Sangrae Cho â?? CEO, Gencurix

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Gencurix was the first Asian company to develop a prognostic diagnostic test for breast cancer. Its CEO, Dr Sangrae Cho, discusses the importance of creating a test tailored to Asian patients, explores the companyâ??s expansion plans into China, Japan, and Southeast Asia, and the synergies in their partnerships with big pharma.

What have been the major achievements in Gencurixâ??s history?

Our biggest achievement is developing Asiaâ??s first prognostic diagnostic test for breast cancer. While there were already several prognostic diagnostic tests available internationally, none were developed in Asia. Therefore, we are the first to develop a test designed specifically for Asian patients.

One of our key motives is to meet the unmet needs of patients. The main differences between Asian and Caucasian breast cancer patients are that in Asia, 50 percent are under the age of 50. Finding the unique algorithm specifically engineered for pre-menopausal Asian patients was an important step for us and was crucial in confirming the accuracy of our test.

One of the main problems we encountered was that alternative tests were over classifying the majority of patients into high-risk groups, in which patients are advised to undergo chemotherapy. Thus, patients were over-treated, with toxic results. Our prognostic diagnostic test accurately

identifies low-risk patients that do not require chemotherapy.

A key pillar to our success has been utilising open source big data to discover unique unpatented biomarkers which are accurate predictors and highly detectable. We also look at developing early diagnostics through specific biomarkers.

How has Gencurix adapted its offering based on new technologies?

Our company began as a manufacturer of reagents for PCR (polymerase chain reaction) platforms. However, we have evolved to specialise in developing algorithms to read test results and detect mutations. Ultimately, our vision is to develop unique property algorithms to help treat individual patients and produce bespoke treatment options. We have the capabilities to conduct the necessary clinical validations. With our strength in developing algorithms, I believe we will advance from our roots as a PCR reagent company into an enterprise designed to provide these specific algorithms to the wider industry.

Ultimately, this technology is dependent on the quality and accuracy of the algorithms used. When we were assessing the prognosis of breast cancer patients, we assessed six unique microarray biomarkers. These were from the gene pool of Caucasian patients. In order to tailor this test for Asian patients, it required a specific algorithm that can be tuned to match the specificities of an Asian patient.

Regardless of technological advancements in the future, finding the precise algorithm for each different platform will become paramount. The industry has changed significantly and now relies far more on machine-based drug discovery. Hence, there is a growing familiarity with such technology.

Most drug development involves clinical trials based on Caucasian patient profiles. How difficult was it to work exclusively with Asian patient profiles?

Indeed, there are huge racial disparities between Asian and Caucasian patients. Previously, Korean patients had to send their specimens to the USA to be tested. However, the reliability of the test was not very high because it was designed in western countries for Caucasian patients.

We tested over 3000 samples from Asian patients in Korea. It was incredibly difficult to find samples over ten years old for patients not treated with chemotherapy, a requirement when conducting our clinical trials. This remains one of the biggest hurdles that we faced when developing our test. Nevertheless, we can collaborate with the largest hospitals in Korea such as the Samsung hospital. They have been an incredible help in acquiring sufficient specimens to complete the clinical trials.

What are your current plans for expansion into other Asian markets?

We already have plans to enter the market in China. Even without receiving regulatory approval, there are still channels to enter the Chinese market. We are going to establish a partnership with a company in China to set up a lab which will provide our BCT tests to Chinese patients.

We are also looking to register our product with Chinese regulatory authorities and are planning to obtain a regulatory permit within three years. This is incredibly difficult due to the requirements of finding high integrity specimens over ten years old, required for the clinical trials. To circumvent this

hurdle, we believe that we will be able to find sufficient specimens over five years old.

In Japan, we have conducted feasibility studies with some of the main hospitals. These studies have shown promising results. Our next step will be to start the process of applying for regulatory approval from the PDMA. This should be completed by the end of this year. In my view, our main challenge in Japan will be receiving reimbursement, our next step post-approval.

For the rest of Asia, we will provide a centralised service. The customers will send the samples directly to our lab in Korea, where they will be analysed. This will remove the need for further regulatory approval. Dependent on market growth in the future, it may be beneficial to set up another local lab based in Singapore to handle demand from the South East Asian market.

You are also developing the *GenesWell ddEGFR Mutation Test* for lung cancer. What is the current status of this project?

We have already received approval from the Korea FDA. It is the first product in the world to receive regulatory approval based on a digital PCR system. The hospitals which possess digital PCR have already adopted our *GenesWell ddEGFR Mutation Test.* The current product can detect 43 mutations, with a second-generation product based on plasma to detect over 100 mutations currently in the pipeline.

In addition to the EGFR lung cancer test, we are also investigating the viability of a comprehensive diagnostic solution package for patients with a screening test for colorectal cancer and with further companion diagnostics available for breast cancer testing.

How important is collaboration with pharmaceutical companies?

We have three current collaborations with big pharma. The first is with Pfizer, partnering on our *GenesWell BCT Test*. Pfizer has a drug called *palbociclib* which is designed for patients suffering a relapse of breast cancer. Our joint project studies how well *palbociclib* can prevent the recurrence of breast cancer in patients categorised as high risk by our test. This collaboration has proven to be highly synergetic. This demonstrates how we are able to expand our offering into companion diagnostics services, helping Pfizerâ??s treatment to target the high-risk patients.

For our EGFR test, we have been in collaboration with AstraZeneca using their treatment *Tagrisso*. This is administered to patients with the T790M mutation, which our tests can detect. We have conducted many clinical evaluations, and given our digital PCR system, we have very high sensitivity in detecting this mutation.

We are also working with another company to develop a new drug for lung cancer patients. For this, they need to detect the C797S mutation, which is where they require our expertise.

Cancer treatments now consist of first, second, and third-line therapies. When the same treatments are administered to a patient, over time they begin to develop a tolerance to the drug. We are also developing a test to detect which drugs can be administered as a third-line treatment when a patient has developed a resistance to the first and second-line treatments.

It is very important for us to collaborate with the pharma companies to meet the unmet needs of the patients. There are many synergies in our partnerships which have always proven to be symbiotic

relationships.

How are you going to finance your plans for growth?

We have already raised USD 60 million through our IPO (Initial Public Offering) and past investments. Korea has the second most heavily invested biomedical industry in terms of venture capital. Thus, we do not foresee any issues in securing funds given the assortment of venture capitalists looking invest in the bio-venture industry. We also have previous investors choosing to reinvest. Consequently, I believe the future looks bright for Gencurix.

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