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Medicines360 and DKT WomanCare Announce Strategic Partnership to Expand Access to the Hormonal IUD Avibela™

Medicines360 and DKT WomanCare are joining forces to increase availability and use of AVIBELA, an affordable, effective, long-acting hormonal IUD developed by Medicines360, across Africa, South and Southeast Asia, Central America, and the Caribbean.

SAN FRANCISCO and PARIS, Jan. 31, 2024 (GLOBE NEWSWIRE) -- Medicines360, a global nonprofit pharmaceutical organization specializing in women's health, and DKT WomanCare, a global marketing and distribution organization focused on increasing the availability and use of high-quality contraceptive and reproductive health products, have entered into a partnership to expand access to AVIBELA, an affordable, quality-assured, long-acting hormonal IUD that is more than 99% effective at preventing pregnancy.¹ This important collaboration will help more women learn about, access, and use this highly effective, modern form of contraception.

The 52 mg levonorgestrel-releasing intrauterine system ("hormonal IUD") has been largely inaccessible in lower- and middle-income countries (LMICs) due to factors limiting availability and affordability. An estimated 218 million women in LMICs have an unmet need for modern contraception, resulting in approximately 111 million unintended pregnancies (nearly 1 in 2) each year.² With this strategic partnership, more women around the world will have the ability to choose from a broader mix of safe, effective, and affordable contraceptive methods, including AVIBELA.

"As a global nonprofit pharmaceutical organization dedicated to expanding access to affordable reproductive health products for women, DKT WomanCare is an ideal partner for our organization," said Dr. Andrea Olariu, CEO of Medicines360. "With their proven track record of building markets for new high-quality contraceptives, DKT WomanCare will help us provide more women across the world with the contraceptive options they want and deserve. Together, we will make meaningful improvements in access to build a brighter future for women."

Leveraging their global marketing expertise and reach, DKT WomanCare will increase awareness of AVIBELA, build markets, and ensure broader access across the public and private sectors in Africa, South and Southeast Asia, Central America, and the Caribbean. DKT WomanCare will draw on the experience of its parent company, DKT International, to leverage the organization's extensive network of national and regional offices alongside DKT WomanCare's established partnerships with ministries of health, global procurement agencies, social marketing organizations, and commercial distributors.

Lauren Archer, DKT WomanCare's Managing Director, celebrated the partnership. "DKT WomanCare looks forward to leveraging our global partnerships and commercial relationships to ensure every woman, regardless of income, can access affordable, high-quality contraception. We look forward to working with Medicines360 to achieve these goals."

"This partnership is a wonderful opportunity to educate users and practitioners about the benefits of hormonal IUDs, expanding long-term contraceptive options to women everywhere with quality products like AVIBELA," said Chris Purdy, President of DKT International.

As the supplier of AVIBELA, Medicines360 will focus on providing quality assurance and regulatory oversight, as well as ensuring sustainable product supply to DKT WomanCare and global procurement agencies.

Together, Medicines360 and DKT WomanCare will meet the growing demand for quality-assured, affordable hormonal IUDs and help build a robust and sustainable global contraceptive market.

AVIBELA is a trademark of Medicines360 in countries across Africa, South and Southeast Asia, Central America, and the Caribbean. For more information about AVIBELA, please visit www.avibela.com.

AVIBELA™ Important Safety Information

Who is not appropriate for AVIBELA

Contraindications to use of AVIBELA include: pregnancy; use for post-coital contraception (emergency contraception); acute pelvic inflammatory disease (PID) or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy; infected abortion in the past 3 months; known or suspected uterine or cervical neoplasia; acute liver disease or liver tumor (benign or malignant); conditions associated with increased susceptibility to pelvic infections; congenital or acquired uterine anomaly, including fibroids, that distorts the uterine cavity and would be incompatible with correct intrauterine system (IUS) placement; uterine bleeding of unknown etiology; untreated acute cervicitis or vaginitis, including bacterial vaginosis, known chlamydial or gonococcal cervical infection, or other lower genital tract infections until infection is controlled; known or suspected breast cancer or other hormone-sensitive cancer, now or in the past; a previously inserted IUS that has not been removed; a history of hypersensitivity reaction to any component of AVIBELA (reactions may include rash, urticaria, and angioedema).

