# *Media Release*

## Roche's Elecsys IL-6 test receives FDA Emergency Use Authorisation to help in identifying patients at high risk of severe inflammatory response

- **FDA EUA[1] now makes IL-6 testing accessible to patients in the United States to assist in identifying severe inflammatory response in patients with confirmed COVID-19 and is also available in markets accepting the CE-mark[2]**
- **Interleukin 6 (IL-6) is an early indicator for acute inflammation to aid in the management of critically ill patients**
- **This test is available on Roche's cobas e analysers which are widely available around the world**

Basel, 04 June 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorisation (EUA) for the Elecsys® IL-6 test. This test measures levels of the biomarker interleukin 6 (IL-6) and can be used to help identify patients with confirmed COVID-19 disease who could be at high risk of intubation with mechanical ventilation.

The test can support physicians, in combination with other examinations and vital signs, to decide early on if a patient with confirmed COVID-19 illness requires mechanical ventilation."The FDA EUA approval of Elecsys IL-6 is another step in our commitment to deliver fast and reliable diagnostic tests to help fight the coronavirus pandemic," said Thomas Schinecker, CEO Roche Diagnostics. "In the current situation, time is specifically critical. The test could help physicians in the quick identification of severe inflammatory response in patients infected with the SARS CoV-2 virus."

"In the current pandemic, Roche's Elecsys IL-6 test was helpful as an early indicator for acute inflammation and in the management of critically ill patients," said Tobias Herold, MD from the Emergency Department, University Hospital, LMU University Munich, Germany. "Elevated IL-6 values help us to identify patients with a high risk of upcoming respiratory failure.

Hospitals and reference laboratories can run the Elecsys IL-6 test on Roche's cobas e® analysers which are widely available around the world. These fully-automated systems can provide test results in approximately 18 minutes, with a test throughput of up to 300 tests/hour, depending on the analyser.

**About Elecsys IL-6**
The IL-6 immunoassay is an in vitro diagnostic test for the quantitative determination of IL-6 (interleukin-6) in human serum or plasma. This assay is used in countries accepting CE-mark to aid in the management of critically ill patients, as an early indicator for acute inflammation. Under the Emergency Use Authorisation in the US, this assay can be used to assist in identifying severe inflammatory response in patients with confirmed COVID-19 illness to aid in determining the risk of intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. IL-6 is released by immune cells, once they are activated by virus, bacteria or other immune cells. IL-6 acts like a messenger to activate other immune cells to fight the infection. Because IL-6 is released so early during a severe infection, it helps

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physicians to identify severely ill COVID-19 patients as early as possible. Hospitals and reference laboratories can run the test on Roche's cobas e analysers which are widely available around the world. These fully-automated systems can provide test results in approximately 18 minutes, with a test throughput of up to 300 tests/hour, depending on the analyser.

**About Roche's response to the COVID-19 pandemic**
The COVID-19 pandemic continues to evolve globally with varying developments from country to country and we are partnering with healthcare providers, laboratories, authorities and organisations to help make sure that patients receive the tests, treatment and care they need.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. On 13 March we received FDA Emergency Use Authorisation for a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, which is also available in countries accepting the CE Mark. On 3 May, Roche announced that its COVID-19 antibody test, aimed at detecting the presence of antibodies in the blood, also received FDA Emergency Use Authorisation and is available in markets accepting the CE mark. Our existing diagnostics portfolio for critical care has also been playing a significant role in supporting patient management during the COVID-19 crisis, with our blood gas and sepsis products being used to monitor patients in the acute setting. Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

While there are currently no approved medicines for the treatment of patients with COVID-19, we are actively involved in understanding the potential of our existing portfolio and are researching options for the future. On 19 March, we announced the initiation of COVACTA - a global Phase III randomised, double-blind, placebo-controlled clinical trial to evaluate the safety and efficacy of intravenous Actemra©/RoActemra© (tocilizumab) plus standard of care in hospitalised adult patients with severe COVID-19 pneumonia compared to placebo plus standard of care. Roche has also initiated an internal early research programme focused on the development of medicines for COVID-19 and is evaluating a large number of potential collaborations.

In these exceptional times, Roche stands together with governments, healthcare providers and all those working to overcome the pandemic.

**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.



**References**

[1] The Emergency Use Authorisation (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of medical countermeasures needed during public health emergencies https://www.fda.gov/home
[2] CE-IVD marking is granted through completion of a comprehensive technical validation and self declaration under the European Directive for In Vitro Diagnostic Medical Devices.

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