



Rainier Therapeutics Announces Results from First Interim Analysis of the FIERCE-22 Trial of Vofatamab in Combination with Pembrolizumab in Patients with Metastatic Urothelial Cell Carcinoma (Bladder Cancer)

-Targeted antibody elicits responses in both FGFR3 wild-type and mutant/fusion patients-

-Favorable tolerability and safety profile and prolonged treatment duration-

- Results presented at America Society of Oncology (ASCO) Annual Meeting-

SAN LEANDRO, Calif., June 3, 2019—Rainier Therapeutics, Inc., a privately held clinical stage drug development company, today announced the first interim analysis results from its ongoing FIERCE-22 trial of vofatamab in patients with metastatic bladder cancer. Results were presented at the 2019 American Society for Clinical Oncology (ASCO) Annual Meeting.

FIERCE-22 is a Phase 1b/2 trial evaluating vofatamab, a FGFR3-targeted antibody, in combination with pembrolizumab, an immune checkpoint inhibitor, to determine safety, tolerability and preliminary 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.

The first interim analysis included data from 28 patients enrolled in the Phase 2 trial, which has a targeted total enrollment of approximately 74 patients. Results demonstrate that treatment with vofatamab and pembrolizumab was well tolerated. Five patients discontinued the study due to treatment emergent adverse events, none related to vofatamab. No dose reductions of vofatamab occurred.

An overall best response rate of 36 percent (8/22) was observed in patients with lesions evaluable by RECIST1.1 criteria, 7/22 (32%) were confirmed. Response rates were similar in both wild type and mutant fusion patients (33% and 43%, respectively). A majority of patients have received at least 8 cycles of therapy (1 cycle=21 days). Responses were notably increased in patients with luminal biology (6 of 9 patients). Paired biopsy data from this trial were recently presented at AACR “Frontiers in Bladder Cancer” ([see poster](#)) showing vofatamab induced immune and inflammatory changes in patients with responses.

“These data provide very encouraging clinical evidence of the effect of vofatamab, an antibody targeted against both wild type and mutated FGFR3, in combination with pembrolizumab. Earlier results from this biopsy-driven trial suggested these responses in the wild type FGFR3 patient cohort occurred in urothelial cancers of luminal subtype which typically have immunologically cold tumors. Biopsies obtained post lead-in treatment with vofatamab showed upregulation of genes associated with an inflammatory response,” said Arlene O. Siefker-Radtke, MD, The University of Texas MD Anderson Cancer Center. *“Further studies are needed to understand the impact of FGFR3 inhibition in urothelial cancer.”*

“The evidence demonstrated vofatamab provided similar clinical benefits in these patients regardless of FGFR3 tumor status. We plan to continue the enrollment of both wild-type and mutant/fusion patients, and to complete the ongoing Phase 2 trial,” said Esteban Abella, MD, Chief Medical Officer of Rainier Therapeutics.

In addition, results were presented from the Phase 2 portion of the FIERCE-21 trial evaluating vofatamab in combination with docetaxel and vofatamab as monotherapy in patients with locally advanced or metastatic bladder cancer with FGFR3 mutations or gene fusions who have relapsed after or are refractory to at least one prior line of chemotherapy. Data presented indicated vofatamab alone and in combination was well tolerated, with no observed long-term safety issues. Vofatamab monotherapy demonstrated single-agent activity in heavily pre-treated patients. In addition, a substantial portion of patients demonstrated long-term benefit from monotherapy and combination therapy.

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.

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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