BIOCENTURY

BLUEJAY: COMBINING HBV THERAPIES TO REACH A FUNCTIONAL CURE

Emerging Company Profile: Led by Keting Chu, Bluejay is advancing HBV assets in-licensed from Novartis

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Bluejay is applying a combination of therapies in-licensed from Novartis with an aim to cure chronic HBV by reducing viral surface antigen in both the liver and blood.

Founder, Chairman and CEO Keting Chu said she had been interested in building a company around HBV assets from **Novartis AG** (NYSE:NVS; SIX:NOVN) after the pharma **exited infectious disease** in 2018. A Novartis alum herself, Chu met **Novartis Institutes** for BioMedical Research's Jennifer Leeds at a California Life Sciences Institute meeting a few years ago; the connection set the stage for an in-licensing deal. Leeds is executive director and head of BD&L search and evaluation, West Coast and Canada.

Chu said she believed in the assets, knowing that NIBR's Donald Ganem was involved in their discovery and early development. Ganem, who was VP and head of global infectious diseases research at NIBR in 2011-18, is a professor emeritus of microbiology and immunology at **University of California San Francisco**, where Chu attended graduate school.

Chu launched Bluejay Therapeutics Inc. in 2019 with exclusive global rights to three of the pharma's therapies: BJT-778, a mAb against HBV surface antigen (HBsAg); BJT-574, a small molecule HBsAg inhibitor; and a small molecule capsid inhibitor.

Most recently a **Lyfe Capital** partner, Chu has led multiple start-ups in addition to holding research and executive roles at The Leukemia & Lymphoma Society, Five Prime Therapeutics Inc., Chiron Corp. and Novartis.

The Swiss pharma will receive an upfront payment, including equity in Bluejay, and is eligible for milestones, plus royalties. Details are not disclosed.

HBV exists in two forms simultaneously in infected liver cells of chronic patients: integrated into the human chromosome and as a circular DNA "minichromosome" in the cytosol.

Several marketed therapies target HBV polymerase and inhibit viral replication. However, the integrated HBV genome and minichromosome still get transcribed and translated into viral proteins.

Looking at the HBV therapy landscape, "there are basically two schools," Chu told BioCentury. The first, developing fourth generation nucleoside analogs or capsid inhibitors, seeks to further reduce viral particle production. The second uses RNAi to lower HBsAg in patient serum.

To reach a functional cure, Chu said, a finite HBV treatment regimen must lead to undetectable HBsAg in patient's blood for six months, a seroconversion from HBsAg positive to anti-HBsAg antibody positive and undetectable HBV DNA in patient's serum.

Chu said standard of care can lead to a 3-11% functional cure rate depending on the regimen used. She also noted that companies are developing alternate strategies to increase the rate. Arbutus Biopharma Corp. (NASDAQ:ABUS), **Gilead Sciences Inc.** (NASDAQ:GILD), **GlaxoSmithKline plc** (LSE:GSK; NYSE:GSK), Johnson & Johnson (NYSE:JNJ), **Roche** (SIX:ROG; OTCQX:RHHBY) and **Vir Biotechnology Inc.** (NASDAQ:VIR) are combining RNAi with innate immune enhancers.

"To get a functional cure for HBV, it's probably going to be a combination of therapies," said Chu. "Our antibody can clear the surface antigen in patients' blood, and our small molecule inhibitor will inhibit viral RNA and viral protein in HBV infected liver cells. Our end goal is to clear the surface antigen in both places."

The antibody and small molecule HBsAg inhibitor are now Bluejay's lead programs. She said the company has preclinical data showing its antibody exhibits a "best-in-class drug product profile."

With a $20 million series A round closed in June, Bluejay aims to begin clinical trials of the lead compounds next year, with plans to eventually test a combination product in a Phase Ib trial. Its small molecule capsid inhibitor is in lead optimization.

RiverVest Venture Partners, Yongjin Ventures and **Octagon Capital** participated in the A round.

"We are always looking for programs addressing serious unmet needs with strong teams and assets," RiverVest Managing Director Nancy Hong told BioCentury. "We often scoop up things from big pharma that were deprioritized for various reasons unrelated to quality. Bluejay fits this strategy to a tee."

Hong met Chu at a BD meeting "years ago."

"I saw her move from strategic to institutional investing as well, but didn't realize until we reconnected for Bluejay how well her background fits this company," Hong said.

Next up for Bluejay is building out the leadership team. Chu is looking to hire a CMO and heads of virology and medicinal chemistry.

She said the company is considering two directions as it expands its pipeline — pursuing other viral diseases, or focusing on liver indications.

Value inflection points over the next 2-3 years could set up exit opportunities through M&A or a public listing, according to the company.

COMPANY PROFILE

Bluejay Therapeutics Inc.
South San Francisco, Calif.
Technology: Oral small molecule HBV inhibitor and human anti-HBsAg mAb
Origin of technology: Novartis AG
Disease focus: Infectious
Clinical status: Preclinical
Founded: 2019 by Keting Chu
Academic collaborators: N/A
Corporate partners: Novartis
Number of employees: 2
Funds raised: $20 million
Investors: RiverVest Venture Partners, Yongjin Ventures and Octagon Capital
CEO: Keting Chu
Patents: 8 issued covering composition of matter for lead compounds