Indianapolis, December 14, 2015

Roche Submits Anti-Müllerian Hormone Assay for FDA Approval

Ovarian reserve fertility diagnostic faster, more reliable than conventional protocols

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has filed a direct de novo application to the U.S. Food and Drug Administration (FDA) for a fully automated Anti-Müllerian (AMH) assay for use on Roche’s full portfolio of laboratory analyzers. The determination of AMH is useful for the assessment of ovarian reserve in women presenting to infertility clinics for evaluation in conjunction with other clinical and laboratory findings. “Our Elecsys® AMH test will help physicians incorporate AMH testing into routine clinical practice and get more reliable results even faster than conventional protocols and manual AMH assays,” explained Dr. Alan Wright, Chief Medical Officer, Roche Diagnostics Corporation. “With over 7.4 million women in the U.S. who have ever used fertility services and 1 in 8 couples having trouble getting or sustaining pregnancy, the need for a standardized, reproducible and robust fertility measurement for women has never been greater.”

Serum levels of AMH have been shown to be relatively stable during the menstrual cycle with substantial fluctuations being observed in younger women. AMH levels further demonstrate lower intra- and inter-cyclic than baseline FSH. Measurement of serum AMH is used for the clinical assessment of ovarian reserve, an important measure for women who are either planning for pregnancy or struggling with infertility. The Elecsys® AMH blood test produces standardized results for assessing ovarian reserve as compared with the use of ultrasound for assessing AFC in which the result is often dependent on the operator or clinic.

The assay is designed for use on all Roche immunoassay systems for low-, mid- and high-volume testing environments, including the cobas e 411, cobas e 601, cobas e 602 and MODULAR ANALYTICS E170 analyzers.

“Once approved, this test will assist clinicians in more predictive, personalized fertility care for their patients,” said Dr. Wright. “Our aim is to give healthcare providers confidence in their patient results and to give women a rapid answer (18 minutes) to a very important, deeply personal question about their fertility.”
Roche currently offers an extensive menu of fertility assays that process in less than 18 minutes, allowing clinicians to evaluate patients quickly during their office visit.

**ABOUT ANTI-MULLERIAN HORMONE:**
In women, Anti-Müllerian hormone (AMH) is exclusively produced by granulosa cells of ovarian follicles during the early stages of follicle development. After an initial increase until early adulthood, AMH concentrations slowly decrease with increasing age until becoming undetectable around five years before menopause. However, major individual variability exists in the pace of follicle pool depletion and the initial size of the follicle pool, reflected by a wide range of age at menopause. Individual AMH serum concentration accurately reflects the size of the pool of antral follicles, representing the quantity of the remaining primordial follicles.

**About Roche**
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-four medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit roche.com.

*All trademarks used or mentioned in this release are protected by law.*

*Error! Hyperlink reference not valid.*

For further information, please contact Roche Diagnostics Corporation:

Todd Siesky  
Senior Director Communications  
(317) 521-3966  
todd.siesky@roche.com

Christina Vysma  
Communications Business Partner  
(317) 521 – 4370  
christina.vysma@roche.com