Roche

FDA grants Breakthrough Device Designation for Roche's Elecsys GALAD score to support earlier diagnosis of hepatocellular carcinoma

- **The Elecsys GALAD score aims to support clinicians in diagnosing hepatocellular carcinoma by giving them more timely and accurate information to make earlier interventions**
- **When hepatocellular carcinoma is detected and managed at the very earliest, patient's 5-year survival rates can increase to over 70%[1]**
- **Utilizing blood-based biomarkers, as part of the Elecsys GALAD score, is minimally invasive to patients**

Basel, 4 March 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation to the Elecsys® GALAD score.* This algorithmic score combines gender and age with the biomarker results of the Elecsys AFP, AFP-L3 and PIVKA-II and is intended to aid diagnosis of early stage hepatocellular carcinoma (HCC).

Dr. Amit Singal, Medical Director of the Liver Tumor Program and Clinical Chief of Pathology at UT Southwestern Medical Center in Dallas, USA, stated, "HCC is the fourth leading cause of cancer-related death worldwide, with the highest burden of disease in East Asia and Africa. This high mortality is largely driven by most patients being detected at a late stage, when curative therapies are no longer possible. Therefore, improving early HCC detection is a critical area of need."

The Elecsys GALAD score will be the first GALAD score, with regulatory approval, for use in In Vitro Diagnostics and is an integral part of the Roche Diagnostics Liver Indication Program, which aims to improve diagnostic workflows throughout chronic liver disease management. Combined with ultrasound, the Elecsys GALAD score has the potential to support clinicians by giving them more accurate information at an earlier stage, thus improving patient outcomes while being minimally invasive for people and potentially also more affordable to healthcare systems.

Liver cancer is one of the few cancers that are on the rise.[2] While recent developments in screening and new treatments are making advances in the prevention, diagnosis and treatment of HCC, clinicians still face challenges in diagnosing the disease early enough. Only 44% of liver cancer patients are diagnosed at an early stage.[3] Of HCC patients, which are diagnosed with late-stage disease, less than 16% survive a period of 5 years. Of the patients diagnosed at an early stage, 70% percent are still alive after five years[1]. Therefore, diagnosing HCC, as early as possible, is essential to improving patient outcomes.

"We are excited about FDA's recognition of the potential clinical benefit the Elecsys GALAD score could bring in diagnosing hepatocellular cancer at an early stage," said Thomas Schinecker, CEO of Roche Diagnostics. "The combination of blood-based biomarkers with clinical algorithms has the potential to significantly reduce mortality of HCC patients as they can receive a more timely diagnosis and treatment."

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About GALAD Score
Pioneered by Professor Philip Johnson, Deputy Director of NWCR Centre and Professor in Translational Oncology at the University of Liverpool, and colleagues from the UK, the GALAD score is a serum biomarker-based model that predicts the probability of having hepatocellular carcinoma in patients with chronic liver disease. This combines gender and age with the results from assays AFP, AFP-L3 and PIVKA-II to give the clinician a clearer picture of HCC risk.

In chronic liver diseases, such as hepatitis and cirrhosis, Alpha1-fetoprotein (AFP) may be chronically elevated. Very high concentrations of AFP may be produced by certain tumors. This characteristic makes the AFP test useful as a tumor marker. AFP-L3 is a subtype of AFP and can be used to differentiate an increase in AFP due to HCC, or benign liver disease. PIVKA-II is a precursor and abnormal form of prothrombin that is found in patients with HCC. This can be used to differentiate HCC from non-HCC hepatic diseases.PIVKA-II is an alternate name for des-gamma-carboxy prothrombin (DCP).

About Hepatocellular Carcinoma
The American Association for the Study of Liver Diseases (AASLD) guidelines recommend surveillance of high risk populations for HCC, every 6 months using ultrasound, either with or without a blood test to check protein levels (AFP).[4] Ultrasound examinations can be sensitive enough to detect small masses on the liver. While easily done in a doctor's office, ultrasound examinations are less conclusive with inexperienced technicians and in patients with obesity and fatty liver disease. A recent meta-analysis suggested that ultrasound may miss more than half of early stage HCCs.[5] Therefore, other methods of diagnosis, such as abdominal CT scan, abdominal MRI scan or liver biopsy are often needed.[4] These are more accurate than ultrasound, though are more invasive and uncomfortable for patients, as well as being costly to the healthcare system.

Liver cancer is one of the few cancers that are on the rise, and hepatocellular carcinoma (HCC), the primary type of liver cancer, accounts for 90% of these cases.[6] Worldwide, the most common risk factor for HCC is viral hepatitis – known to cause inflammation of the liver.[6,7] Chronic hepatitis B accounts for approximately 50% of all cases of HCC, and the majority of cases of childhood HCC.[8] Other risk factors include aflatoxin – a carcinogenic mould found in contaminated foods, especially rice, in hot and humid climates.[6]

Viral hepatitis B has a particularly high prevalence in most countries in Asia, and this prevalence directly contributes to higher incidences of HCC in the region.[7,9] An increasingly important risk factor for the development of HCC is non-alcoholic fatty liver disease (NAFLD), linked with fatty foods and obesity.[10] This is the fastest-growing rate of any cancer and is thought to be driven in part by this risk factor, along with increased alcohol use.[11]

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 eleventh 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.

*This product is not, currently, commercially available.

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