FDA grants Breakthrough Device Designation for Roche's Elecsys Growth Differentiation Factor-15 (GDF-15) assay to help identify patients suitable for innovative treatment addressing unintentional weight loss in cancer patients

- **FDA BDD acknowledges the importance of GDF-15 testing in identifying eligible cachexic patients with solid tumours to be treated with Pfizer's investigational drug PF-06946860**
- **Unintentional weight loss (cachexia) is a highly prevalent complication of cancer, affecting more than half of all cancer patients worldwide, potentially leading to significant functional impairment and increased risk of death**
- **Successful cachexia treatment can potentially contribute to improved cancer treatment worldwide**

Basel, 8 February 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to their Elecsys® GDF-15 assay as a companion diagnostic (CDx) in cancer treatment. This in vitro diagnostic immunoassay is intended for measurement of Growth Differentiation Factor-15 (GDF-15) in cachectic patients 18 years of age and older with solid tumours for treatment with Pfizer Inc.'s (NYSE: PFE) investigational drug PF-06946860.

Cachexia is a metabolic disorder and comorbidity that occurs with several chronic diseases including cancer, heart failure, chronic obstructive pulmonary disease (COPD), and chronic kidney disease (CKD). It impacts more than 30 million people globally. Cachexia manifests as marked involuntary body weight loss, muscle atrophy, and reduced appetite, progressing to significant functional impairment and increased risk of death.[1] Elevated GDF-15 is associated with cachexia in cancer patients. Cachexia is a highly prevalent complication of cancer, affecting between 50 to 80% of all cancer patients. This range depends on the tumour type, the patient response to tumour progression and on individual body type.[2]

“We are pleased to partner with Pfizer to address this unmet medical need in oncology through strong companion diagnostics”, said Thomas Schinecker, CEO Roche Diagnostics. “The FDA BDD grant for the Elecsys GDF-15 assay shows the importance of these strong partnerships. The ability to detect elevated GDF-15 in patients who are experiencing weight loss may provide a precision-medicine approach to identifying patients likely to respond to a GDF-15 therapeutic treatment.”

About Elecsys GDF-15

Elecsys GDF-15 is a quantitative serologic, two-incubation step electrochemiluminescence immunoassay (ECLIA) using the sandwich test format for the detection of GDF-15 in human serum. The Elecsys GDF-15 assay is indicated as an aid in identifying cachectic patients 18 years of age and older with solid tumours for treatment with PF-06946860. The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers. GDF-15 has CE approval in several intended uses in cardiology including risk prediction of major bleeding events of atrial fibrillation patients, risk stratification of patients with acute coronary syndrome or chronic heart failure.

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About Cachexia
Cachexia impacts more than 30 million people globally but is poorly understood due to its complexity. It has traditionally been seen as a complication of chronic diseases or end stages of cancer. The burden cachexia poses on patients, their caregivers and loved ones, as well as the healthcare system, is significant. Cancer cachectic patients experience numerous complications including, but not limited to, reduced effectiveness of chemotherapy, reduced mobility and reduced functionality of muscle-dependent systems, such as the respiratory and cardiovascular systems, leading to decreased quality of life and survival.

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 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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.

References
[1] Baracos et al., Cancer-associated cachexia, Nature Reviews, 2018
[2] Argilés et al. Cancer cachexia: understanding the molecular basis. Nat Rev Cancer 2014

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