Media Release

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Roche to initiate testing for Babesia parasite at U.S. Blood Centers under FDA Investigational New Drug Application protocol

- **Babesia parasite transmission is reported to be the most common cause of transfusion-related infectious fatalities in the United States**
- **New cobas® Babesia test will screen whole blood samples for parasitic infection from four common species of Babesia under an Investigational New Drug Application protocol**
- **cobas® Babesia test can run in conjunction with cobas® Zika test under clinical study protocol with the cobas® 6800/8800 Systems**

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced immediate plans to initiate screening of blood samples with the **cobas**® Babesia test under an Investigational New Drug Application protocol. The **cobas**® Babesia test for use with the **cobas**® 6800/8800 mid- and high-volume molecular diagnostics systems, is a qualitative in vitro nucleic acid screening test for the direct detection of Babesia DNA and RNA in whole blood specimens from individual human blood donors. Roche is currently working with designated study sites in the United States to commence testing under the study protocol.

The Babesia parasite is commonly transmitted to humans through the bite of an infected tick, although the parasite can also be transmitted through blood transfusions, or from mother to fetus during pregnancy. The parasite infects and destroys red blood cells. This can lead to anemia and related life-threatening complications in the elderly, immunocompromised, and individuals without a spleen. In healthy individuals the infection called babesiosis can be asymptomatic, or cause a range of mild flu-like symptoms. Over 200 cases of transfusion-transmitted Babesia infections have been documented in the United States since 1979.[1]

“Identifying solutions to re-emerging threats to the safety of blood supply, such as the Babesia parasite, is a key element of our commitment to our partners in the donor screening community,”

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said Uwe Oberlaender, Head of Roche Molecular Diagnostics. “The Babesia test adds to our rapidly expanding menu on the industry-leading **cobas**® 6800/8800 Systems, which in turn helps healthcare professionals diminish potential risks of infection from transfused blood products.”

The **cobas**® Babesia test is the newest test to have been specifically designed for use on the **cobas**® 6800/8800 Systems, enabling the detection of four common strains of Babesia in samples of donated blood. Where needed, the **cobas**® Babesia test can be run alongside the **cobas**® Zika test from Roche, which was introduced under a separate Investigational New Drug Application protocol in 2016. When implemented on the **cobas**® 6800/8800 Systems, the **cobas**® Babesia test provides labs with a fully-automated, high-volume testing solution to detect the parasite in whole blood samples, ensuring that potentially infected blood units are removed from the blood supply.

About the cobas® Babesia test

Manufactured by Roche, the **cobas**® Babesia test is based on fully automated sample preparation (nucleic acid extraction and purification) from a whole blood sample followed by PCR amplification and detection with the **cobas**® 6800 or **cobas**® 8800 System. The **cobas**® 6800/8800 Systems consist of the sample supply module, the transfer module, the processing module and the analytic module. Automated data management is performed by the **cobas**® 6800/8800 software which assigns test results for all tests as non-reactive, reactive, or invalid.

About IND status

- The **cobas**® Babesia test has not been FDA cleared or approved.
- It can be used under an IND protocol by US blood screening laboratories.
- All testing laboratories will need to be enrolled in and contracted into the clinical trial as specified and agreed upon with the FDA Center for Biologics Evaluation and Research (CBER).

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. 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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.

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References

1. Centers for Disease Control (CDC). Surveillance for Babesiosis - United States, 2014 Annual Summary.pdf (February 29, 2016)