bintrafusp alfa

INTR@PID CLINICAL TRIALS™

Investigating the effect of bintrafusp alfa, a bifunctional fusion protein designed for colocalized, simultaneous inhibition of the TGF-β and PD-L1 pathways, in multiple cancer types.

Bintrafusp alfa is under clinical investigation and has not been proven to be safe and effective. There is no guarantee that bintrafusp alfa will be approved in the sought-after indication by any health authority worldwide.

INTR@PID™ UROTHELIAL 152[1]

Now Enrolling

LOCALLY ADVANCED/METASTATIC UROTHELIAL CANCER | PHASE 1 | MONOTHERAPY

INTR@PID UROTHELIAL 152 (NCT04349280; GSK213152) is a phase 1b, single-arm study evaluating bintrafusp alfa for the treatment of patients with unresectable locally advanced or metastatic urothelial cancer that progressed or recurred after platinum-containing chemotherapy.*

GSK213152

Study design | Europe and the United States

Unresectable locally advanced or metastatic urothelial cancer* N=40 → **Bintrafusp alfa** 1200 mg IV Q2W†

Primary endpoint: ORR per investigator

Secondary endpoints: DOR, PFS, ORR per IRC, OS, safety, pharmacokinetics

Key inclusion criteria‡

- Participants must have histologically confirmed locally advanced or metastatic urothelial cancer that is unresectable and an ECOG PS of 0 or 1. Participants must have experienced disease progression or recurrence following platinum-containing chemotherapy* for urothelial cancer

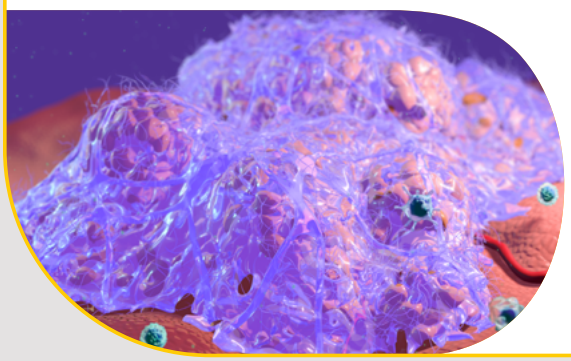
Key exclusion criteria‡

- Participants must not have received >2 lines of systemic therapy for metastatic disease§ or any prior therapy targeting T-cell costimulation, checkpoint pathways, or TGF-β. Participants must not have pneumonitis or history of noninfectious pneumonitis that required systemic immunosuppressive treatment

*Participants must have experienced disease progression or recurrence either following platinum-containing chemotherapy given for unresectable locally advanced or metastatic urothelial cancer or within 12 months from completion of neoadjuvant or adjuvant platinum-containing chemotherapy for localized muscle-invasive urothelial cancer. †Up to 2 years or until progressive disease, death, unacceptable toxicity, or study withdrawal. ‡For a full list of inclusion and exclusion criteria, please visit www.clinicaltrials.gov. §If the most recent therapy was not a platinum-based regimen, the participant must have progressed on or after that therapy.

DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; ORR, overall response rate; OS, overall survival; PD-L1, programmed death ligand 1; PFS, progression-free survival; Q2W, every 2 weeks; TGF-β, transforming growth factor β.

Reference: 1. ClinicalTrials.gov. A study to evaluate the efficacy and safety of bintrafusp alfa (M7824) monotherapy in metastatic or locally advanced urothelial cancer. Accessed March 11, 2021. https://clinicaltrials.gov/ct2/show/NCT04349280. GSK Identifier: 213152.



Are your patients eligible?

For more information, visit
www.intrapidclinicaltrials.com
www.clinicaltrials.gov

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