PRESS RELEASE

Idylla™ Ebola Virus Triage Test Granted Emergency Use Authorization by U.S. FDA

Mechelen, Belgium, 1 June 2016 – Biocartis (Euronext Brussels: BCART), an innovative molecular diagnostics company, announced today that it has received Emergency Use Authorisation (EUA) by the U.S. Food and Drug Administration (FDA) for the Idylla™ Ebola Virus Triage Test (Idylla™ EBOV Test) that may be used to detect Ebola Zaire virus in patients with signs and symptoms of Ebola virus disease. This is a molecular diagnostic test for the Ebola Zaire virus which was co-developed by Biocartis NV, Janssen Diagnostics (a division of Janssen Pharmaceutica NV) and the Belgium Institute of Tropical Medicine that co-discovered the Ebola virus 40 years ago. The test, which delivers results within 100 minutes on a single cartridge, runs on the Biocartis Idylla™ platform, a fully automated, sample-to-result, real-time RT-PCR (Reverse Transcription Polymerase Chain Reaction) system, which allows for rapid deployment in both developed and emerging market countries.

The 2014 Ebola virus outbreak in West Africa was the largest outbreak since its discovery 40 years ago. With over 11,000 deaths reported[1] and affecting multiple countries, that outbreak demonstrated a clear need for improved infectious disease surveillance and management. Today, further preparation is needed, as specialists[1] expect sporadic Ebola virus outbreaks to continue in the future.

The test is intended for the detection of the Ebola Zaire virus in patients with signs and symptoms of Ebola from the 2014 West Africa outbreak. In the Idylla™ Ebola Virus Triage Test, sample manipulation is reduced to a single step, i.e. entering the blood sample into the Idylla™ cartridge, after which the cartridge becomes a hermetically closed container. This reduces the risk of exposure to the Ebola virus for healthcare workers. Furthermore, the Idylla™ Ebola Virus Triage Test requires only minimal training of healthcare professionals and can be transported and stored at ambient temperature conditions, which enables rapid global deployment during outbreaks.

Rudi Pauwels, Founder and Chief Executive Officer Biocartis, commented: "The 2014 Ebola and more recently the Zika outbreak, demonstrates that in today's global world we need rapid, highly accurate and easily deployable diagnostic systems. We are very pleased to collaborate with Johnson & Johnson as well as the Institute of Tropical Medicine in a joint effort towards improved readiness for disease outbreaks. The Idylla™ Ebola Virus Triage Test is the first infectious disease outbreak test authorised by the FDA on our Idylla™ platform, which is - thanks to its unique features - perfectly suited for outbreak control through early and fast testing. The test allows healthcare professionals in the field to rapidly diagnose infection, implement control measures and as such, open doors to faster and better treatment decisions."

Intended Use

The Idylla™ Ebola Virus Triage Test is a real-time reverse transcription polymerase chain reaction (rRT–PCR) test intended for the qualitative detection of RNA from the Ebola Zaire virus (detected in the West Africa outbreak in 2014) in EDTA venous whole blood from individuals with signs and symptoms of Ebola virus infection in conjunction with epidemiological risk factors. Testing with the Idylla™ Ebola Virus Triage Test should not be performed unless the patient meets clinical and epidemiologic criteria for testing suspect specimens. Results are for the presumptive identification of Ebola virus RNA. The definitive identification of Ebola virus RNA requires additional testing and confirmation procedures in consultation with public health or other authorities for whom reporting is required. The diagnosis of Ebola virus infection must be made based on history, signs, symptoms, exposure likelihood, and other laboratory evidence in addition to the identification of Ebola virus RNA. Negative results do not preclude Ebola virus infection and should not be used as the sole basis for patient management decisions. The level of the Ebola virus that would be present in blood from individuals with early systemic infection is unknown. Due to the difficulty in obtaining clinical specimens positive for Ebola, the Idylla™ Ebola Virus Triage Test was evaluated with limited numbers of contrived specimens spiked with live Ebola Zaire virus RNA. The Test has not been evaluated with blood from individuals with Ebola Zaire virus infection.

The Idylla™ Ebola Virus Triage Test is for use only under Emergency Use Authorisation (EUA) by laboratories in the United States certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests, and by laboratories in the United States certified under CLIA to perform high complexity tests, or in similarly qualified non- U.S. laboratories, by clinical laboratory personnel who have received specific training on the use of the Idylla™ Ebola Virus Triage Test on the Idylla™ System.

[1] Centres for Disease Control (CDC) Case Counts, updated 13 April 2016: http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/

Notification of Public Health authorities: local, state and national public health agencies (for example, county and state health departments or the U.S. Centers for Disease Control and Prevention (CDC)) should be notified of any patient suspected to have Ebola Virus Disease (EVD). Confirmatory testing at the state/local public health laboratory or at CDC is necessary for positive detection results and may be necessary for negative detection results. Laboratories should consult with local, state or national public health officials on any positive or negative Idylla™ Ebola Test result on the need for additional testing and appropriate transportation of specimens.

- *This test has not been FDA cleared or approved;*
- *This test has been authorized by FDA under an EUA for use by authorized laboratories;*
- *This test has been authorized only for the detection of Ebola Zaire virus (detected in the West Africa outbreak in 2014);*
- *This test is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection of Ebola virus under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.*

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About Biocartis

Biocartis (Euronext Brussels: BCART) is an innovative molecular diagnostics (MDx) company providing next generation diagnostic solutions aimed at improving clinical practice for the benefit of patients, clinicians, payers and industry. Biocartis' proprietary MDx Idylla™ platform is a fully automated sample-to-result, real-time PCR (Polymerase Chain Reaction) system that offers accurate, highly reliable molecular information from virtually any biological sample in virtually any setting. Biocartis launched the Idylla™ platform in September 2014 in Europe. Biocartis is developing and marketing a rapidly expanding test menu addressing key unmet clinical needs in oncology and infectious diseases. These areas represent respectively the fastest growing and largest segments of the MDx market worldwide. Today, Biocartis has four oncology tests and one infectious disease test on the market in Europe. More information on: www.biocartis.com. Follow us at @Biocartis .