Rainier Therapeutics Announces Presentation of Patient Biopsy Data Demonstrating Vofatamab's Ability to Increase Immune Cell Activation

- Vofatamab activates immune changes in immunologically cold tumors and in combination increases patient response rates -

- Data from FIERCE-22 Trial in Patients with Metastatic Bladder Cancer Presented at AACR Bladder Cancer Conference -

SAN LEANDRO, Calif., May 20, 2019—Rainier Therapeutics, Inc., a privately-held clinical stage drug development company, today announced the presentation of data from its FIERCE-22 trial where vofatamab, the company's lead therapeutic stimulates an increase in immune cell activation in patients with metastatic bladder cancer. The data is being presented in an oral and poster presentation at the 2019 American Association for Cancer Research (AACR) Bladder Cancer: Transforming the Field Special Conference.

Researchers at John Hopkins School of Medicine and MD Anderson analyzed RNA from 22 paired biopsy samples from metastatic bladder cancer patients enrolled in Rainier's Phase 1b / 2 FIERCE-22 trial. Patients who had progressed following platinum-based chemotherapy but had not received prior immune checkpoint inhibitor therapy were eligible to enroll. Tumor biopsies were taken pre- and post-treatment with vofatamab, and prior to the start of combination treatment with pembrolizumab. Patient biopsies were taken to understand changes to gene signatures induced with vofatamab and to correlate this with clinical outcomes.

"The unique design of the trial allowed us to evaluate the effect of FGFR3 inhibition on gene signatures," said David McConkey, Ph.D., John Hopkins School of Medicine. "Vofatamab, an FGFR3 specific antibody, significantly upregulated genes associated with inflammation in both wild-type *and* FGFR3 mutant tumors. This was associated with an increased response rate to the combination with pembrolizumab in these patients and was particularly marked in patients with luminal biology."

"Tumors that are immunologically 'cold' tend to exist in luminal bladder cancer and these patients have historically responded poorly to checkpoint inhibitors. The enhanced response rate seen suggests this combination may provide a valuable new treatment option," said Graeme Currie, Ph.D., Chief Operating Officer, Rainier Therapeutics. "We look forward to presenting interim clinical data from FIERCE-22 at the upcoming 2019 ASCO annual meeting."

Key Findings:

- Compared to historical data with pembrolizumab, response rates with vofatamab treatment appear higher.

- Vofatamab responders had upregulation of genes associated with an inflammatory response in the tumor.

- Responses were enriched in the cohort with a luminal gene expression profile (also referred to as "immunologically cold").

About Vofatamab

Vofatamab (formerly B-701) is an antibody specifically targeted against the fibroblast growth factor receptor 3 (FGFR3), a known driver of bladder and potentially other FGFR-driven cancers. Vofatamab is the most advanced targeted antibody specific for FGFR3 known by Rainier Therapeutics to be in clinical development. Vofatamab is currently being evaluated in two clinical trials: FIERCE-22 and FIERCE-21.

FIERCE-22 is a Phase 2 trial 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 additional information on FIERCE-22, please visit www.clinicaltrials.gov (NCT03123055).

About Rainier Therapeutics

Rainier Therapeutics, Inc. is a privately held, clinical stage biotechnology company developing vofatamab, a targeted antibody, for the potential treatment of metastatic bladder cancer. For more information, please visit www.rainierrx.com.

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