Media & Investor Release

Roche IL-6 is the first immunoassay approved to aid sepsis diagnosis in newborns

- **Neonatal sepsis is a leading cause of death for newborns**
- **Testing IL-6 can indicate a neonatal sepsis infection earlier than other biomarkers**
- **Earlier diagnosis of neonatal sepsis can lead to improved outcomes and a reduction of long-term complications from sepsis**

Basel, 18 October 2023 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the Elecsys IL-6 immunoassay has become the first IL-6 test to have a certified claim for use in diagnosis of neonatal sepsis, in countries accepting the CE Mark.*

Elecsys IL-6 aids physicians in combating the impact of neonatal sepsis by facilitating an early diagnosis. Early and improved diagnosis can contribute to appropriate use of antibiotics, as well as potentially decreasing mortality rates and mitigating long-term consequences of sepsis.

“Sepsis is one of the leading causes of death in newborns and we need to do everything we can to prevent these deaths," said Matt Sause, CEO of Roche Diagnostics. "Receiving the first approval for IL-6 use with newborns, is a significant step forward in helping clinicians confidently diagnose neonatal sepsis earlier and save more lives.”

Neonatal sepsis is an infection involving the bloodstream within the first four weeks of life and results in high rates of morbidity and mortality. Neonatal sepsis can initially present with subtle signs, but can rapidly progress to multisystem organ failure. Early detection and prompt intervention are essential to prevent severe and life-threatening complications.

Testing IL-6 is suitable for early diagnosis of neonatal sepsis as it increases rapidly in response to infection, much earlier than other markers, making it a better early warning marker of inflammation, infection, or sepsis. With earlier diagnosis, clinicians can make earlier and more appropriate interventions to give neonates the best chance of a positive outcome. The Elecsys IL-6 can help to achieve this with the test only taking 18 minutes to run and only using a small amount of blood.

About neonatal sepsis

Sepsis is a condition that can be caused by bacteria, fungi or viruses in the blood and is the result of the body’s response to infection. Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection. 20% of deaths worldwide are sepsis-related and patient survival decreases by ~8% with each hour of delay before effective treatment.

The first 28 days of life (the neonatal period) are the most vulnerable time for child survival. Every year, an estimated 2.5 million neonates die in their first month of life, accounting for nearly one-half of deaths in children under 5 years of age. An estimated 375 000 neonatal deaths due to sepsis occurred globally in 2018, which represented 15% of all neonatal deaths, making sepsis one of the leading causes of newborn death.

Newborns often present with non-specific signs and symptoms, which means an early diagnosis of neonatal sepsis can be difficult. Some laboratory tests used in sepsis diagnosis have a low sensitivity, particularly in the early phase of infection. It is also difficult to collect sufficient blood volumes from neonates, especially low birthweight infants, so using a small sample size is important to be minimally invasive to the baby. If a sufficient blood sample cannot be taken, it may lead to low positivity rate in blood cultures. In addition, blood culture results can take up to 48 hours, therefore treatment is often started before results are known.

The prognosis of neonatal sepsis depends on early recognition and appropriate treatment, although signs and symptoms are often nonspecific and may overlap with those of other severe conditions, such as meningitis and pneumonia. These clinical signs include respiratory distress and cyanosis, apnoea, feeding difficulties, lethargy or irritability, and poor perfusion.

About Elecsys IL-6

Elecsys IL-6 immunoassay is an in vitro diagnostic test for the quantitative determination of IL-6 (interleukin-6) in human serum and plasma. This assay is used to assist in identifying severe inflammatory responses in patients. A test takes 18 minutes to run and only needs a sample volume of 30 µL (cobas® e411, e601, e602); or 18 µL (cobas® e402, e801), one of the smallest volumes on the market. The Elecsys IL-6 immunoassay is an electrochemiluminescence immunoassay "ECLIA" and is intended for use on **cobas e** immunoassay analyzers.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavour to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects

our efforts to improve access to healthcare together with local partners in every country we work.

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.

*The claim certification is supported by an investigator-initiated study (IIS) from the Medical University of Vienna, evaluating ~8500 Elecsys IL-6 measurements from 1695 neonates. Elecsys IL-6 demonstrated excellent performance for the detection of neonatal sepsis. AUC = 0.92 (95% CI: 0.89–0.94), Global specificity 88% (95% CI: 83–92%), Global sensitivity 82% (95% CI: 77–86%)

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Roche Global Media Relations

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

Hans Trees, PhD
Phone: +41 79 407 72 58

Nathalie Altermatt
Phone: +41 79 771 05 25

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Nina Mählitz
Phone: +41 79 327 54 74

Kirti Pandey
Phone: +49 172 6367262

Rebekka Schnell
Phone: +41 79 205 27 03

Sileia Urech
Phone: +41 79 935 81 48

Roche Investor Relations

Dr. Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@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