



RNS Press Release

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Indian approval of import licence for Genedrive® TB molecular diagnostic test

Epistem Holdings Plc (LSE: EHP), the personalised medicine and biotechnology company, announces today that the Drug Controller General of India (DCGI), Ministry of Health and family Welfare, Government of India has issued an import licence to its Indian distribution partner, Xcelris Labs, for the import of Epistem's tuberculosis (TB) and antibiotic resistance test. The licence, which has been granted for a period of three years, enables Xcelris Labs to import Epistem's new molecular test subject to normal conditions for such a product. Epistem and Xcelris Labs will now commence the process of preparing for the launch of Genedrive® and the TB and antibiotic resistance test into the Indian and Indian-sub continent markets.

Over the coming months, Epistem and Xcelris Labs, one of India's leading Genomics research and Diagnostic testing companies will begin to place Genedrive® and its TB and antibiotic resistance tests with selected Key Opinion Leaders (KOL's). Epistem and Xcelris Labs will work closely with the KOL's to train and carefully monitor the operation of the first Genedrive® field-based units to ensure the rapid and accurate diagnosis of TB sufferers.

Commenting on the approval, Matthew Walls, CEO of Epistem said: "The Indian regulator's approval of our TB test represents a powerful endorsement of our strategy of developing Genedrive® for infectious diseases and our continuing strengthening focus on the TB market. We are now focused on obtaining the support of Indian based KOL's to support the use and adoption of our device and assays. We see great potential for our TB test and its technical and commercial advantages for roll out in low income and developing countries in addition to the emerging potential for our Genedrive® platform in other disease areas."

About Genedrive®

Genedrive® (www.genedrive.com) provides a major advance in molecular diagnostic testing by providing a rapid, low cost, simple to use 'Point of Care' device with high sensitivity and specificity for the diagnosis of infectious diseases. Genedrive® aims to provide a 'gold standard' for the identification of TB & antibiotic resistance. The World Health Organisation (WHO) has publicly recommended that nations incorporate new rapid molecular tests for TB into their disease testing programs. In addition to preparing for launch in India, the Genedrive® device is also undergoing clinical testing in countries across the World after which regulatory submissions will be filed to enable a global access and further roll-out of the TB test.

Epistem's Genedrive® platform has applications across a wide range of nucleic acid (molecular) based tests covering bacterial, viral and fungal diseases and gene somatic mutations for which Epistem is developing a menu of diagnostic tests.

About Tuberculosis (TB)

TB represents a significant global healthcare challenge. Nearly 10 million cases of TB are reported annually and over USD 1 Billion is spent on diagnostic testing, with India and China having the largest numbers of TB sufferers. The global TB testing market is expected to reach USD 2.62 billion by 2020. In 2013, the incidence of TB cases increased by 4.7% from 8.6 million cases in 2012 to over 9 million cases. This high prevalence and incidence of TB coupled with the availability of new and improved tests, growing awareness levels, developing healthcare infrastructure and improving purchasing power of the general population are the major factors responsible for the growth of tuberculosis testing market.

India has the largest number of TB sufferers in the world, more than twice the number in China, which has the second highest infection rate. According to the WHO, every year 2 million new patients in India develop TB of which roughly half a million cases are fatal with the highest incidence occurring in remote rural areas.

TB accounts for a large share of the global infectious disease burden. The disease was most widespread in the 1950s and 1960s across the world and the WHO declared TB as a global emergency in 1993. However, due to the continuous and effective control measures and programs such as Stop TB and DOTS (Directly Observed Treatment, Short-course) most developed nations have been able to minimize the spread of this disease. However, TB is still highly prevalent in many parts of the world and affects millions of lives, notably in Asia and Africa.

TB is a highly contagious disease and is the second leading cause of death, after human immunodeficiency virus (HIV). Active tuberculosis and latent tuberculosis are the two most common forms of TB that affect individuals. Over time, TB has also developed into more diverse and potent strains that are referred to as multi-drug resistant (MDR) or extensively drug resistant (XDR) TB. These conditions are also spreading at a rapid rate and require extensive diagnostic and treatment measures to halt their spread worldwide.

The major commercially available TB tests include culture tests, tuberculin skin tests, sputum smear microscopy, chest X-ray and drug susceptibility testing. Culture-based TB tests represent the largest segment in terms of revenue of the global TB testing market, valued at USD 691.2 million in 2013. Factors such as high sensitivity, accuracy and reliability of culture-based TB tests over other TB tests such as smear microscopy, Mantoux test and chest radiography have attributed to its higher market share. More recently, molecular technology testing, in which Genedrive® represents a major low cost and affordable advance, has enabled high sensitivity and accuracy

with rapid turnaround times. Molecular testing is now projected to be the fastest growing diagnostic test segment.

In addition, the increased involvement of the world's leading organizations such as the WHO and FIND (Foundation for Innovative New Diagnostics) in the promotion of new TB diagnostic tests is also responsible for the growth of the TB testing market. The WHO, through its Stop TB initiative, has provided the world with a vision to eradicate TB by 2050. Whilst the cost of funding new testing procedures and equipment might hinder the advance of new processes, low cost and technological advances in the TB diagnostics market are observed to be a promising prospect with many new product developers and manufacturers expected to venture into the market with a robust pipeline of new testing technologies.

The global market for TB testing segments into four key geographical markets, namely, North America, Europe, Asia Pacific, and Rest of the World (RoW). In 2013, Asia Pacific accounted for the largest share, i.e. over 35% of the overall TB testing market. The major share of Asia Pacific is attributed to its vast patient pool and very high incidence rate of TB. North America is the second largest market for tuberculosis testing in terms of revenue followed by Europe. Major Western European economies such as the U.K., Germany, France, Spain and Italy are the key contributing nations towards the overall tuberculosis testing market revenue in the region.

There is a clearly identified need for improved diagnostic devices which provide a 'gold standard' of molecular testing at low cost and capable of being adopted in developing country settings. Epistem's Genedrive® platform offers the opportunity to diagnose a broad range of infectious diseases, with its first test in TB providing diagnosis of both infection and antibiotic drug resistance, rapidly and accurately at an affordable cost.

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Notes for editors

Epistem is a personalised medicine and biotechnology company developing innovative diagnostics and biomarkers alongside providing contract research services to drug development companies.

Genedrive® provides a major advance in molecular diagnostic testing by providing a rapid, low cost, simple to use 'Point of Care' device with high sensitivity and specificity for the diagnosis of infectious diseases and for use in patient stratification (genotyping). Genedrive® aims to provide a 'gold standard' identification of Tuberculosis & 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 its first Tuberculosis test is now being prepared for launch in India and the Indian sub-continent. Genedrive® is undergoing clinical studies in countries across the World after which regulatory submissions will be filed to enable global access and roll-out of Epistem's first Tuberculosis test product. Further details can be found at: www.genedrive.com and www.epistem.co.uk

Xcelris Labs is one of India's leading genomics research organisations providing cutting edge solutions to the life science industry and research institutions with expertise in Next Generation Sequencing (NGS) Technology, Molecular Diagnostics and Bioinformatics.

Xcelris Molecular Diagnostics (XMDx) offers genetic testing services based on sequencing and genotyping using the latest next generation sequencing technology platforms and leading molecular diagnostic technologies. Xcelris Labs provide genetic tests for cancer diagnosis and therapy selection, drug response, infectious diseases and hereditary genetic disorders in humans. Further details can be found at: www.xcelrisdiagnostics.com