NEWS RELEASE

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

6/1/2016

BEERSE, Belgium, June 1, 2016 /PRNewswire/ -- As part of Johnson & Johnson's commitment to combat Ebola, Janssen Pharmaceutica NV today announced that the Idylla™ Ebola Virus Triage Test (Idylla™ EBOV Test) was granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA)[1]. The Idylla™ Ebola Virus Triage Test is a diagnostic that detects the presence of the Ebola Zaire virus in patients with signs and symptoms of Ebola virus disease and was jointly developed by Janssen Diagnostics, a division of Janssen Pharmaceutica, Biocartis NV (Biocartis), and the Belgium Institute of Tropical Medicine.

The 2014 Ebola virus outbreak in West Africa was the largest outbreak since its discovery 40 years ago. With over 11,000 deaths reported[2] and affecting multiple countries, that outbreak demonstrated a clear need for improved infectious disease surveillance and management. Today, further preparation is needed, as specialists[2] expect sporadic Ebola virus outbreaks to continue in the future.

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. The blood sample is placed into a sealed cartridge and requires no further manipulation of potentially infected blood. After processing, the outside of the cartridge can be decontaminated prior to disposal. Results are delivered within 100 minutes. The Idylla™ Ebola Virus Triage Test does not require cold chain reagent storage. It is highly standardized, automated, and requires minimal training to interpret the results.

"We are very pleased that the FDA has granted Emergency Use Authorization for the Idylla™ Ebola Virus Triage Test," commented Jorge Villacian, M.D., Chief Medical Officer, Janssen Diagnostics. "Across Johnson & Johnson, we

are mobilizing our resources and expertise to help prevent another outbreak of Ebola."

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 Authorization (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.

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 EBOV Test result on the need for additional testing and appropriate transportation of specimens.

Our Commitment to Global Public Health

For 130 years, Johnson & Johnson has been committed to improving the health of individuals, families and communities around the world, including the most vulnerable populations. Today, our vibrant, entrepreneurial and committed employees bring business acumen and their collaborative spirit to help solve some of the most complex global health problems. By harnessing our collective breadth and scale, and our employees' passion and purpose, we strive to advance health care and positively impact the lives of all people.

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at **www.janssen.com**. Follow us at **@JanssenGlobal** or **@JNJGlobalHealth**.

[1] An application for the test, the Idylla™ Ebola Virus Triage Test, was submitted for Emergency Use Authorization to the FDA by Janssen Diagnostics' partner, Biocartis NV.

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

Press Contact:

Frederik Wittock
+32 14 60 57 24
fwittock@its.jnj.com

Investor Contacts:

Louise Mehrotra
+1 (732) 524-6491

Lesley Fishman
+1 (732) 524-3922

To view the original version on PR Newswire, visit:**http://www.prnewswire.com/news-releases/new-idylla-ebola-virus-triage-test-granted-emergency-use-authorization-by-us-fda-300277380.html**

SOURCE Janssen Pharmaceutica NV

News Provided by Acquire Media