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Chembio Diagnostics, FIND to develop HCV POC diagnostic test

30 July 2018 | News

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Chembio Diagnostics, Inc., a leader in point-of-care (POC) diagnostic testing, has announced a collaboration with the Foundation for Innovative New Diagnostics (FIND) to expedite the feasibility testing of a rapid diagnostic test for hepatitis C virus (HCV). Chembio is one of three companies selected by FIND for HCV feasibility studies, and Chembio will use its patented DPP technology platform for the testing of a rapid HCV core antigen assay.

The selection follows a Request for Proposal (RFP) that FIND initiated in the first half of 2018 – as part of the Hepatitis C Elimination Through Access To Diagnostics ("HEAD-Start") project that is supported by a grant from Unitaid – for the development of improved rapid POC diagnostic tests for hepatitis C diagnosis, based on the detection of HCV core antigen. In parallel, FIND is conducting pilot projects in six countries to introduce novel algorithms for HCV testing and demonstrate the impact of HCV diagnostics.

"Easy-to-use, accurate and affordable diagnostic tests are essential elements in the drive for HCV elimination," said Catharina Boehme, Chief Executive Officer of FIND. "Chembio was selected based on the high sensitivity offered by its DPP technology, together with the company's product development, manufacturing and distribution capabilities."

According to the World Health Organization, an estimated 71 million people are living with HCV infection, mostly in low- and middle-income countries. The disease claims nearly 400,000 lives each year, predominantly through cirrhosis and hepatocellular carcinoma. Despite being widespread, HCV often manages to go undetected: 80% of people infected are not aware of their status.

"We are pleased to collaborate with FIND on this important global health initiative, addressing the burden caused by the hepatitis C virus," stated John Sperzel, Chembio's Chief Executive Officer. "Our DPP® technology is being successfully leveraged across many areas, and we are optimistic that it will serve as a robust platform for the point-of-care detection of HCV."

FIND plans to assess the outcomes of the feasibility studies in December 2018 and award one company with further funding for the development and validation of the HCV core antigen assay, including the design and conduct of clinical trials to

comply with WHO Pre-Qualification and CE mark requirements.