

BeyondSpring Looks to Future After IPO/PIPE Launch

Sep 15, 2017 - A co-founder describes its unique approach to oncology.

BeyondSpring Inc. ([BYSI](#)) went public this spring in a dual initial public offering and private-investment-in-public-equity offering, and the company is moving forward with several pipelines in clinical trials.

New York-based BeyondSpring develops oncology products with Plinabulin, a small molecule that attacks tumors and can activate the Rho guanine nucleotide exchange factor GEF-H1, which could play around in managing a variety of diseases.

Beyond Spring has Plinabulin in clinical trials for the treatment of conditions including neutropenia and several non-small cell lung cancers (NSCLs). Pre-clinical trials are developing applications for metastatic brain tumor. Neutropenia is a condition involving an abnormally low count of neutrophils, which help fight off illnesses -- particularly those caused by bacteria.

Co-founder, chairperson and CEO Lan Huang provided The Deal with a look at Plinabulin and how testing drugs in China works in conjunction with the Food and Drug Administration.

Huang previously co-founded Wuxi MTLH Biotechnology Co. Ltd., which was acquired by Shanghai Pharmaceutical Group in 2010, and Paramax International, which was acquired RPS, then sold to Warburg Pincus in 2011.

Huang and the company's CSO, CRO and CMO all have doctorates in scientific specialties, and the CMO has M.D and M.B.A degrees as well. It's not a company managed purely by business experts who are not developing new products.

"Plinabulin is a first-in-class, small molecule immuno-oncology agent. By activating a novel target, GEF-H1, it activates the dendritic cell maturation and leads to tumor action-specific T-cell activation," Huang said.

"With this activity, it has anti-cancer effects, such as in non-small cell lung cancer. It also has a neutrophil protection function by releasing IL-1beta and IL-6, both of which protect neutrophils from apoptosis (genetically programmed cell death), which led to the prevention of neutropenia indication."

The company's approach differs from many cancer therapies that rely on the PD-1 programmed cell death protein. PD-1 can increase cell death where its beneficial for cancer treatment while inhibiting cell death in cells that bolster the immune system.

"Plinabulin ... is different from PD-1 antibodies, which release the brake from the immune system so that the T-cell can see the cancer cells," Huang said. "Instead, Plinabulin adds fuel to the car, basically adding T-cells into the system to kill cancer. That is how it is differentiated in its mechanism for the anti-cancer effect."

As it develops its pipeline, BeyondSpring is bringing together efficiencies from the FDA and China Food and Drug Administration.

"BeyondSpring's business model is unique in that it integrates both U.S. and Chinese clinical resources, resulting in both time- and cost-efficiency in drug development," according to Huang.

"The team is conducting clinical trials with rigorous quality control, with the China component of the clinical trial headed by one of China's foremost clinical oncology researchers, to generate data that adheres to the most stringent FDA clinical and regulatory standards. This allows BeyondSpring to conduct one global trial to support dual U.S.-China approvals in Plinabulin and pipeline assets in registrational trials in two large indications.

As Huang pointed out, the U.S. and China are the two largest pharmaceutical markets.

The CFDA approved the two Phase 3/2 three trials in June, and they are going forward to assess Plinabulin treatment effects on chemotherapy-induced neutropenia.

The company expects data later this year from NSCL studies being conducted by collaborators at the Fred Hutchinson Cancer Center and the University of Washington.

The company went public through an initial public offering that included a \$50.82 million private-investment-in-public-equity offering from fund managed by Shenzhen Sangel Venture Capital Co. and China Huarong Asset Management Co.