



December 19, 2017

Five Prime Therapeutics and Zai Lab Announce Exclusive License Agreement for FPA144 Anti-FGFR2b Antibody in Greater China and Global Strategic Development Collaboration

Planned global Phase 3 FIGHT trial in front-line gastric and gastro-esophageal junction cancers to include sites in China where disease incidence is the highest in the world

SOUTH SAN FRANCISCO, Calif. and SHANGHAI, China, Dec. 19, 2017 (GLOBE NEWSWIRE) -- [Five Prime Therapeutics, Inc.](#) (NASDAQ:FPRX), a biotechnology company discovering and developing innovative immuno-oncology protein therapeutics, and [Zai Lab Limited](#) (NASDAQ:ZLAB), a Shanghai-based innovative biopharmaceutical company, today announced an exclusive license agreement for FPA144 in Greater China and global strategic development collaboration. Five Prime's FPA144 is a first-in-class isoform-selective, humanized monoclonal antibody in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, including gastric and gastro-esophageal junction cancer. China has one of the highest incidence rates of gastric cancer in the world, with approximately 680,000 new cases annually.^{1,2} The randomized, controlled Phase 3 portion of the FIGHT trial evaluating FPA144 plus chemotherapy is expected to start in the second half of 2018 and would serve as a global registrational study for the treatment of front-line gastric and gastro-esophageal junction cancers. Zai Lab will manage the Phase 3 portion of the trial in China.

"We believe Zai Lab is the right partner for FPA144 in Greater China for this innovative product," said Aron Knickerbocker, Chief Operating Officer of Five Prime and incoming Chief Executive Officer (effective January 1, 2018). "China accounts for more than 40% of new gastric cancer cases globally², so it is critical to align strategically with a strong collaborator with the infrastructure, relationships and resources to help us advance FPA144 global development expeditiously. Zai Lab is ideally positioned given their experienced leadership team, focus on innovative drugs, and established expertise and network within oncology. We look forward to working with Zai Lab to carry out our worldwide development program for FPA144 and accelerate enrollment in the global Phase 3 portion of the FIGHT trial."

"Five Prime has pioneered the development of some very exciting and highly-targeted antibodies, including FPA144, which we believe holds tremendous promise for cancer patients in Greater China. We are committed to working with Five Prime to accelerate the global development timelines for this important investigational therapy," stated Samantha Du, Chairman and CEO of Zai Lab. "This strategic collaboration highlights the strength of our team and business model as the partner of choice in China and in delivering innovative therapies to patients in China and beyond."

Under the terms of the agreement, Five Prime has granted Zai Lab an exclusive license to develop and commercialize FPA144 in the Greater China territory: China, Hong Kong, Macau, and Taiwan. Zai Lab will be responsible for conducting the Phase 3 FIGHT trial in Greater China, including screening, enrollment and treatment of patients, and for commercialization of FPA144 in the Greater China territory. Five Prime will manufacture and supply FPA144 for the study. A Joint Steering Committee will be formed between the companies to oversee development, regulatory and commercialization activities in greater China. Five Prime will receive a \$5 million upfront payment and is eligible to receive up to \$39 million in development and regulatory milestone payments. Five Prime is also eligible to receive from Zai Lab a royalty percentage on net sales of FPA144 in Greater China ranging from the high teens to the low twenties. Given the strategic importance of China to the development and commercialization of FPA144 and to align the interests of the two companies globally, Zai Lab is also eligible to receive a low single-digit royalty from Five Prime on net sales of FPA144 outside of Greater China.

"Gastric cancer is the fifth most common cancer in the world and the second most common in China. Patients whose tumors overexpress FGFR2b or have *FGFR2* gene amplification have an especially poor prognosis," said Dr. Shukui Qin, the Executive Member of the Asian Clinical Oncology Society, Senior Vice President of Chinese Society of Clinical Oncology and the Director of Cancer Center of People's Liberation Army. "I am encouraged that we may be able to identify those patients with companion diagnostics and potentially treat them more effectively with a highly targeted therapy like FPA144. There is a critical need for more effective and safe therapies for gastric cancer patients here, so I am pleased that I and my fellow oncologists throughout China can play an important role in the FIGHT trial."

