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Roche launches AVENIO ctDNA Analysis Kits for Oncology Research

- First blood-based distributed oncology tests covering all four mutation classes
- Three test choices provide accurate insights into different stages and types of cancer
- Streamlined testing generates results in five days

Roche (SIX: RO, ROG; OTCQX:RHHBY) today announced the global commercial launch of the AVENIO circulating tumor DNA (ctDNA) Analysis Kits, a portfolio of three next-generation sequencing (NGS) liquid biopsy assay kits for oncology research: the AVENIO ctDNA Targeted Kit, Expanded Kit and Surveillance Kit. The kits include all reagents, bioinformatics and software to make ctDNA testing accessible to all NGS laboratories.

“We are pleased to introduce these state-of-the-art AVENIO ctDNA Analysis Kits^{1,2,3} that combine the convenience of liquid biopsy with the power of next generation sequencing,” said Roland Diggelmann, Chief Executive Officer, Roche Diagnostics. “Roche believes the AVENIO ctDNA assays can help researchers around the world advance personalized oncology by enabling them to carry out their own testing.”

The AVENIO ctDNA Analysis Kits are aligned with NCCN guidelines to support oncology research⁴. The kits detect all four mutation classes with high sensitivity³. With three different kits available, researchers can profile the genomic complexities of different cancer stages and tumor types, obtaining results in five days.

“As a cancer researcher, I see a tremendous advantage to using the AVENIO ctDNA Analysis Kits”, said Peter Meldgaard, MD, PhD, Associate Professor of Oncology at Aarhus University in Denmark. “Cancer is a highly complex disease, so the ability to obtain a complete and accurate genomic profile of malignant tumors and monitor changes in tumor burden is invaluable.”

About the AVENIO ctDNA Analysis Kits

The AVENIO ctDNA Analysis Kits are for research use only and not for use in diagnostic procedures.

Three NGS assay kits are available for oncology research:

- The AVENIO ctDNA Targeted Kit is a 17 gene pan-cancer assay for identifying guideline-related biomarkers
- The AVENIO ctDNA Expanded Kit is a 77 gene pan-cancer with both guideline-related and emerging biomarkers to profile well-characterized genetic mutations as well as those identified in clinical studies
- The AVENIO ctDNA Surveillance Kit contains 197 genes and is optimized to longitudinally monitor tumor burden in lung cancer and colorectal cancer

Each kit includes all the reagents for DNA extraction, library preparation and target enrichment, as well as the software required to analyze sequencing data and generate reports. The AVENIO kits utilize Roche's enhanced hybrid capture target enrichment techniques to analyse all four mutation classes - single nucleotide variant (SNV), insertion or deletion (indel), fusion and copy number variant (CNV) - in a single workflow. In addition, Roche's proprietary error-suppression strategies enable the AVENIO ctDNA Analysis Kits to detect variant allele frequencies down to 0.1% while maintaining a low error rate down to 0.001%.^{2,3} The AVENIO product line of NGS solutions from Roche will include instruments and reagents that aim to make sequencing simple and accessible for everyday use.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims for improving patient access to medical innovations by working with all relevant stakeholders. 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 cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 billion. 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 www.roche.com.

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¹ Newman AM, Bratman SV, To J, et al. An ultrasensitive method for quantitating circulating tumor DNA with broad patient coverage. *Nature Medicine*. 2014;20(5):548–554. doi:10.1038/nm.3519.

² Newman AM, Lovejoy AF, Klass DM, et al. Integrated digital error suppression for improved detection of circulating tumor DNA. *Nature Biotechnology*. 2016;34(5):547–555. doi:10.1038/nbt.3520.

³ Data on file.

⁴ National Comprehensive Cancer Network. <http://www.nccn.org>. October 15, 2016.