Media Release

New publication shows consistent clinical performance in screening common fetal trisomies with Harmony™ Prenatal Test

San Jose, Calif. – Nov. 3, 2015 – Roche (SIX: RO, ROG; OTCQX:RHHBY) and Ariosa Diagnostics, Inc., a global leader in non-invasive prenatal testing (NIPT)[1] technology and maker of the Harmony™ Prenatal Test, today announced the results of a new clinical study on the company's targeted cell-free DNA analysis using microarray quantitation which demonstrated high sensitivity, specificity and extremely low false positive rates for prenatal assessment of Down syndrome and other chromosomal disorders. The consistent assay performance of the Harmony Prenatal Test, published in Prenatal Diagnosis, was attributed to its targeted cell-free DNA analysis method regardless of whether evaluated via microarray or next generation sequencing (NGS).

"This publication establishes that the Harmony proprietary targeted assay demonstrates consistently high sensitivity and extremely low false positive rates for common autosomal trisomies across different quantitation platforms," said Thomas Musci, Chief Medical Officer for Ariosa Diagnostics. "Quantitation using both array and next generation sequencing provide equivalent performance for the Harmony test, and the microarray-based quantitation has the advantage of lower cost and higher throughput."

Targeted cell-free DNA analysis using DANSR™ and FORTE™, the key components of the Harmony Prenatal Test, was used to evaluate the risk of trisomy 21 (Down syndrome), 18 and 13 in blinded samples from 799 single, twin, natural and IVF pregnancies. DANSR and FORTE with microarray quantification identified 107 out of 108 trisomy 21 cases (99.1 percent), 29 out of 30 trisomy 18 cases (96.7 percent), and 12 out of 12 trisomy 13 cases (100 percent).

When combined with data from nine previously published clinical studies using the DANSR/FORTE method involving 23,000 pregnancies, screening for all three trisomies was accurate in 99.9 percent of cases.

Features of the Harmony Prenatal Test technology include rapid turnaround time, scalability, fetal fraction measurement and reporting incorporated into an individualized patient risk score. Developed and distributed by Ariosa, the Harmony Prenatal Test is recognized worldwide for being exceptionally tested and validated in published prospective clinical studies.[2] Ariosa's proprietary FORTE software has received the CE mark (Conformité Européenne).

Read more about the clinical study here.

About the Harmony Test

The Harmony Prenatal Test is a screening test for pregnant women that can be used as early as 10 weeks in pregnancy. By evaluating cell-free DNA found in maternal blood, including accurate measurement of the fetal fraction of DNA, the test assesses the risk of trisomy 21 (Down syndrome) in the fetus. It has been validated to Clinical Laboratory Improvement Amendments (CLIA) requirements by a robust clinical data set and supported by clinical studies in more than 23,000 women of all ages and risk categories.[3] It is available in more than 100 countries and territories and has been used to guide clinical care in over 500,000 pregnancies worldwide.

[1]Non-invasive prenatal testing (NIPT) based on cell-free DNA analysis is not diagnostic; results should be confirmed by diagnostic testing. Ariosa Diagnostics is a laboratory certified under the Clinical Laboratory Improvement Amendments (CLIA). As with other laboratory-developed tests, this test service has not been cleared or approved by the US FDA.
[2] Data have not been submitted to or evaluated by Federal regulatory agencies and the test is not for sale as an In Vitro Diagnostic (IVD) in the US or the EU.
[3]Both under 35 and over 35 age groups, studies have included women ages 18-48.

About Ariosa Diagnostics

Ariosa Diagnostics, Inc. is a leading global molecular diagnostics company committed to improving overall patient care by developing and delivering innovative, affordable, and widely-accessible testing services through its CLIA laboratory. Tests are fully validated to CLIA requirements by rigorous and comprehensive methodologies to ensure healthcare practitioners and patients can be confident in the test's performance. Ariosa has developed leading-edge technologies to perform a directed analysis of cell-free DNA in blood. Ariosa is located in San Jose, California, and was acquired by Roche in 2015. For more information, visit www.ariosadx.com.

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-nine 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.

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