

## **RNS Press Release**

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### **Epistem Holdings Plc**

# Announcement of collaborative funding agreement with Global Health Investment Fund I, LLC.

Epistem Holdings Plc (LSE: EHP) (Epistem), the personalised medicine and biotechnology company, is pleased to announce today that it has entered into a collaborative funding agreement with the Global Health Investment Fund I, LLC (GHIF) to support the roll-out of its Genedrive® molecular diagnostic platform as the company's tuberculosis assay enters pivotal field trials in key developing world locations. Under the terms of the agreement, Epistem has issued to the GHIF a five-year convertible bond totaling \$8.0 million (GBP4.7 million) (the Bond). As part of the collaborative funding agreement, the GHIF and Epistem have made global access commitments to mutually support and facilitate the introduction, distribution and sale of the Genedrive® platform and the expanding menu of infectious disease assays under development for low-and middle-income countries.

The GHIF is an investment fund designed to provide financing to commercialise new and improved tools to fight challenges such as tuberculosis, malaria, HIV/Aids and maternal and infant mortality in the world's poorest countries. The GHIF was capitalized by individual investors, private foundations, institutional investors, three leading pharmaceutical companies, a multilateral development bank and the Governments of Canada and Germany, with the benefit of a partial guarantee from the Bill & Melinda Gates Foundation and the Swedish International Development Cooperation Agency. LHGP Asset Management, the London-based asset management arm of Lion's Head Global Partners, authorised by the FCA, serves as the Investment Manager for the GHIF. The Bond represents the GHIF's inaugural investment.

The proceeds of the Bond will be applied to the further development, production and commercialization of Genedrive® devices and an expanded menu of tests for the diagnosis of infectious diseases which cause significant morbidity and mortality in the developing world.

Under the collaborative funding agreement, Epistem has agreed to make its Genedrive® platform available for sale in developing countries under a pricing framework that reflects the needs of poor patients in low- and middle-income countries. The GHIF will seek to leverage its network to support Epistem in the final stages of clinical testing and regulatory approval, and the subsequent roll-out of Genedrive® and its infectious disease assays globally. The Genedrive® platform has the potential to dramatically improve the lives of those most at risk of diseases such as tuberculosis, which require sophisticated diagnostic techniques to identify the presence of the disease and prescribe the proper course of treatment. Current "gold standard" techniques are labour-intensive, time-consuming and require the shipping of biological samples to central laboratories for testing. The potential for Genedrive® to offer affordable, specific and rapid diagnosis of diseases like tuberculosis at or near the point-of-care would introduce significant public health benefits globally, which drove the GHIF's interest in collaborating with Epistem on this product.

Genedrive® provides a major advance in next-generation molecular diagnostic testing by providing a rapid, low-cost, simple-to-use 'point of care' device with high sensitivity and specificity for diagnosis of infectious diseases. Genedrive® aims to provide a 'gold standard' identification of tuberculosis and antibiotic resistance. The World Health Organisation (WHO) has publicly recommended that nations incorporate new rapid molecular tests for tuberculosis into their disease testing programs. The Genedrive® platform and tuberculosis test are preparing for launch later this year. The Genedrive® device is currently undergoing clinical studies in five countries, after which regulatory submissions will be filed to enable a global access and roll-out of the tuberculosis test.

Epistem's Genedrive® platform has applications across a wide range of bacterial, viral and fungal and somatic mutation diseases for which Epistem is developing a menu of diagnostic tests.

# **Bond Interest Coupon & Maturity Date**

The \$8 million (GBP4.7 million) Bond was issued at par and has an annual coupon of 5% commencing from 21 January 2015. Interest is payable semi-annually in arrears and the Bond matures on 21 July 2019, unless previously converted into fully-paid ordinary shares of Epistem ("Ordinary Shares").

# **Conversion Terms**

- (i) GHIF has the option to convert the Bond into 967,298 Ordinary Shares at a conversion price of GBP 4.89 at any time during the period 15 January 2015 to 15 May 2019. This issue of 967,298 ordinary shares is equivalent to 9.67% of the current issued share capital of Epistem.
- (ii) Epistem shall have the option to convert the Bond into Ordinary Shares at a conversion price of GBP 4.89 during the period 21 January 2015 to 7 July 2019 if the Epistem share price shall exceed GBP 5.87.

Further details of the conversion, early redemption and cancellation provisions of the Bond are included in the appendix to this statement.

Commenting on the agreement, Matthew Walls, CEO of Epistem said: "The support of the GHIF represents a very powerful endorsement of our strategy of developing Genedrive® for infectious disease applications and our decision to target the tuberculosis market with our first assay. We are very excited about the potential of the GHIF's global network to financially support and commercially advance the roll-out of the Genedrive® unit and our menu of new molecular diagnostic tests for 'Point of Care' application in low resource settings."

