Media Release

FDA approves cobas Babesia, Roche's first whole blood test for donor screening

- **Roche is dedicated to helping save patients' lives by delivering state-of-the-art solutions to aid in the protection of the global blood supply from infectious diseases**
- **If undetected, Babesia infection can be fatal in patients receiving blood transfusions from infected donors**
- **The availability of the new whole blood collection tube simplifies Babesia sample preparation, enabling more efficient laboratory processing and future menu expansion**

Basel, 20 September 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that it has received approval from the U.S. Food and Drug Administration (FDA) for the cobas Babesia test for use on the cobas 6800/8800 Systems for individual blood donation testing. This is Roche's first commercially available whole blood test to screen donations and follows May 2019 FDA-updated industry guidance recommending screening and testing for Babesia, to reduce the risk of transmitting the parasite through transfusions.[1]

cobas Babesia detects parasites that live in red blood cells. This test is an important advancement because the Babesia parasite cannot be detected in traditional plasma or serum samples. The test is able to detect the four common species of Babesia and employs the new whole blood collection tube, which simplifies Babesia sample preparation by consolidating steps within the tube itself to provide an efficient solution for testing laboratories.

In most cases, the Babesia parasite is transmitted to humans through the bite of an infected tick; however, the parasite can also be transmitted through blood transfusions or from mother to foetus during pregnancy. The parasite infects and destroys red blood cells which can lead to anaemia and related life-threatening complications, particularly in the elderly or otherwise immunocompromised patients. In healthy people, the infection can be asymptomatic, or cause a range of mild flu-like symptoms.

"We are dedicated to helping save patients' lives by providing advanced solutions to enable the protection of the global blood supply from infectious diseases. With the approval of Roche's first whole blood test used in blood screening we can help healthcare professionals further diminish potential risks of infection from transfused blood products," said Thomas Schinecker, CEO Roche Diagnostics. "In addition, we hope to help customers improve their lab efficiency by simplifying sample prep while ensuring maximum detection of infectious pathogens in the blood and the safety of the blood supply for the patients we serve."

The Roche Blood Safety Solutions offering now provides the most comprehensive testing solution for blood donor screening utilising the fully automated cobas 6800/8800 System. This novel test approval follows the successful launch of the cobas Zika test, which was the first Zika test available for donor screening in the U.S. This new Babesia test expands the menu of tests available for the cobas 6800/8800 Systems for use in U.S. donor screening laboratories. This menu includes cobas MPX, cobas WNV and cobas Zika. In addition, the menu includes cobas DPX[2], which is used in testing labs that support plasma fractionators.

F. Hoffmann-La Roche Ltd 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

About the cobas Babesia test for use on the cobas 6800/8800 Systems
The cobas Babesia test for use on the cobas 6800/8800 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. It detects the four species of Babesia known to cause disease in humans and can be performed with the other routine blood donor screening tests.

The fully automated cobas 6800/8800 Systems offer the fastest time to results with the highest throughput and the longest walk-away time available among automated molecular platforms, providing donor screening laboratories with improved operating efficiency and the flexibility to adapt to changing testing demands. The cobas Babesia test is the latest addition to Roche's assay menu for donor screening laboratories — which includes cobas MPX, cobas DPX, cobas HEV, cobas WNV, cobas CHIKV/DENV and cobas Zika (US-IVD) — all of which are run on the cobas 6800/8800 Systems. Not all assays are available in all markets.

Since 2014, the cobas 6800 and cobas 8800 Systems have established the new standard for routine molecular testing by delivering fully integrated, automated solutions that serve the areas of donor screening, infectious disease, sexual health, transplant, respiratory and antimicrobial stewardship.

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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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] “Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis”, FDA, May 2019 [
[2] This test has been submitted to the FDA as a Master File and will not have a regulatory classification, and will not be cleared, licensed or approved by the FDA.

Roche Group Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com
- Nicolas Dunant (Head)
- Patrick Barth
- Ulrike Engels-Lange
- Daniel Grotzky
- Karsten Kleine
- Nathalie Meetz
- Barbara von Schnurbein