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Epistem Announces Successful External Assessment of Genedrive® Hepatitis C Test at the Institut Pasteur and Commencement of Clinical Studies

Epistem Holdings Plc (LSE: EHP), the personalised medicine and biotechnology company, announces today that its Genedrive® point of care Hepatitis C ("HCV") test has successfully completed its first external assessment. The assessment was conducted on reference material and patient samples at the Institut Pasteur, Paris, and its success allows clinical trials of the HCV test to commence, in anticipation of regulatory approval and market launch in the EU during 2017.

The qualitative HCV test, which is proprietary to Epistem, has been developed for use on its Genedrive® platform in collaboration with Inserm, the French National Institute of Health and Medical Research, under a €6m funded programme supported by the European Commission's 7th Framework HCV programme (EU FP7 PoC-HCV, www.poc-hcv.eu) which commenced in September 2013.

The Genedrive® qualitative HCV test detects viral RNA, covers all HCV genotypes and is performed at "point of need" medical centres directly on plasma without the requirement for complex laboratory equipment or highly trained operators. The test is completed within 90 minutes and has shown excellent alignment to target product profile specifications for HCV, as specified by the Foundation for Innovative New Diagnostics (FIND)[1].

An estimated 150 – 200 million people are understood to be living with chronic HCV viral infection and some 350,000 people die each year from HCV related diseases. The advent of Direct Acting Antiviral Drugs promises to revolutionise the treatment of HCV but to maximise their impact qualitative diagnostic testing will be required. The new Genedrive® HCV test has been developed to address this need, particularly in parts of the world where access to centralised diagnostic laboratories is limited.

Dr Darragh Duffy, programme co-coordinator of the EU FP7 PoC-HCV programme, said: "We are pleased to have successfully demonstrated the performance of the Genedrive® HCV test in this initial assessment at the Institut Pasteur and we look forward to further assessment in the upcoming clinical studies of retrospective and prospectively collected patient samples."

Dr Matthew Albert, M.D, Ph.D, Director of the Immunobiology of Dendritic Cell biology unit at Institut Pasteur, Paris, said: "The Genedrive® HCV test delivers results in under 90 mins rather than days — with the simplicity and ease of use of a point of care test. It is suitable for confirmation of infection and monitoring of HCV, and, once approved, should assist scale up and roll out of HCV diagnostics in resource limited countries."

Dr Ian Gilham, Chairman of Epistem, commented "The commencement of clinical trials of our HCV assay is an important step in our ongoing commercialisation of Genedrive®, alongside the introduction of our TB test into the Indian market. The excellent results seen with HCV serve as a key proof of principle of our ability to develop blood-based tests and allow us to proceed with the development of tests for Hepatitis B and HIV, positioning Genedrive® as the point of care platform of choice for the diagnosis of infectious diseases."

It is anticipated that the Genedrive® HCV test will be available as a Research Use Only (RUO) product from mid-2016 and for market launch in 2017.

1 http://www.finddiagnostics.org/programs/hepC/target-product-profile/

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