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genedrive Soon To Launch First Decentralized-Setting HCV Test

by Tina Tan

The HCV testing paradigm has changed since the advent of direct-acting antiviral drugs. genedrive PLC is looking to capitalize on this growth opportunity with its hepatitis C test, designed for decentralized use in resource-limited settings.

Positive data validating the diagnostic sensitivity and specificity of genedrive PLC's hepatitis C test has paved the way for the UK-headquartered firm to submit its application for CE-IVD marking in the EU by the end of March. If all goes well, the company expects the Genedrive HCV ID Kit to be CE-marked by end of April, making it the first commercially-available HCV molecular diagnostic test designed for decentralized use in resource-limited settings.

Studies performed at the Institut Pasteur in Paris, France. and Queen's Medical Center in Nottingham, UK, assessed the *Genedrive HCV ID Kit* in a 955-sample cohort and compared its performance against Abbott Laboratories' *RealTime HCV Viral Load Assay*, considered to be one of the gold standards in hepatitis C testing alongside Roche Diagnostics' Taqman HCV test. The studies found that Genedrive demonstrated overall sensitivity of more than 99% and specificity of 100%.

While this performance is on par with Abbott's test, Genedrive differentiates itself from its larger competitors in that it is designed for labs that do not have high-volume testing requirements and is available for a less prohibitive price than Abbott's or Roche's large, hospital-based systems, David Budd, CEO of genedrive, told *Medtech Insigh*t. “Those types of products are very expensive, you're into hundreds of thousands of dollars to buy that type of system. What we've shown in the study is that you can take our Genedrive device, which only costs $3,000, $4,000 dollars and get very comparable results to a lab-based setting," he said.

The result turnaround time for the Genedrive test is 90 minutes. This is particularly important in order to ensure the patient who is tested positive for HCV would actually get the treatment they

need. “In many countries where HCV testing is not widely available in small private clinic settings, the patient would present themselves to be tested and that test gets sent to a lab for analysis and the patient is sent home to wait for the results. But many patients are lost in that process – they might get a positive result but they don't come back and you might never see them again. In a decentralized setting, we can do the test quickly and give the patient treatment the same day," said Budd.

genedrive is targeting resource-limited countries to commercialize its HCV test, including India, the south-east Asian region and selected parts of Africa. The firm is trying to line up the correct distribution channels for those markets. "We're engaging with lots of different companies around the world, either large multinational diagnostic companies or the more regional, traditional distribution companies. We're trying to find what the right mix is for us to drive market acceptance of the product."

genedrive already has a partner in India, Xcelris Laboratories, which is currently commercializing the Genedrive MTB/RIF (Mycobacterium tuberculosis/ rifampicin-resistant) ID Kit in that market. Budd said that Xcelris' exclusive distribution rights in India would very likely extend to the HCV ID Kit too. "But all the other [target] geographies will be new for us, so they are new markets, a new upside for us."

One of the key factors that would drive the demand for genedrive's test in these markets is the availability of direct-acting antiviral drugs. This therapy replaced the older-generation interferon-based therapies and marked a turning point in HCV treatment and also in HCV testing. Previously, Budd explained, HCV required a complex testing regiment that encompassed genotype testing to see if the patient had the right genotype to receive interferon therapy, viral load testing to find out how much virus is in the blood and also qualitative HCV testing to see if the virus is in the blood in the first place. The advent of direct-acting anti-viral drugs, spearheaded by pharma company Gilead Sciences, signaled a pan-genotypic therapy for HCV that could reduce the viral load very quickly. "As it was pan-genotypic, we moved from a very complicated HCV testing regiment to just one test to just find out if the patient is HCV-positive or not, because 99% of patients will respond and be cured of the disease if they go on this direct-acting antiviral drug therapy," Budd explained.

However, the cost of this therapy was initially very prohibitive for resource-limited countries and Gilead has now gone on to license the therapy as a generic product in many emerging markets. "So in the US, you may pay $60,000-80,000 for Gilead's [hepatitis C-drug] *Sovaldi* (sofosbuvir), but in the emerging markets, you can get a generic equivalent for $200-300. That's a 99% cost reduction. So we have a new class of drugs that are inexpensive and the driver for the market is to go out there and find patients with hepatitis C and to be able to diagnose them in a decentralized setting."

Budd added that the firm is also hoping to establish partnerships with pharma companies; the CEO believes its test could be a good business-development opportunity for pharma companies who are looking for a tool that could identify the patients who would require treatment with their drugs.

From the editors of Clinica.