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Investor News

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68th Meeting of American Society for Reproductive Medicine in San Diego:

Bayer HealthCare's new hormone-releasing intrauterine systems proven effective and well tolerated in Phase III study

Leverkusen, Germany, October 25, 2012 –Bayer HealthCare presented results of a pivotal Phase III study evaluating two investigational levonorgestrel-releasing intrauterine systems (IUSs), LNG-IUS12 and LNG-IUS16 at the American Society for Reproductive Medicine (ASRM) 68th Annual Meeting in San Diego, California.[1]

The Pearl Index was the primary efficacy endpoint used to assess contraceptive reliability. The data showed that the LNG-IUS12 and LNG-IUS16, which release a lower dose of hormone and are smaller than the currently available LNG-IUS20, are more than 99 percent effective in preventing pregnancy. This is consistent with existing evidence that IUS are one of the most effective and reliable forms of birth control available.[2]

"The data we observed are encouraging for both investigational IUSs," said Dr. Dan Apter, an investigator in the Phase III study and Chief Physician and Director of the Sexual Health Clinic, Family Federation of Finland. "As many as 41 percent of pregnancies worldwide are unplanned which highlights the need for continued research into highly effective and long-acting birth control options for women."

"We are encouraged by these data and are developing both of these investigational hormone-releasing IUSs to offer women new choices for their individual contraceptive needs," said Kemal Malik, M.D., member of the Bayer HealthCare Executive Committee and Head of Global Development.

In December 2011 Bayer HealthCare submitted an application for marketing authorization in the European Union and in the U.S. for the new low-dose levonorgestrel-releasing intrauterine system (LNG-IUS12) for long-term contraception of up to three years.

About the Phase III Study Design

The global, randomized, Phase 3, open-label study (abstract #651846) included 2,884 women aged 18-35 years with regular menstrual cycles (21-35 days) requesting contraception. Study participants were randomized to either LNG-IUS12 (n=1,432) or LNG-IUS16 (n=1,452), a second investigational IUS. Among those who participated in the study, 39 percent had never had a child (nulliparous) while the remainder had at least one child (parous).[1]

The study was carried out in 138 centers across 11 countries. Participants were blinded to treatment allocation. However, it was not possible to blind investigators to treatment allocation owing to discernible differences between the LNG-IUSs in the length of the hormone reservoir.

At the end of the three-year study, women in the LNG-IUS12 group were required to have their IUS removed. However, women in the LNG-IUS16 group had the option to enter an extension study in which they could continue using their IUS for up to two more years (five years in total). The extension part of the study continues for LNG-IUS16.

Both LNG-IUSs were generally well tolerated, with no unexpected adverse events (AE) reported. Low incidences of ectopic pregnancy, pelvic inflammatory disease (PID), expulsion of the device from the uterus and uterine perforation were seen.

About levonorgestrel-releasing intrauterine systems (LNG-IUS)

LNG-IUSs are small, T-shaped devices made of flexible plastic. Once placed, they release a low dose of the progestogen levonorgestrel directly into the uterus and provide effective birth control for up to three (LNG-IUS12) or five (LNG-IUS20 / LNG-IUS16) years. As a result of the smaller hormone reservoir required, LNG-IUS12 and LNG-IUS16 have a smaller T-frame and can be placed with a narrower placement tube (3.8mm in diameter compared with 4.7mm diameter for LNG-IUS20).

References

1 Global, Randomized, Phase III, Pearl Index Study Comparing the Efficacy and Safety of Two Low-Dose Levonorgestrel-Releasing Intrauterine Systems (LNG-IUSs) in Nulliparous and Parous Women "*Baseline Characteristics*"

2 Stoddard, A et al. Efficacy and Safety of Long-Acting Reversible Contraception. Therapy In Practice 2011; 71(8)

To learn more about contraception, please visit:
www.bayerpharma.de/contraception

About Bayer HealthCare

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