FLX BIO ANNOUNCES FIRST PATIENT DOSED WITH FLX475, A BEST-IN-CLASS CCR4 INHIBITOR FOR THE TREATMENT OF MULTIPLE CANCERS

-- Phase 1/2 Study to Assess FLX475 as Single Agent and in Combination with PD-1 Inhibitor --

SOUTH SAN FRANCISCO, Calif. – September 27, 2018 – FLX Bio, Inc., a clinical-stage, biopharmaceutical company focused on the development of oral small-molecule drugs that target drivers of cancer and other immune-related disorders, today announced that the first patient has been treated in its Phase 1/2 clinical trial of FLX475 in patients with various advanced cancers. FLX475 is an oral, small molecule CCR4 antagonist that selectively inhibits migration of regulatory T (T_{reg}) cells into the tumor microenvironment.

"The dosing of our first patient with FLX475 is a significant milestone for FLX Bio as we continue to advance our novel therapeutic approach targeting the tumor microenvironment," said Brian Wong, M.D., Ph.D., CEO of FLX Bio. "T_{reg} cells play fundamental roles in inhibiting the immune response to the tumor and are a major resistance mechanism to many cancer immunotherapies including PD-1 inhibitors. FLX475 represents a best-in-class approach to selectively decrease T_{reg} numbers in the tumor thereby unlocking the antitumor immune response. In addition, our big data and proprietary informatics platform has revealed the tumor types most likely to respond to FLX475. We are excited to evaluate this new therapeutic modality in these enriched patient populations through our ongoing global Phase 1/2 clinical trial."

"FLX475 has demonstrated an excellent safety, pharmacokinetic and pharmacodynamic profile in a recently-completed study of healthy volunteers and we believe this compound holds tremendous promise for directly addressing the suppressive effects of T_{reg} in the tumor microenvironment," said Bill Ho, M.D., Ph.D., Chief Medical Officer of FLX Bio. "Treatment with FLX475 should allow the selective blocking of tumor-associated T_{reg} recruitment while sparing normal tissues and beneficial cells. This may offer a safer and more efficacious treatment alternative for patients with many different types of cancer, as compared to the several existing strategies used to suppress or deplete T_{reg} cells."

The open-label, dose-escalation and cohort expansion Phase 1/2 study will enroll patients with multiple types of cancer at leading cancer centers across the United States, Australia and Asia. The trial will evaluate the safety and tolerability of FLX475 as a monotherapy and in combination with pembrolizumab. In addition, the study will evaluate changes in the tumor microenvironment and the antitumor activity of both monotherapy and combination therapy. Patients with tumors positive for the Epstein-Barr Virus (EBV), which has been shown to be an indicator of tumors with a higher number of T_{reg} cells, will be enrolled in a biomarker-selected cohort. Tumors that can be positive for EBV include nasopharyngeal cancer and Hodgkin lymphoma. In addition, the company intends to enroll patients with tumors that express high levels of CCR4 receptor and ligands, which include non-small cell lung cancer, head and neck

cancer, triple negative breast cancer, and cervical cancer. For more information please visit clinicaltrials.gov identifier NCT03674567.

About FLX475

FLX475 is a best-in-class oral, small molecule antagonist of CCR4. FLX Bio has completed a study of FLX475 in healthy volunteers, demonstrating that the compound is safe with excellent pharmacokinetic and pharmacodynamic properties. 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 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 proprietary informatics 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.

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