FOR IMMEDIATE RELEASE

Rainier Therapeutics Announces Fast Track Designation Granted by FDA for Vofatamab in Treatment of FGFR3-Positive Urothelial Cell Carcinoma (Bladder Cancer)

SAN LEANDRO, Calif., January 7, 2019—Rainier Therapeutics, Inc., a privately-held clinical stage drug development company, today announced that its targeted antibody vofatamab has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for treatment of patients with advanced or metastatic urothelial cell carcinoma (bladder cancer) that is positive for FGFR3 mutation and/or fusion.

“This Fast Track designation underscores the great unmet medical need that exists for the treatment of bladder cancer,” said Scott Myers, Chairman and CEO of Rainier Therapeutics. “As the only antibody specifically targeted to FGFR3 we know to be in clinical development, we believe vofatamab offers a promising therapeutic option. We look forward to further data from our ongoing trials and working to advance our development efforts.”

The FDA’s Fast Track designation is a process to facilitate development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. Through the Fast Track program, more frequent meetings may be scheduled with the FDA to discuss the drug’s development plan and to ensure the collection of appropriate data needed to support approval. Additionally, the drug may qualify for accelerated approval and priority review and, at the time of a biologics license application (BLA) filing, the drug candidate’s sponsor may be eligible to submit completed sections of the BLA on a rolling basis before the complete application is submitted.

“Fast Track designation offers the potential to reduce development time and cost associated with bringing a drug to patients,” said Valerie Fauvelle, Vice President, Regulatory Affairs at Rainier Therapeutics. “We look forward to working with the FDA to rapidly advance vofatamab through the clinical development and regulatory processes.”

Vofatamab (B-701) is an antibody specifically targeted against the fibroblast growth factor receptor 3 (FGFR3), a known driver of bladder and other cancers. Vofatamab is the most advanced targeted biologic specific for FGFR3 known by Rainier to be in clinical development.

Rainier Therapeutics has ongoing Phase 1b and Phase 2 clinical studies of vofatamab in metastatic bladder cancer – the Fierce 21 and Fierce 22 studies. In addition, Rainier Therapeutics plans to study vofatamab in early stage bladder cancer – the Fierce 23 trial.

The Fierce 21 trial is evaluating vofatamab alone and in combination with docetaxel versus docetaxel alone to determine safety and efficacy in the treatment of patients with locally advanced or metastatic bladder cancer with FGFR3 mutant/fusion who have relapsed after, or are refractory to, at least one prior line of chemotherapy. For more on this trial, visit www.clinicaltrials.gov (NCT0240542).

The Fierce 22 trial is evaluating vofatamab in combination with pembrolizumab, an immune checkpoint inhibitor, to determine safety, tolerability and efficacy in the treatment of patients with locally advanced or metastatic bladder cancer, who have progressed following platinum-based chemotherapy and who have not received prior immune checkpoint inhibitor therapy. For more on this trial, visit www.clinicaltrials.gov (NCT03123055).

The Fierce 23 trial will evaluate vofatamab monotherapy in non-muscle invasive bladder cancer (NMIBC). This trial is planned to start in 2019.

About Rainier Therapeutics

Rainier Therapeutics, Inc. is a privately-held, clinical stage biotechnology company developing a targeted biologic for the potential treatment of metastatic bladder cancer. The company's antibody, vofatamab (B-701) is focused specifically on the fibroblast growth factor receptor 3 (FGFR3), a known driver of bladder and other cancers. Rainier's website is: www.rainierrx.com.

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