



**Rainier Therapeutics Presents Data on Vofatamab in Patients with Advanced Urothelial Cell Carcinoma (Bladder Cancer) Previously Treated with Chemotherapy at ASCO GU 2019**

- Preliminary data from FIERCE-21 Phase 2 trial highlighted in oral presentation supports advancement to pivotal study –
- Single agent activity and long-term treatment duration demonstrated–

**SAN LEANDRO, Calif., February 15, 2019**—Rainier Therapeutics, Inc., a privately-held clinical stage drug development company, today announced the presentation of preliminary data from its Phase 2 trial of vofatamab, a fibroblast-growth-factor-receptor 3 (FGFR3) targeted antibody, at the 2019 ASCO Genitourinary Cancers Symposium in San Francisco. The study, FIERCE-21, is evaluating vofatamab in combination with docetaxel and vofatamab as monotherapy in patients with locally advanced or metastatic bladder cancer with FGFR3 mutation/fusions who have relapsed after, or are refractory to, at least one prior line of chemotherapy.

“There are limited and, in some cases, no approved treatment options for patients with advanced metastatic bladder cancer who have failed chemotherapy and, if indicated, checkpoint inhibitors. FGFR3 inhibitors have the potential to revolutionize the clinical management of metastatic bladder cancer in biomarker-selected and potentially poor checkpoint responding patients,” said Andrea Necchi, M.D., Urologic Oncology, Department of Medical Oncology, Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy. “Vofatamab has the potential to be a differentiated FGFR3 inhibitor with a tolerability and activity profile that may provide a much-needed therapeutic option to patients.”

“We are pleased with this preliminary data in the FIERCE-21 trial that indicate vofatamab is providing clinical benefit in a group of patients at a very advanced stage of disease. Vofatamab in combination with docetaxel is showing a benefit to patients in the trial that has surpassed historical results of single-agent docetaxel in other trials. In addition, single agent activity was also observed with vofatamab in a heavily pretreated patient group,” said Steve Abella, M.D., Chief Medical Officer, Rainier Therapeutics. “We look forward to reporting further data later this year and believe the data reported today supports moving forward with the planning of a

pivotal trial of vofatamab in combination with docetaxel intended to improve treatment outcomes for this patient population.”

Details from the oral abstract presentation: “*FIERCE-21: Phase II study of vofatamab (B-701), a selective inhibitor of FGFR3, as salvage therapy in metastatic urothelial carcinoma (mUC)*” (abstract #409) are as follows:

### **FIERCE-21 Study Design/Prior Treatments**

- A total of 42 patients with bladder cancer previously treated with one or more prior lines of chemotherapy and, if available, a checkpoint inhibitor, were enrolled in two groups of 21. One study group received a combination of docetaxel (75mg/m<sup>2</sup>) followed by an infusion of vofatamab (25mg/kg). The other group received vofatamab (25mg/kg) as monotherapy. Study treatment was administered on day one of each 21-day cycle.
- In the combination group receiving vofatamab and docetaxel, 57 percent of patients had received a median of two or more prior lines of therapy (range 1-4) and 71 percent of patients in the vofatamab monotherapy group had received a median of three or more prior therapies (range 1-7). More than 50 percent of patients in both arms had received prior checkpoint therapy treatment.
- The primary endpoints of the study are safety and efficacy as measured by objective response rate (ORR), progression free survival (PFS) and overall survival (OS).

### **Preliminary FIERCE-21 Results**

- Of 21 evaluable patients who received the combination therapy of vofatamab plus docetaxel:
  - A preliminary disease control rate (DCR) of 27 percent (at 180 days) was reported.
  - Fifty-seven percent of these patients remain on study and 43 percent remain on treatment at the time of the data analysis.
  - Patients continue to be followed for ORR, PFS and OS.
- Of 21 evaluable patients in the vofatamab monotherapy cohort:
  - A median PFS of 4 months was reported in fourth line patients
  - A preliminary DCR of 21 percent (at 180 days) was reported.
  - Fifty-seven percent of these patients remain on study and 19 percent remain on treatment at the time of the data analysis.
  - Patients continue to be followed for ORR and OS.

- In both groups, treatment was generally well-tolerated, with the most common vofatamab-related adverse events being asthenia, diarrhea, decreased appetite and rash; all were Grade 1 or 2. There were few dose interruptions and discontinuations. No cases of severe skin/nail toxicity, hyperphosphatemia, or ocular events were reported.

The full poster can be viewed on the Rainier Therapeutics website at:  
<http://www.rainierrx.com/posters/>.

### **About Bladder Cancer**

Bladder cancer is the fifth most common cancer in each of the United States and Europe. Over the past 30 years, the only novel therapies approved in the United States for bladder cancer patients have been checkpoint inhibitors for patients who failed first line chemotherapies. Several immune check point inhibitors targeting the programmed cell death-1 or PD-1 or programmed cell death ligand-1, or PDL-1 pathway, have been approved by the FDA for use in bladder cancer patients who have failed platinum-based chemotherapy. Despite these developments, objective response rates in clinical trials with checkpoint inhibitors have been between 15% and 21%, when used as salvage therapy, with median overall survival reported between 8-10 months and limited benefit in progression-free survival, leaving patients with bladder cancer with a high unmet need for effective and tolerable therapies.

In addition, studies have shown that bladder cancer tumors with genetic alterations in FGFR3 have inappropriate FGFR3 signaling driven by these genetic alterations or overexpression and are implicated in the development of bladder cancer. Tolerable and effective therapies for these patients in advanced and metastatic bladder cancer are needed.

### **About Vofatamab**

Vofatamab 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 biologic specific for FGFR3 known by Rainier Therapeutics to be in clinical development.

In addition to FIERCE-21, Rainier Therapeutics has an ongoing Phase 2 clinical trial, FIERCE-22. FIERCE-22 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 additional information on FIERCE-21, please visit [www.clinicaltrials.gov NCT02401542](http://www.clinicaltrials.gov/NCT02401542) and for more information on FIERCE-22, please visit [www.clinicaltrials.gov \(NCT03123055\)](http://www.clinicaltrials.gov/NCT03123055).

Rainier Therapeutics also plans to study vofatamab in non-muscle invasive bladder cancer (NMIBC) – the FIERCE-23 trial. 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 (formerly B-701), is focused specifically on the fibroblast growth factor receptor 3 (FGFR3), a known driver of bladder and other cancers. For more information, please visit [www.rainierrx.com](http://www.rainierrx.com).

#### CONTACT

Robert Uhl  
Westwicke Partners, LLC  
[Robert.uhl@westwicke.com](mailto:Robert.uhl@westwicke.com)  
(858) 356-5932

#### CONTACT

Julie Rathbun  
Rathbun Communications  
(206) 769-9291  
[julie@rathbuncomm.com](mailto:julie@rathbuncomm.com)

###