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Sebela Women's Health Announces Publication of Phase 3 Pivotal Study Results for the Investigational Copper 175 mm^2 Intrauterine Device (IUD) in *Contraception*

ROSWELL, GA, January 24, 2025 – Sebela Women's Health Inc., a part of Sebela Pharmaceuticals, today announced *Contraception* published positive results online from the Phase 3 study of the investigational Copper 175mm^2 intrauterine device (IUD), concluding that data from this trial support the efficacy, safety and tolerability of the Copper 175mm^2 IUD during the first three years of use.[1]

"Publication of the results from the Phase 3 study of the Copper 175mm^2 IUD in *Contraception* further supports the potential impact this hormone-free IUD option can have for women looking for a non-hormonal, long-acting birth control option," said Kelly Culwell, MD, Head of Research and Development, Sebela Women's Health.

The investigational Copper 175mm^2 IUD utilizes a flexible frame made of nitinol and contains less than half the copper of the currently available copper IUD (380mm^2). The Phase 3 study was conducted at 42 research sites throughout the U.S. by the Copper 175mm^2 IUD Phase 3 Clinical Investigator Group, and it was funded by Sebela Women's Health Inc. (Clinicaltrials.gov NCT03633799). Data subsets have previously been presented at major women's health meetings in the U.S., including the American College of Obstetrics and Gynecology annual meeting, and various past publications may have referred to the investigational product as VeraCept. The study is part of a New Drug Application currently under review by the U.S. Food and Drug Administration. The study remains ongoing to evaluate efficacy, safety and tolerability of the Copper 175mm^2 IUD up to eight years.

"This uniquely designed, flexible copper IUD would be the first new hormone-free IUD available in 40 years and would be a welcome addition to the clinician's armamentarium in the U.S.," said Principal Investigator and one of the study authors David K. Turok, MD, MPH, Professor, Department of Obstetrics and Gynecology, University of Utah. "A wide range of birth control options should be available to all people that need them, and a lot of the people I care for prefer a non-hormonal, long-acting option."

"In addition to the efficacy we saw in this study of the Copper 175mm^2 IUD, it's also promising that bleeding and pain observed in some participants dramatically decreased after the first three months of use, as tolerability is a key aspect of a long-acting, non-hormonal option," Turok continued.

For some people, long-acting reversible contraceptive (LARC) methods like intrauterine devices and contraceptive implants offer many advantages. They are recognized as the most effective contraceptive methods, they have few contraindications, and almost all patients are appropriate candidates for them, per American College of Obstetrics and Gynecology (ACOG).[2]

Study Details

This single-arm trial recruited participants at risk of pregnancy aged 17-45 years at 42 U.S. centers to receive a Copper 175mm^2 IUD. The trial assessed efficacy in participants ≤35 years old at enrollment and all safety outcomes in the entire population. The Pearl Index (pregnancies/100 person-years) was calculated through 3 years as the primary efficacy outcome. Secondary outcomes included pregnancy percentages by life-table analysis, placement success, safety (adverse events), and tolerability.

Of 1620 enrollees, 1601 (98.8%) had successful IUD placement, with 1397 ≤35 years at enrollment. The pregnancy risk was about 1% per year, consistent with copper IUDs. The 1-year Pearl Index was 0.94 (95%CI 0.43-1.78) and the 3-year cumulative Pearl Index was 1.05 (95%CI 0.66-1.60). The most common adverse events included bleeding and pain similar to those seen with use of all IUDs. The incidence of these adverse events decreased over time. Over 3 years, 15.4% of participants discontinued due to bleeding or pain. Device expulsions occurred in 36 (2.2%) and 63 (3.9%) participants over 1 and 3 years, respectively. Eight related serious adverse events occurred, including five ectopic pregnancies and one each of uterine perforation, anemia, and uterine hemorrhage.

About Sebela Pharmaceuticals Inc.

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 investigational 175mm^2 Copper intrauterine device (IUD), Sebela Women's Health has another next-generation, hormonal IUD for contraception in the late stages of clinical development. Braintree Laboratories, Inc., a part of Sebela Pharmaceuticals, is the market leader in colonoscopy screening preparations for over 40 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 belongs to a new class of drugs called potassium competitive acid blockers and is currently 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.

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.

References

1. 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.
2. ACOG, Clinical Practice Bulletin #186, Nov. 2017 reaffirmed 2021; Committee Statement #5, April 2023. Accessed on Jan. 20, 2025: https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2017/11/long-acting-reversible-contraception-implants-and-intrauterine-devices and Improving access to intrauterine devices and contraceptive implants. Committee Statement No. 5. American College of Obstetricians and Gynecologists. Obstet Gynecol 2023;141:866–72.

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