About FPA144

FPA144 is an isoform-selective, humanized monoclonal antibody in clinical development as a targeted immuno-therapy for tumors that overexpress FGFR2b, a splice variant of a receptor for some members of the fibroblast growth factor (FGF) family. FPA144 has also been engineered for enhanced antibody-dependent cell-mediated cytotoxicity (ADCC) to increase direct tumor cell killing by recruiting natural killer (NK) cells.

FPA144 is being evaluated as a potential treatment for gastric cancer and bladder cancer. In a Phase 1 trial, FPA144 demonstrated monotherapy activity in heavily pre-treated patients with FGFR2b-positive gastric cancer and did not exhibit certain toxicities that have been seen with less selective FGFR2 small molecule therapeutics. An estimated 10% of patients with gastric cancer have tumors that overexpress FGFR2b or have FGFR2 gene amplification, which is associated with poor prognosis.

About Five Prime

Five Prime Therapeutics, Inc. (NASDAQ:FPRX) discovers and develops innovative therapeutics to improve the lives of patients with serious diseases. Five Prime's comprehensive discovery platform, which encompasses virtually every medically relevant extracellular protein, positions it to explore pathways in cancer, inflammation and their intersection in immunology, an area with significant therapeutic potential and a growing focus of the company's R&D activities. Five Prime has entered into strategic collaborations with leading global pharmaceutical companies and has promising product candidates in clinical and late preclinical development. For more information, please visit www.fiveprime.com.

About Zai Lab

Zai Lab (NASDAQ:ZLAB) is a Shanghai-based innovative biopharmaceutical company focused on bringing transformative medicines for cancer, autoimmune and infectious diseases to patients in China and around the world. The company's experienced team has secured partnerships with leading global biopharma companies, generating a broad pipeline of innovative drug candidates targeting the fast-growing segments of China's pharmaceutical market and global unmet medical needs. Zai Lab's vision is to become a fully integrated biopharmaceutical company, discovering, developing, manufacturing and commercializing its partners' and its own products in order to impact human health worldwide.

Five Prime Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Five Prime's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Actual results may differ materially from these forward-looking statements. Forward-looking statements contained in this press release include statements about (i) the timing of the initiation, progress and scope of the FIGHT clinical trial; (ii) the potential use of FPA144 to treat patients with gastric and gastro-esophageal junction cancer; (iii) the extent of FGFR2 gene amplification and FGFR2b protein overexpression in patients with gastric and gastro-esophageal junction cancer; and (iv) Five Prime's potential receipt of milestone payments and royalties. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during non-clinical or clinical studies, clinical site activation rates or clinical trial enrollment rates that are lower than expected and changes in expected or existing competition. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Five Prime's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" contained therein. Except as required by law, Five Prime assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

Zai Lab Forward-Looking Statements

This press release includes certain disclosures which contain "forward-looking statements," including, without limitation, statements regarding the timing of the initiation, progress and scope of the FIGHT clinical trial, the potential use of FPA144 to treat patients with gastric and gastro-esophageal junction cancer, Five Prime's potential receipt of milestone payments and royalties from Zai Lab and Zai Lab's potential receipt of royalties from Five Prime. You can identify forward-looking statements because they contain words such as "believes" and "expects." Forward-looking statements are based on Zai Lab's current expectations and assumptions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that may differ materially from those contemplated by the forward-looking statements, which are neither statements of historical fact nor guarantees or assurances of future performance. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in Zai Lab's filings with the Securities and Exchange Commission. Zai Lab undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

REFERENCES:

¹ Translational Gastrointestinal Cancer, Vol 2, Supplement 1 (June 2013); *A current view of gastric cancer in China*, Zhaode Bu, Jiafu Ji

² CA: A Cancer Journal for Clinicians, 25 January 2016; *Cancer statistics in China, 2015*, Wanqing Chen et al

FIVE PRIME CONTACT:

Derek Cole
Investor Relations Advisory Solutions
720-785-4497
derek.cole@iradvisory.com

ZAI LAB CONTACTS:

Zai Lab
Jonathan Wang
+86 21 6163 2588
jwang@zailaboratory.com

The Trout Group
John Graziano
+1 646 378 2942
jgraziano@troutgroup.com

 [Primary Logo](#)

Source: Five Prime Therapeutics, Inc.

News Provided by Acquire Media