Clinical considerations for use of AVIBELA

Use AVIBELA with caution after careful assessment in patients with coagulopathy or who are taking anticoagulants; migraine, focal migraine with asymmetrical visual loss, or other symptoms indicating transient cerebral ischemia; exceptionally severe or frequent headache; marked increase of blood pressure; or severe arterial disease such as stroke or myocardial infarction. Consider removal of the IUS if any of these conditions arise during use. Also consider removing AVIBELA if uterine or cervical malignancy, or jaundice arise during use.

IUSs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. About 1/3 of women diagnosed with PID developed the infection within a week of AVIBELA insertion, while the remainder were diagnosed more than six months after insertion. PID is often associated with sexually transmitted infection (STI), and AVIBELA does not protect against STIs. PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae.

Pregnancy related risks with AVIBELA

In the case of pregnancy with AVIBELA in place, advise the woman of the increased risks for pregnancy complications, including miscarriage, premature delivery, infection and sepsis. Ectopic pregnancy should be excluded, and removal of the system should be considered. Removal of AVIBELA or probing of the uterus may result in spontaneous abortion. When a woman becomes pregnant with AVIBELA in place, the relative likelihood of ectopic pregnancy is increased. Ectopic pregnancy may require surgery and may result in loss of fertility. Women with a previous history of ectopic pregnancy, tubal surgery, or pelvic infection have a higher risk of ectopic pregnancy.

Be aware of other serious complications and most common adverse reactions

Some serious complications with IUSs like AVIBELA are sepsis, perforation, and expulsion. Severe infection or sepsis, including Group A streptococcal sepsis (GAS), have been reported following

insertion of other LNG-releasing IUSs. Aseptic technique during insertion of AVIBELA is essential in order to minimize serious infections such as GAS.

Perforation (total or partial, including penetration/embedment of AVIBELA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy and result in pregnancy. If perforation is suspected, the IUS should be removed as soon as possible. Delayed detection or removal of AVIBELA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera.

Partial or complete expulsion of AVIBELA may occur, resulting in the loss of contraceptive protection.

Ovarian cysts may occur and are generally asymptomatic but may be accompanied by pelvic pain or dyspareunia. Evaluate persistent ovarian cysts.

In a large clinical trial of 1,751 women using AVIBELA for contraception, very common undesirable effects (occurring in more than 10% of users) include procedural bleeding, vaginal bacterial infections, vulvovaginal mycotic infections, nausea or vomiting, and acne.

About Medicines360

Located in San Francisco, California, Medicines360 is a nonprofit global women's health pharmaceutical organization with a mission to accelerate the timeline from health innovation to access for all women. Medicines360 is committed to working with healthcare providers, advocacy groups, and patients to deliver innovative and meaningful treatments that help women around the world have greater access to the medicines they need. For more information, visit www.medicines360.org.

About DKT WomanCare

Together, non-profits DKT WomanCare and DKT International are among the largest providers of reproductive health products, services, and technology in the world. Operating in more than 100 countries, they leverage principles of social entrepreneurialism and focus on ensuring wide access and availability of products, building up the capacity of health providers, and empowering consumers. For more information, see www.dktinternational.org and www.dktwomancare.org.

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References:

1. Avibela (levonorgestrel-releasing intrauterine system) 52 mg [Summary of Product Characteristics and Prescribing Information]. Impact RH360; 2022.
2. Sully EA et al., Adding It Up: Investing in Sexual and Reproductive Health 2019, New York: Guttmacher Institute, 2020, <https://www.guttmacher.org/fact-sheet/investing-sexual-and-reproductive-health-low-and-middle-income-countries>