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 (1,2)

-Abbott to pursue this new indication in all countries in which it currently markets dydrogesterone

ABBOTT PARK, Ill., Aug. 30, 2017 — Abbott today announced regulatory approval in Russia and the Netherlands for a new indication 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[1, [i]] 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 [ii]. 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[iii],[iv]. 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[v]. While MVP is the most commonly used method of administering progesterone in IVF centers globally[vi], it is also associated with side effects, such as irritation and discharge, as well as poor patient acceptance[6].

Lotus I, a Phase III randomized controlled clinical study [vii], 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."

Abbott manufacturers oral dydrogesterone in the Netherlands and markets the medicine under the brand name Duphaston in more than 100 countries. Abbott intends to apply for regulatory approval of the IVF indication in all countries in which it currently markets the product. Dydrogesterone is not registered in the United States.

About Dydrogesterone

Dydrogesterone has been marketed for conditions related to progesterone insufficiency for more than 50 years. The safety and tolerability profile of the drug has been established with an estimated exposure to 113 million patients globally[8].

The use of dydrogesterone is specific to the regulatory approval in each country and includes the treatment of threatened or recurrent miscarriage, as well as luteal phase support in infertility and menstrual disorders, endometriosis and hormone replacement therapy post menopause. The use of dydrogesterone in pregnancy is not indicated in all countries.

Currently, dydrogesterone is approved in Moldova, Russia and the Netherlands for the treatment of luteal phase support in IVF, an ART treatment.

About Abbott

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[i] Chambers GM, Hoang VP, Zhu R, Illingworth PJ. A reduction in public funding for fertility treatment – an econometric analysis of access to treatment and savings to government. BMC Health Services Research 2012; 12:142

[ii] 'Factsheet - In vitro fertilization (IVF): what are the risks?' The Patient Education Website of the American Society for Reproductive Medicine http://www.reproductivefacts.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/risksofivf.pdf [Accessed 7 February 2017]

[iii] 'Factsheet: Progesterone Supplementation During In Vitro Fertilization (IVF) Cycles' The Patient Education Website of the American Society for Reproductive Medicine http://www.reproductivefacts.org/FACTSHEET_Progesterone_Supplementation_During_IVF_Cycles/ [Accessed 7 February 2017]

[iv] Chakravarty BN, Shirazee HH, Dam P, et al. Oral dydrogesterone versus intravaginal micronised progesterone as luteal phase support in assisted reproductive technology (ART) cycles: results of a randomised study. *J Steroid Biochem Mol Biol* 2005;97(5):416–420

[v] Mesen TB and Young SL. Progesterone and the Luteal Phase. *Obstetrics and Gynecology Clinics of North America*. 2015;42(1):135-151.

[vi] Vaisbuch E, Leong M, Shoham Z. Progesterone support in IVF: is evidence-based medicine translated to clinical practice? A worldwide web-based survey. *Reprod Biomed Online* 2012;25:139–145.

[vii] Tournaye H, Sukhikh G, Kahler E, and Griesinger G. A Phase III randomized controlled trial comparing the efficacy, safety and tolerability of oral dydrogesterone versus micronized vaginal progesterone for luteal support in *in vitro* fertilization. *Human Reproduction*. 2017

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