BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Five Prime, Roche collaborate for IHC companion diagnostics assays

31 May 2018 | News | By Priyanka Bajpai

Five Prime and Roche are collaborating to develop, validate and commercialize a tissue-based IHC companion diagnostic (CDx) assay to help identify patients whose tumors overexpress FGFR2b and are eligible for treatment with bemarituzumab.

Singapore- Five Prime Therapeutics, a clinical-stage biotechnology company focused on discovering and developing innovative immuno-oncology protein therapeutics, announced it has entered into a collaboration with Roche to develop immunohistochemistry (IHC) companion diagnostic assays for use with Five Prime's first-in-class investigational drug candidates, bemarituzumab, an anti-FGFR2b antibody (also known as FPA144), and FPA150, a B7-H4 antibody.

"We are pleased to collaborate with Roche, a world leader and innovator of tissue-based diagnostic solutions, to identify patients with advanced cancers who might be eligible for treatment with our targeted immuno-oncology agents," said Aron Knickerbocker, chief executive officer of Five Prime Therapeutics, Inc. "We believe targeted therapies, such as bemarituzumab and FPA150, could provide clinical benefit to patients. Roche's tissue-based assays will be important tools to help us identify the patients who might benefit most from these treatments."

Five Prime and Roche are collaborating to develop, validate and commercialize a tissue-based IHC companion diagnostic (CDx) assay to help identify patients whose tumors overexpress FGFR2b and are eligible for treatment with bemarituzumab. The CDx assay will be used in Five Prime's global registrational study of bemarituzumab in combination with 5-fluorouracil (5-FU), leucovorin, and oxaliplatin, a regimen known as mFOLFOX6, as front-line treatment in patients with advanced gastric or gastroesophageal junction cancer whose tumors overexpress FGFR2b or have *FGFR2* gene amplification (the FIGHT trial) that Five Prime expects to start in the second half of 2018. Five Prime plans to use the Roche IHC assay along with a circulating tumor DNA (ctDNA) test in the FIGHT trial to identify the estimated 10 percent of patients with gastric and gastroesophageal junction cancer who would be eligible for treatment with bemarituzumab.

Five Prime and Roche will also collaborate to develop and validate a tissue-based IHC diagnostic assay for use as a laboratory developed test (LDT) to help identify patients whose tumors overexpress B7-H4. Five Prime plans to use this IHC assay in the expansion portion of the ongoing Phase 1 clinical trial of FPA150 to identify patients with advanced or metastatic breast, ovarian, endometrial and bladder cancers whose tumors overexpress B7-H4.

Financial terms of the agreement were not disclosed.