

Roche launches cobas PIK3CA Mutation Test for patients with advanced or metastatic breast cancer in countries accepting the CE mark

- This genetic test identifies mutations in the PIK3CA gene that can cause cells to grow uncontrollably, which may lead to cancer
- PIK3CA is the most commonly mutated gene in advanced or metastatic breast cancer, with nearly 40 percent of patients harbouring a mutation in this gene¹
- The cobas® PIK3CA Mutation Test is a PCR-based test that detects PIK3CA mutations in patients with metastatic breast cancer to help identify those most likely to benefit from approved therapy²

Basel, 15 December 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the launch of the cobas® PIK3CA Mutation Test for patients with advanced or metastatic breast cancer. Previously only available as research use only (RUO), this in vitro diagnostic (IVD) test is now available in countries accepting the CE mark.

“Nearly two million women are diagnosed with breast cancer each year, and an estimated half a million could harbour a PIK3CA mutation.^{3,4} If correctly identified, some of these women may benefit from targeted therapy,” said Thomas Schinecker, CEO Roche Diagnostics. “We are pleased to offer the cobas PIK3CA Mutation Test CE-IVD, enabling clinicians to accurately and quickly manage their breast cancer patients.”

In advanced or metastatic breast cancer, PIK3CA mutations are associated with tumour growth, resistance to endocrine treatment, and a poor overall prognosis. The cobas PIK3CA Mutation Test detects 17 mutations in the PIK3CA gene and can help clinicians identify patients who may benefit from phosphoinositide 3-kinase (PI3K) targeted therapy as supported by medical guidelines.^{5,6}

About the cobas PIK3CA Mutation Test

The cobas PIK3CA Mutation Test is a real-time PCR test for the qualitative detection and identification of 17 mutations in exons 2, 5, 8, 10, and 21 in the gene encoding the catalytic subunit of PIK3CA in DNA isolated from formalin-fixed paraffin-embedded tissue (FFPET). The cobas PIK3CA Mutation Test is intended to identify patients with metastatic breast cancer whose tumours harbour these mutations.

The cobas PIK3CA Mutation Test provides automated results reporting, with flexible throughput to process up to 30 samples per run on the widely available cobas z 480 Analyzer. Specimens are processed using the cobas® DNA Sample Preparation Kit to isolate genomic DNA from FFPET human specimens. Using a standardised workflow, the cobas PIK3CA Mutation Test provides fast time-to-results in under eight hours.

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 to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty 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. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

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

References

- [1] Vasan N et al Annals of Onco 2019
- [2] **cobas**® PIK3CA Mutation Test CE-IVD package insert
- [3] GLOBOCAN 2018
- [4] seer.cancer.gov/statfacts/html/breast-subtypes.html. Accessed on 30 Nov 2020
- [5] 5th ESO-ESMO international consensus guidelines for advanced breast cancer (ABC 5)
<https://doi.org/10.1016/j.annonc.2020.09.010>
- [6] 6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.6.2020

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Patrick Barth
Phone: +41 61 688 44 86

Dr. Daniel Grotzky
Phone: +41 61 688 31 10

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mähltitz

Nathalie Meetz

Phone: +41 79 327 54 74

Phone: +41 61 687 43 05

Dr. Barbara von Schnurbein

Phone: +41 61 687 89 67

Roche Investor Relations

Dr. Karl Mahler

Phone: +41 61 68-78503

e-mail: karl.mahler@roche.com

Jon Kaspar Bayard

Phone: +41 61 68-83894

e-mail: jon_kaspar.bayard@roche.com

Dr. Sabine Borngräber

Phone: +41 61 68-88027

e-mail: sabine.borngraeber@roche.com

Dr. Bruno Eschli

Phone: +41 61 68-75284

e-mail: bruno.eschli@roche.com

Dr. Birgit Masjost

Phone: +41 61 68-84814

e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin

Phone: +41 61 68-72942

e-mail: gerard.tobin@roche.com

Investor Relations North America

Loren Kalm

Phone: +1 650 225 3217

e-mail: kalm.loren@gene.com

Dr. Lisa Tuomi

Phone: +1 650 467 8737

e-mail: tuomi.lisa@gene.com