

Puma Biotechnology enters into a collaborative agreement with Strata Oncology

19 July 2018 | News

The companies have entered into a collaborative agreement to accelerate patient enrollment in Puma's ongoing Phase II SUMMIT trial of PB272 (neratinib). Neratinib, an oral irreversible pan-HER kinase inhibitor, was approved by the FDA in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed in the United States as NERLYNX.



Puma Biotechnology, Inc., a biopharmaceutical company, and Strata Oncology, Inc., a precision oncology company, have entered into a collaborative agreement to accelerate patient enrollment in Puma's ongoing Phase II SUMMIT trial of PB272 (neratinib). The SUMMIT trial is a global, multi-histology, open-label, precision-medicine 'basket' study evaluating the safety and efficacy of neratinib in patients with a wide variety of solid tumors with activating EGFR, HER2 or HER4 mutations.

Neratinib, an oral irreversible pan-HER kinase inhibitor, was approved by the FDA in July 2017 for the extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer following adjuvant trastuzumab-based therapy and is marketed in the United States as NERLYNX®. Data published in the journal *Nature* earlier this year showed neratinib has activity across multiple tumor types with HER2-activating mutations.

Under the terms of the agreement, Strata will exclusively refer HER2-mutated advanced cancer patients identified through the Strata Trial for consideration of enrollment to Puma's SUMMIT Trial for neratinib.

The Strata Trial is a screening protocol providing comprehensive tumor molecular profiling to advanced cancer patients at no cost and proactive enrollment support for a portfolio of pharma-sponsored precision therapy trials. Tumor profiling through the Strata Trial is provided as part of routine care to solid tumor patients across the Strata Precision Oncology Network, a network of 11 leading health systems representing more than 85,000 new cancer patients annually. This large network of trial-ready health systems with fully pre-screened advanced cancer populations enables rapid and predictable enrollment of precision therapy trials.

"We are pleased to partner with Puma Biotechnology to accelerate the path to new approvals for neratinib," said Dan

Rhodes, Ph.D., CEO of Strata Oncology. "We frequently identify HER2-mutant patients across the Strata Precision Oncology Network and we believe this partnership will greatly facilitate patient access to this promising clinical trial."

"Puma's ultimate goal is to deliver new treatment options and improve the lives of patients with various types of cancer," said Alshad S. Lalani, V.P., Translational Medicine of Puma Biotechnology. "We believe Puma's partnership with Strata will help us reach patients with multiple tumor types who may not otherwise know about the SUMMIT study, giving them a chance to participate in research that's designed to provide important new information for future treatment."