



FLX Bio Highlights Phase 1 Data for FLX475 at SITC 2018

-- Data Confirm FLX475 Offers Potential for Selectively Targeting Tumor Regulatory T Cells --

-- Additional Preclinical Data Features Beneficial Immune Activation Properties for FLX's GCN2 Inhibitor Program --

SOUTH SAN FRANCISCO, Calif. – November 8, 2018 – FLX Bio, Inc., a clinical-stage, biopharmaceutical company focused on the development of oral small-molecule drugs that target immune drivers of cancer and other immune-related disorders, today announced that data from a Phase 1 study of FLX475 in healthy volunteers which demonstrated excellent pharmacokinetics, pharmacodynamics, and safety and tolerability will be presented on November 10, 2018 at the Society for Immunotherapy of Cancer Meeting in Washington D.C. Preclinical data showing the benefits of using a GCN2 inhibitor to treat cancer will also be featured at the meeting.

“These Phase 1 data confirm that FLX475 fully engages its intended target, CCR4, on regulatory T cells at well-tolerated doses which is predicted to specifically block their recruitment into tumors without reducing regulatory T cells in healthy tissues or beneficial cells that mediate the anti-tumor immune response,” said Brian Wong, M.D., Ph.D., CEO of FLX Bio. “We believe that inhibiting regulatory T cells in the tumor microenvironment with such high precision and selectivity could remove a major barrier to attaining deep and durable remissions in patients with cancer.”

Pharmacokinetics, pharmacodynamics, and safety of FLX475, an orally-available, potent, and selective small-molecule antagonist of CCR4, in healthy volunteers (Poster #P484; Presenter: William Ho, M.D., Ph.D.)

- A Phase 1, first-in-human, randomized, double-blind, placebo-controlled study of FLX475 in 104 healthy volunteers
- FLX475 was well tolerated with no serious adverse events reported at any dose level, including those projected to achieve or exceed maximal inhibition of human T_{reg}
- Long half-life and oral absorption of FLX475 support once-daily oral dosing
- These results have enabled an accelerated Phase 1/2 trial, which is now enrolling, to evaluate FLX475 in the treatment of multiple types of cancers, both as a monotherapy and in combination with the anti-PD1 antibody pembrolizumab

“Based on these highly informative and encouraging clinical data, we are now enrolling our Phase 1/2 study of FLX475, which is designed to accelerate the development of this novel agent in patients with tumor types predicted to be more likely to respond to FLX475 treatment, including those that contain relatively high numbers of regulatory T cells and higher CCR4 ligand expression,” commented Bill Ho, M.D., Ph.D., CMO of FLX Bio.

Targeting the stress response kinase GCN2 to restore immunity in the tumor microenvironment (Poster #P202; Presenter: Lisa Marshall)

- The tumor microenvironment is characterized by deficiencies in oxygen and key nutrients such as glucose and amino acids
- Myeloid-derived suppressor cells (MDSCs), tumor and other cells can create a nutrient-poor environment that inhibits immune function and supports tumor growth
- GCN2 plays a key role in sensing and modulating the response to nutrient deprivation resulting in immune suppression in the tumor microenvironment
- Results of preclinical studies show that FLX Bio's selective GCN2 inhibitor relieves immune suppression (takes the brakes off) and promotes T effector cell activation to recover the function of effector T cells

“Our GCN2 inhibitors have shown a direct ability to relieve immune suppression, allowing the immune response to once again attack tumors effectively,” continued Dr. Ho. “We look forward to selecting a preclinical candidate for this program in early 2019.”

About FLX475

[FLX475](#) is a best-in-class oral, small molecule antagonist of CCR4. FLX Bio is conducting an open-label, dose-escalation and cohort expansion Phase 1/2 study in patients with multiple types of cancer to evaluate the safety and tolerability of FLX475 as a monotherapy and in combination with pembrolizumab. In preclinical studies, FLX475 inhibited tumor growth and increased tumor regression as a single agent. In addition, FLX475 enhanced the antitumor effects of various checkpoint inhibitors including anti-PD-L1 and anti-CTLA4 antibodies as well as immune agonists such as anti-4-1BB antibodies. FLX475 also has the potential to enhance cell-based immunotherapies such as CAR-T and cancer vaccines. Unlike antibodies to CCR4, FLX475 selectively blocks the recruitment of regulatory T cells to the tumor site and does not deplete cells beneficial to an antitumor response or regulatory T cells in healthy tissue such as blood, spleen and skin cells.

About GCN2 Inhibitors

FLX Bio is developing orally-bioavailable, highly-selective [GCN2](#) inhibitors that stimulate an immune response by limiting [T_{reg}](#) and [MDSC](#) functions as well as promoting effector T cell proliferation and function. A GCN2 inhibitor has the potential to be highly efficacious since this key protein acts downstream of multiple tumor-promoting enzymes such as indoleamine deoxygenase (IDO) and arginase (ARG), which breakdown the amino acids tryptophan and arginine, respectively. In cell-based assays, FLX Bio's GCN2 inhibitors increase CD8 T cell proliferation and function in tryptophan-, arginine- and glucose-limited conditions. Additional preclinical activities are ongoing for this series of compounds. FLX expects to select a preclinical candidate in early 2019.

About FLX Bio

FLX Bio, Inc. is a privately-held biopharmaceutical company focused on the discovery, development and commercialization of best-in-class, oral small molecule therapeutics for the treatment of cancers and other immune disorders. Our lead compounds inhibit the CCR4 pathway which plays a key role in both suppressing the immune response to cancer and in the initiation, progression and persistence of allergic inflammation. We leverage big data and machine learning together with our advanced drug discovery capabilities and deep biology expertise, to develop therapeutics that address key pressure points in pathways that propagate an abnormal immune response.

Located in South San Francisco, Calif., and funded by leading investors, including The Column Group (TCG), Kleiner Perkins (KP), Topspin Partners, GV (formerly Google Ventures) and Celgene Corporation, FLX Bio has assembled a leadership team and advisory group with a proven track record of success and team of scientists with substantial knowledge and expertise in drug discovery and translational areas essential to execute on this approach. For more information, please visit www.flxbio.com.

Contact:

Angela Bitting

For FLX Bio, Inc.

media@flxbio.com

(925) 202-6211