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Sebela Women's Health Announces Further Positive Data from the Pivotal Phase 3 Study of the Investigational Copper 175 mm² Intra-Uterine Device (IUD)

Sub-analyses of the pivotal phase 3 data demonstrated that within three years following insertion of the novel, low-dose copper IUD:

- *Bleeding and pain dramatically decreased after the first three months.*
- *IUD discontinuation rates due to AEs of bleeding and pain were infrequent and decreased over three years of use.*
- *Risk of pelvic infection was low regardless of past medical history or baseline infection.*

ROSWELL, GA, October 30, 2023—Sebela Women's Health Inc., a part of Sebela Pharmaceuticals, today announced additional positive data from the pivotal Phase 3 open-label study of the investigational Copper 175 mm² intra-uterine device (IUD). The data presented at three recent women's health scientific congresses provide further support for the investigational, next-generation, hormone-free IUD as exhibited in its pivotal phase 3 trial.

"Sebela Women's Health remains encouraged by the additional analysis of the pivotal Phase 3 trial for what would be the first hormone-free IUD coming to market in almost 40 years." said Kelly Culwell, MD, Head of Research and Development at Sebela Women's Health. "In a study conducted by the non-profit group, [HealthyWomen](#), 60% of the more than 5,000 respondents indicated they preferred a birth control without hormones, and effectiveness was the most important factor to both patients and their practitioners. This innovative investigational low-dose copper IUD clearly helps to fill a gap in the need for more than one hormone-free, long-acting, highly effective contraceptive option for women."¹

About the Investigational Copper 175 mm² IUD

The hormone-free Copper 175 mm² IUD has a flexible frame made of nitinol, a material that 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.²⁻³ In the United States, the Copper 175 mm² IUD utilizes the smallest hormone-free frame measuring 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 a 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, 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

"As both a researcher and practitioner in the field of women's health, analysis of these additional data from the pivotal Phase 3 study of the investigational low-dose copper IUD is not only encouraging, but also important," said Principal Investigator David K. Turok, MD, MPH, Associate Professor, Department of Obstetrics and Gynecology, University of Utah. "Clinicians tend to believe that IUDs increase the risk of pelvic infection, and that the bleeding and pain experienced with hormone-free IUDs is long-lasting and leads to discontinuation of



use. These data suggest we may need to re-visit some of our common beliefs about IUDs with this product, as well as expand our thinking to the many women who may actually be appropriate hormone-free IUD candidates based on this new data.”

Bleeding and Pain Dramatically Decreased After First Three Months

“Bleeding and pain over time with a novel low-dose copper intrauterine device with a flexible nitinol frame”

- *Society of Family Planning (SFP) Annual Meeting in Seattle, WA*
- *Oral Presentation by Dr. David Turok, Associate Professor of Obstetrics and Gynecology, Chief of the Division of Family Planning, University of Utah, Saturday, Oct. 28, 1:15 pm*

This post-hoc analysis of the Phase 3 study assessed participant bleeding and pain with use of the investigational hormone-free, low-dose copper (175mm²) IUD with a flexible nitinol frame. Treatment-emergent adverse events (TEAEs) related to bleeding or pain, their frequency over time, and the number resulting in study discontinuation at three years were assessed.

In total, 1601 of 1620 (98.8%) enrolled participants had a successful IUD insertion. Heavy menstrual bleeding among participants decreased over time and was reported at months 0-3; 69.0%, >3-6; 25.0%, >6-12; 23.1%, >12-24; 8.9%, and >24-36; 4.7%. During this same timeframe, dysmenorrhea reports decreased similarly from 63.8% to 5.2%. Over three years of observation, bleeding or pain-related TEAEs (>1.0%) reported as the primary reason for study discontinuation were heavy menstrual bleeding (6.1%), dysmenorrhea (3.9%), pelvic discomfort (1.7%), and pelvic pain (1.3%). Similarly, IUD discontinuations due to bleeding and pain decreased over time.

Phase 3 Pivotal Data

“A Novel Low-Dose Copper Intrauterine Contraceptive with a Flexible Nitinol Frame (Copper 175mm²): Clinical Trials Overview” (Encore Data)

- *Nurse Practitioners in Women’s Health (NPWH) Annual Meeting in San Diego, CA*
- *Poster presentation by Dr. Anita Nelson, Essential Access Health, Monday, Oct. 30, 11:45 am*

This encore presentation reaffirmed the positive results of the pivotal Phase 3 study demonstrating the efficacy of the investigational Copper 175 mm² IUD 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. This prospective study, which enrolled women of child-bearing potential from 42 centers across the United States, following the U.S. Food and Drug Administration’s rigorous clinical trial standards of Good Clinical Practice, demonstrated the Copper 175 mm² 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%.

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) representing subjects 35 years and younger, 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, with rates decreasing 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 2.4% in year 1 to 1.1% in year 3.



Risk of Pelvic Infection Low Regardless of Past Medical History or Baseline Infection

“Pelvic infection risk after insertion of a novel low-dose copper IUD with a flexible nitinol frame in participants with a history of chlamydia trachomatis (CT) or Neisseria Gonorrhoeae (NG)”

- *American Society of Reproductive Medicine (ASRM) Scientific Congress in New Orleans, LA*
- *Oral presentation by David Turok, MD on Monday, Oct. 16, 1:30 pm CST*

This post-hoc analysis of the Phase 3 study assessed the risk for pelvic infection over three years after insertion of investigational Copper 175 mm² IUD with a flexible nitinol frame. Data demonstrated that of the 1601 total study participants, only 1.2% developed an on-study pelvic infection overall. Of the 131 study participants with a past medical history or positive for CT/NG at screening, only 2.3% developed an on study pelvic infection. The majority of infections occurred more than a year into the study, most infections were treated as outpatient, and no infections resulted in IUD removal.

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 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; has annual net sales of approximately \$200 million; and has grown to over 300 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 Sebel 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

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