ABBOTT RECEIVES APPROVAL IN RUSSIA AND THE NETHERLANDS FOR DYDROGESTERONE AS THE FIRST ORAL TREATMENT TO PREPARE UTERUS LINING FOR IN VITRO FERTILIZATION

Oral dydrogesterone has the potential to become the new standard of care for an estimated 1.5 million women worldwide who undergo IVF treatment each year.

Abbott today announced regulatory approval in Russia and the Netherlands for its oral dydrogesterone medicine. Oral dydrogesterone, which has been used for more than 50 years to treat conditions related to progesterone insufficiency, is now approved in these countries as a treatment option to prepare the uterus in women who undergo in vitro fertilization (IVF) treatment. In pill form, dydrogesterone’s ease of use offers the potential for it to become the new treatment of choice for the estimated 1.5 million women worldwide who undergo IVF treatment each year.

Dydrogesterone is not registered in the United States.

ABBOTT PARK, Ill., Aug. 30, 2017 — Abbott today announced regulatory approval in Russia and the Netherlands for its oral dydrogesterone medicine. Oral dydrogesterone, which has been used for more than 50 years to treat conditions related to progesterone insufficiency, is now approved in these countries as a treatment option to prepare the uterus in women who undergo in vitro fertilization (IVF) treatment. In pill form, dydrogesterone’s ease of use offers the potential for it to become the new treatment of choice for the estimated 1.5 million women worldwide who undergo IVF treatment each year.

IVF is one of several methods of assisted reproductive technology (ART) whereby a fertilized embryo is transferred to the woman’s uterus. Progesterone or a related hormone, such as dydrogesterone, is used in IVF to prepare the lining of the uterus (luteal phase support) to allow a fertilized egg to implant. To date, no oral form of progesterone has been demonstrated to be effective and safe in women requiring luteal support as part of an ART treatment. This has resulted in the use of alternate and less convenient treatments.

Approval of dydrogesterone’s new IVF indication follows study results published in March 2017 in the scientific journal Human Reproduction. The Lotus I study involved more than 1,000 women across 38 international sites and found oral dydrogesterone had similar efficacy and tolerability to micronized vaginal progesterone (MVP), which is the current standard of care globally for IVF. While MVP is the most commonly used method of administering progesterone in IVF centers globally, it is also associated with side effects, such as irritation and discharge, as well as poor patient acceptance.

Lotus I, a Phase III randomized controlled clinical study, evaluated the effects of oral dydrogesterone in luteal support in IVF. Besides its ease of administration, the Lotus I study concluded that oral dydrogesterone is similarly well-tolerated and efficacious compared to MVP.

“The findings from this study have important implications for women undergoing IVF,” said Herman Tournaye, M.D., Ph.D., Director of the Center for Reproductive Medicine at Universitair Ziekenhuis Brussel, and lead clinical researcher for the Lotus I study. “We found oral dydrogesterone to be effective, well tolerated and easy to administer – all of which point to it becoming the new preferred treatment option.”

About Abbott

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