIUDELLA is a next-generation, hormone-free, low-dose copper intrauterine device or IUD, the first to be approved by the FDA in the United States in over 40 years.

"Sebela Women's Health is thrilled to be able to bring this hormone-free IUD option for birth control to women in the United States," said Kelly Culwell, MD, Head of Research and Development, Sebela Women's Health. "Our innovative copper IUD MIUDELLA® offers effective pregnancy prevention using less than half the copper of the currently available copper-based IUD in the U.S., utilizing a small, flexible nitinol frame. We believe these and other features of MIUDELLA may help address barriers to use, while also providing women with the hormone-free option some prefer."

Guidelines from the American College of Obstetrics and Gynecology state that long-acting reversible contraceptive (LARC) methods, including intrauterine devices and contraceptive implants, are the most effective contraceptive methods, have few contraindications, and are appropriate for almost all patients.[1] While there are a variety of contraceptive methods available to women, 41.6 percent of pregnancies in the U.S. are unintended.[2]

MIUDELLA® is a hormone-free IUD with a flexible frame made of nitinol, a material that has super-elastic properties that enables strategic placement of the copper in a manner that allows the device to achieve similar efficacy to the currently available copper IUD with less than half the dose of copper ($175mm^2$). MIUDELLA® uses the smallest hormone-free flexible IUD frame available in the United States, measuring 32 mm horizontally and 30 mm vertically with pre-cut retrieval strings. Miudella does not require loading by a healthcare professional; it comes fully preloaded within a tapered, rounded tip inserter with a small insertion tube diameter of 3.7 mm.[3]

"Considering it has been four decades since we've been able to offer women a new hormone-free IUD option, I find the clinical data supporting MIUDELLA® efficacy and safety to be very exciting," said Principal Investigator David K. Turok, MD, MPH, Professor, Department of Obstetrics and Gynecology, University of Utah. "This innovative intrauterine device may allow for improvements in discontinuation rates due to pain and bleeding and in expulsion rates. This would be very meaningful for women looking for hormone-free options."

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). In the efficacy cohort 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) or 99% efficacy. Both clinicians and study participants

also reported positive experiences with placement of Miudella, with an overall placement success rate of 98.8%. The most common adverse events across all three clinical trials were similar to those seen with use of IUDs – heavy menstrual bleeding, dysmenorrhea and intermenstrual bleeding. The incidence of these adverse events decreased over time. In the first year, 8.5% of participants across all three studies discontinued due to bleeding or pain adverse events, which decreased to 3.2% by year 3. Expulsion rates were low ranging from 1.9% in year 1 to 0.9% in year 3.

MIUDELLA® will be available to patients through trained healthcare providers in the U.S. later in 2025. For more information on MIUDELLA, please visit miudella.com.

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 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: Don't use MIUDELLA® if you are or may be pregnant, have a uterine anomaly that distorts the uterine cavity and would be incompatible with correct IUS placement, acute pelvic inflammatory disease, postpartum endometritis or postabortal endometritis in past 3 months, known or suspected uterine or cervical malignancy, 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 and/or hypersensitivity to any component of Miudella including to polypropylene, copper, nitinol, an alloy of nickel and titanium, or any trace elements present in the copper components of Miudella®. Do not use MIUDELLA® for post-coital contraception (emergency contraception)
- Pregnancy with MIUDELLA® is rare but can be life threatening and cause infertility or loss of pregnancy.
- MIUDELLA® may attach to or go through the uterus and cause other problems.
- Tell your healthcare provider (HCP) if you develop severe pain or fever shortly after placement, miss a period, have abdominal pain, or if MIUDELLA® comes out. If it comes out, use backup birth control.
- At first, periods may be altered and result in heavier and longer bleeding with spotting in between.
- Tell your HCP you have MIUDELLA® before having an MRI or a medical procedure using heat therapy.
- Additional common side effects include painful periods, pelvic discomfort/pain, procedural pain, post procedural bleeding, and pain during sex.
- MIUDELLA® does not protect against HIV or STDs.

Only you and your HCP can decide if MIUDELLA® is right for you. Available by prescription only.

You are encouraged to report negative side effects of prescription drugs to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

For important risk and use information about Miudella, please see Full Prescribing Information.

About Sebela Pharmaceuticals®

Sebela Pharmaceuticals is a US pharmaceutical company with a market leading position in gastroenterology and a focus on innovation in women's health. In addition to the newly approved MIUDELLA, Sebela Women's Health has another next-generation hormonal IUD for contraception in late-stage clinical development. Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals, is the market leader in colonoscopy screening preparations for over 35 years, having invented, developed and commercialized a broad portfolio of innovative prescription colonoscopy preparations and multiple gastroenterology products. Braintree also has several gastroenterology programs in late-stage clinical development including Tegoprazan which is in phase 3 trials for gastro-esophageal reflux disease (GERD), specifically, erosive esophagitis (EE) and non-erosive reflux disease (NERD).

Sebela Pharmaceuticals has offices/operations in Roswell, GA; Braintree, MA; and Dublin, Ireland. Please visit sebelapharma.com for more information or call 844-732-3521.

MIUDELLA is a registered trademark of Sebela Women's Health Inc.

Forward Looking Statements

This press release and any statements made for and during any presentation or meeting contain forward-looking statements related to Sebela Women's Health Inc. under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995, as amended, and are subject to risks and uncertainties that could cause actual results to differ materially from those projected. In some cases, forward-looking statements can be identified by terminology such as "will," "may," "should," "could," "expects," "intends," "plans," "aims," "anticipates," "believes," "estimates," "predicts," "potential," "continue," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. There are a number of 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, the development, launch, introduction and commercial potential of IUDs as described herein; growth and opportunity, including peak sales and the potential demand for these IUDs, as well as their potential impact on applicable markets; market size; substantial competition; our ability to continue as a growing concern; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third-party payer reimbursement; dependence upon third parties supply and manufacturing uncertainties; 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 failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. There are no guarantees that future clinical trials discussed in this press release will be completed or successful or that any product will receive regulatory approval for any indication or prove to be commercially successful. While the list of factors presented here is considered representative, no such list should be considered to be 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, are based on

current expectations, and Sebela Women's Health Inc. does not undertake any obligation to update publicly such statements to reflect subsequent events or circumstances except as required by law.

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