Christopher Egerton-Warburton of the GHIF said: "There is a critical need for improved diagnostic devices that are designed for resource-limited settings. Epistem's Genedrive® platform offers the opportunity to diagnose a broad range of infectious diseases, with its first test in tuberculosis seeking to identify the presence of the disease and detecting drug resistance accurately, quickly and at an affordable cost. Globally, nearly 10 million cases of tuberculosis are reported annually resulting in approximately 1 million premature deaths each year. However, it is estimated that of the 10 million cases, up to one-third are either not diagnosed, or if diagnosed, not screened for drug resistance. Epistem has sought to improve this situation with its Genedrive® platform and as a result the GHIF is delighted to make this our first investment. We look forward to supporting Epistem to achieve the potential large-scale impact that Genedrive® offers."

For further details please see contact:

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Please see <a href="http://www.epistem.co.uk">http://www.epistem.co.uk</a> for additional information.

### Notes to editors:

Epistem is a personalised medicine and biotechnology company commercialising its expertise in adult stem cells in the areas of infectious and epithelial disease (oncology, gastrointestinal and dermatological). Epistem develops innovative diagnostics and biomarkers (Genedrive<sup>®</sup>), target discovery therapeutics and contract research services for drug development companies. Epistem operates three divisions, Personalised Medicine (Diagnostics and Biomarkers), Contract Research Services and Novel Therapies.

### Personalised Medicine (Diagnostics and Biomarkers)

For DNA genotype analysis, Epistem utilizes its proprietary Point of Care platform, Genedrive®. Genedrive® provides a major advance in next generation molecular diagnostic testing by providing a rapid, low cost, simple to use 'Point of Care' device with high sensitivity. Genedrive® has applications across a wide range of areas including bacterial, viral and fungal identification as well as germline and somatic genotype analysis.

Epistem's Personalised Medicine Division also provides services to drug development companies in DNA genotype analysis and gene expression (mRNA/miRNA). For RNA analysis, Epistem utilises its proprietary RNA-Amp™ biomarker platform. RNA-Amp™ is a highly sensitive cDNA amplification technique for gene expression analysis of tissue biopsies, blood, plucked scalp hair, skin and laser captured microdissected (LCM) samples to measure drug-induced gene expression changes. Epistem's knowledge of adult epithelial cells and the ability to obtain gene expression information from small starting materials enables the group to be a preferred partner of choice for Pharmaceutical and Biotechnology companies in providing biomarker information to support drug development programmes.

The Global Health Investment Fund I, LLC is a \$108 million social impact investment fund designed to provide financing to advance the development of drugs, vaccines, diagnostics and other interventions against diseases that disproportionately burden low-income countries. The GHIF provides a novel opportunity to help bring about significant improvements in the treatment and prevention of disease and the reduction of maternal and child mortality, along with the prospect of a net financial return for investors. Please see <a href="http://www.ghif.com">http://www.ghif.com</a> for additional information.

# Appendix:

Further details of the Conversion, Early Redemption and Cancellation of the Bond are listed below:

- I. Epistem may redeem the whole of the Bond on any interest payment date from 21 July 2016. In this event, the GHIF may elect to receive payment in cash or Ordinary Shares. If the GHIF does elect to receive payment in Ordinary Shares, and on redemption, the current market price is at or above GBP4.89, the conversion price will be GBP4.89. In the event that, on redemption, the current market price is below GBP4.89 the conversion price will be the current market price with ordinary share to be issued up to a maximum of 967,298 shares with the balance of the principal of the Bond paid in cash.
- II. In the event of a change of control (takeover) of Epistem where the offer price is equal to or above GBP4.89, the Bond will automatically be converted into 967,298 Ordinary Shares at a conversion price of GBP4.89. In the event of a change of control where the offer price is below GBP4.89, GHIF may elect to request redemption of the Bond and request that payment be received either in cash or in shares and, if in shares, the conversion price will be set at the offer price up to a maximum of 967,298 shares with the balance of the principal of the Bond paid in cash.
- III. In circumstances where there is a change of control, the Bond may be converted into Ordinary Shares or redeemed by the issue of Ordinary Shares and where the share price is below the conversion price, the maximum number of Ordinary Shares which may be issued will be 968,080 with the balance of the principal of the Bond being repaid in cash, so that the combined cash payment plus the Ordinary Shares valued at their conversion price will equal \$8 million.

IV.	Under the terms of the collaboration and funding agreement Epistem will be restricted to carrying maximum debt of GBP10 million without further recourse to GHIF.