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Sebela Women's Health Announces Positive Phase 3 Data for its Investigational, Next-Generation, Hormone-Free, Low-Dose Copper Intrauterine Device (IUD)

If approved by the U.S. Food and Drug Administration, this newly designed, low-dose copper IUD could be the first hormone-free IUD in almost 40 years

ROSWELL, GA, May 18, 2023—Sebela Women's Health Inc., a part of Sebela Pharmaceuticals, today announced positive results of a Phase 3 study demonstrating that investigational Copper 175 mm^2 IUD — a next-generation, hormone-free, low-dose copper intrauterine device — met the primary efficacy outcome measurement of prevention of pregnancy through 3 years of use, with a cumulative 3-year Pearl Index (number of pregnancies per 100 women over 1 year) of 0.96 (95% CI, 0.59-1.48) or 99% efficacy. The study, which enrolled women of child-bearing potential from 42 centers across the United States, demonstrated the Copper 175 mm^2 IUD was well tolerated. Both clinicians and study participants also reported positive experiences with placement of the IUD, with an overall placement success rate 98.8%.

"We're excited to present positive data from our Phase 3 study of this innovative hormone-free intrauterine device," said Kelly Culwell, MD, Head of Research and Development at Sebela Women's Health. "It has been nearly 40 years since there has been a newly designed hormone-free IUD in the United States and we believe this will be a significant advancement not only in long-acting reversible birth control, but also in hormone-free contraception."

Phase 3 Study Details

The Copper 175 mm^2 IUD was investigated in a Phase 3 prospective, multicenter, single-arm, open-label study. The study assessed 3-year outcomes of women aged 17-45 years at 42 centers across the United States. The intent-to-treat population included 1,620 women aged 17-45, 60.1 % nulliparous and 39.9% parous. The primary outcome for the study was 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). The study remains ongoing to assess use beyond 3 years.

In the efficacy cohort (n=1397), the first-year Pearl Index was 0.94 (95% CI, 0.43-1.78) and the cumulative 3-year Pearl Index was 0.96 (95% CI, 0.59-1.48). The most common adverse events were similar to those seen with use of IUDs – heavy menstrual bleeding, dysmenorrhea, and intermenstrual bleeding. However, the Copper 175 mm^2 IUD adverse events rates trended down over time. Over three years, 15.4% discontinued for bleeding or pain adverse events (8.6% in the first year). Expulsion rates were low throughout the study, ranging from 1.9% in year 1 to 0.9% in year 3.

"This newly designed, flexible frame allows the Copper 175 mm^2 IUD to prevent pregnancies using less than half the amount of copper used in the only other copper IUD on the market," said Principal Investigator David K. Turok, MD, MPH, Associate Professor, Department of Obstetrics and Gynecology, University of Utah. "The possibility of having another hormone-free IUD with low discontinuation rates due to pain and bleeding, as well as low expulsion rates, is exciting."

Dr. Turok will be presenting a subset of the Copper 175 mm^2 IUD Phase 3 data on May 21, 2023, at the ACOG Annual Clinical & Scientific Meeting in Baltimore, MD.

The Copper 175 mm^2 IUD has a flexible frame made of nitinol, a material which has superelastic properties and allows for the copper to be strategically placed near the ostia of the fallopian tubes and the internal os of the cervix for proximal effect. [1-3] The Copper 175 mm^2 IUD frame measures 32 mm horizontally and 30 mm vertically with pre-cut retrieval strings. The sterile IUD does not require loading; it comes fully preloaded within a tapered rounded tip inserter with the small insertion tube diameter of 3.7 mm.

According to guidelines from the American College of Obstetrics and Gynecology, long-acting reversible contraceptives (LARC), or intrauterine devices and contraceptive implants, are among the most effective contraceptive methods, they have few contraindications, and almost all patients are appropriate candidates for them.[4] While there are a variety of contraceptive methods available to women in the U.S., 45% of pregnancies are unplanned.[5]

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. Sebela Women's Health has two next-generation intrauterine devices (IUDs) for contraception in the final stages of 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. Sebela Pharmaceuticals has offices/operations in Roswell, GA; Braintree, MA; and Dublin, Ireland; has annual net sales of approximately $200 million; and has grown to over 320 employees through strategic acquisitions and organic growth. 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.

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