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Predicine Building Out Combined DNA/RNA Liquid Biopsy Business in China

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Premium

NEW YORK (GenomeWeb) – With the grand opening of a new R&D facility in Shanghai late last month, liquid biopsy firm Predicine is moving forward with a plan to build a clinical testing business in China, which it eventually hopes to expand to the US.

Ahead of this ongoing move into clinical liquid biopsy testing, the company, which has only been in operation since early this year, has been mainly working with pharmaceutical companies to support clinical trials and drug development with its unique combined DNA and RNA liquid biopsy platform.

Shidong Jia, the company's founder and CEO, told GenomeWeb that Predicine was founded to address an unmet need in clinical drug development for non-invasive biomarker testing that wasn't limited to DNA.

"I originally came from Genentech … and one of the things we recognized that was a major unmet need … was liquid biopsy tests that can help define drug resistance and monitor therapeutic response at the RNA level, not just the DNA level," Jia said.

"That's one reason we decided to start the company," he added. "With that goal of bringing [liquid biopsy] testing to the next level."

"It's quite clear that right now DNA-only tests are not enough," Jia said. "For example, for BRAF inhibitors targeting V600 … just because there is a DNA mutation it doesn't mean there is transcription at the RNA level. That is why in [clinical trials] not every patient who is positive for the mutation responds. So that is why these companies want to be able to look at the next level."

According to Jia, another good example is the prostate cancer space, where tests like Epic Sciences' have recently emerged to predict patient response to hormonal versus chemotherapies.

Jia worked with Epic while he was at Genentech, "but in the end, we found that CTCs were just not abundant enough for the majority of patients."

"What you want is to be able to make a call on status for every patient to [determine their eligibility], that's part of the reason we started to look at addressing these kinds of unmet needs," he added.

To do this, Predicine developed an approach it calls Gene RADAR, which stands for "ctRNA and ctDNA single-molecule digital reading."

Jia said that the company shared its first data on the approach, which analyzes both DNA and RNA in a single blood sample, at the annual meeting of the American Association for Cancer Research this spring,

and then at the American Society of Clinical Oncology in June.

This is what spurred the buildout of the company's clinical trial services work with pharma companies, he said. And from there, Predicine has continued to expand its technologies to the clinical testing space.

Predicine is not the only company to recognize a need for both DNA and RNA analysis from blood. Exosome Diagnostics, for example, has developed a methodology to combine analysis of RNA from exosomes, a type of extracellular vesicle, with circulating cell-free DNA.

So far, Predicine's business in the US has been focused on applying its technology in the context of clinical drug development, with what Jia said are leading pharmaceutical companies, though he did not provide further details. He did say that this work will also be an important part of the company's activities in China.

"Part of the reason we started the China side [of the company] is that clinical trials are all global now. A problem I [ran into] when I worked at Genentech was that a trial had to be completed in China, but I couldn't find a high-quality vendor to do the types of tests we were looking for,"

"We want to bridge east and west to make drug trials truly global using this combined DNA/RNA liquid biopsy approach," he said.

The other thing that a base in China gives Predicine is the ability to expand from research work to clinical testing.

Jia said that the company has three tiers that it is focused on in terms of molecular analyses. The first is a comprehensive sequencing method it calls PrediSeq, which comprises an approximately 80-gene NGS panel.

Alongside PrediSeq, the company has also developed smaller disease-specific tests, called PrediAct. Most likely, Jia said, patients will receive PrediAct in the clinical setting, although if the tests do not reveal any actionable information, a doctor could then test a patient using the larger PrediSeq in a clinical research context in order to open up eligibility for off-label or developing drugs.

Earlier this year, Predicine signed a deal with Shanghai-based CloudHealth Genomics to provide clinical genetic testing infrastructure and sequencing capacity in China for these and other tests, and the two partners launched tests for prostate and lung cancer in June.

According to Jia, Predicine is working with opinion leaders at major Chinese hospitals in a number of disease-specific areas. The idea is that these collaborations will help validate its tests, and then become a jumping-off point for a clinical customer base.

Beyond PrediSeq and PrediAct, Jia said that the firm is also working on launching a third test called PrediScreen, next year. PrediScreen will be a liquid biopsy-based early detection assay for individuals with an elevated risk of developing cancer.

This area has attracted growing attention over the past year with notable forays by Pathway Genomics, Illumina's Grail, Guardant Health, and others.

Although Predicine's clinical testing expansion is limited to China right now, Jia said the eventual plan is to move to offer similar products in the US.

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