Xagenic readies X1 molecular diagnostic beta trials

April 19, 2016 by leonardzehr

Closely-held Xagenic plans to conduct beta studies this year, in advance of a major chlamydia and gonorrhea clinical trial, with its rapid X1 molecular diagnostic testing system in preparation for market launches in Europe and the U.S.

“The Xagenic X1 platform is a revolutionary diagnostic system that allows the user to perform lab-quality molecular assays in a physician’s office or other clinical care setting, with a time-to-result of 20 minutes or less,” Ihor Boszko, VP of business development, says in an interview with BioTuesdays.com. “This system is poised to transform the way healthcare is delivered.”

Mr. Boszko explains that the X1 instrument has been carefully designed to meet the requirements for use in a physician’s office, including its compact size, affordable pricing and ease of use.

“We are initially targeting physicians’ offices with our panel for chlamydia and gonorrhea,” he says, noting that the platform is user-friendly, with minimal training and no lab skills required.

Mr. Boszko says a rapid diagnosis will allow physicians to prescribe antibiotics, if necessary, before a patient leaves the office, improving patient compliance and outcomes, while reducing complications and unnecessary healthcare costs.

All of the reagents to perform the diagnostic test are stored on the single-use cartridge, which contains a proprietary sensor chip that enables direct detection of chlamydia and gonorrhea, without the use of enzymes. This electrochemical amplification-based technology is protected by 17 patent families globally.

In addition to room-temperature storage and low cost of goods, the Xagenic X1 cartridges have multiplexing capability of up to 40 analytes each. “Multiplexing has huge potential down the road in the design of other testing panels,” he points out. “An important part of our competitive advantage is that the technology is scalable for our initial market segments and beyond.”

Xagenic, which was formed in 2010 and has raised $52.7-million (Canadian) in financing to date, has published peer-reviewed studies demonstrating the versatility of the technology to detect RNA, DNA, SNPs or single nucleotide polymorphisms, proteins and small molecules in a variety of conditions.

“Our vision is to have a wide variety of cartridges available in a physician’s office for rapid diagnostic detection on our platform,” he adds.

The company initially plans to expand its product line for the women’s health and sexually transmitted disease markets to include herpes simplex virus, Types 1 and 2, and for Trichomonas vaginalis, another common sexually transmitted infection.

Mr. Boszko further explains that the integrated, self-contained format of Xagenic’s molecular diagnostic platform has also been designed to obtain a waiver under the Clinical Laboratory Improvement Amendments (CLIA) in the U.S.

A CLIA waiver would permit distribution of the X1 test to a broad variety of non-traditional testing sites, including more than 122,000 physicians’ offices, hospital emergency rooms, health department clinics, and other health care facilities.

“In our case, to get a CLIA waiver, we will have to demonstrate to the FDA that virtually anyone in a physicians’ office can run our product with minimal training and without putting a patient at risk, and that the risk of our platform making a diagnostic error is remote,” he adds.

According to Mr. Boszko, a large, unaddressed, high-growth market opportunity opened when the Alere i Influenza A & B test received the first CLIA waiver for a molecular diagnostic product in January 2015.

Industry forecasts suggest that 35% of nucleic acid-based tests will be conducted at point-of-care offices by 2020, compared with less than 1% in 2015. In addition, point-of-care molecular diagnostic testing could represent a $1-billion to $1.4-billion market opportunity by 2020.

“Since molecular diagnostic tests for flu and strep A are already on the market, we are uniquely positioned with a potential rapid time-to-result platform for the women’s health and sexually transmitted disease market segments,” Mr. Boszko contends.

“This market is driven by recommendations from the CDC, U.S. Preventive Services Task Force and medical associations that sexually active women, aged 24 and under, should have annual screenings done for both chlamydia and gonorrhea,” he adds.

There are more than 50 million tests for chlamydia and gonorrhea done annually around the world, of which 25 million are performed in the U.S.

Mr. Boszko says U.S. reimbursement codes already exist for molecular chlamydia and gonorrhea diagnostic tests and there is mandatory insurance coverage for screening under the Affordable Care Act, without a co-pay.

In 2014, the Xagenic platform was recognized by Frost & Sullivan, which said the technology is “comparable with PCR’s performance in terms of specificity and sensitivity, and outperforms it in speed, simplicity, size, ease of use, cost and compatibility with an office setting.”

According to Mr. Boszko, polymerase chain reaction (PCR) technology is the most commonly used technology in molecular diagnostics, with approximately 85% to 90% of products using PCR. However, competitive attempts to automate PCR to a point-of-care product, with results in 15-to-20 minutes, have been largely unsuccessful.

As part of its program for commercialization, Xagenic plans to obtain performance data from third parties beta testing with the X1 platform, beginning in May this year.

Following these studies, the company plans to initiate a large clinical study for regulatory approval, with approximately 8,000 patients, comparing the X1 technology with two other FDA-cleared systems.

Mr. Boszko estimates it will take eight-to-10 months to complete the clinical study. Once concluded, the results will be used to apply for marketing approvals in Europe and the U.S., as well as for a CLIA waiver.

“We also have a partnership program underway to license our technology for applications outside of clinical diagnostics, leveraging the platform’s broad detection capabilities in areas that include animal health, bio-threat detection, industrial, and food and water testing,” he adds.

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