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.

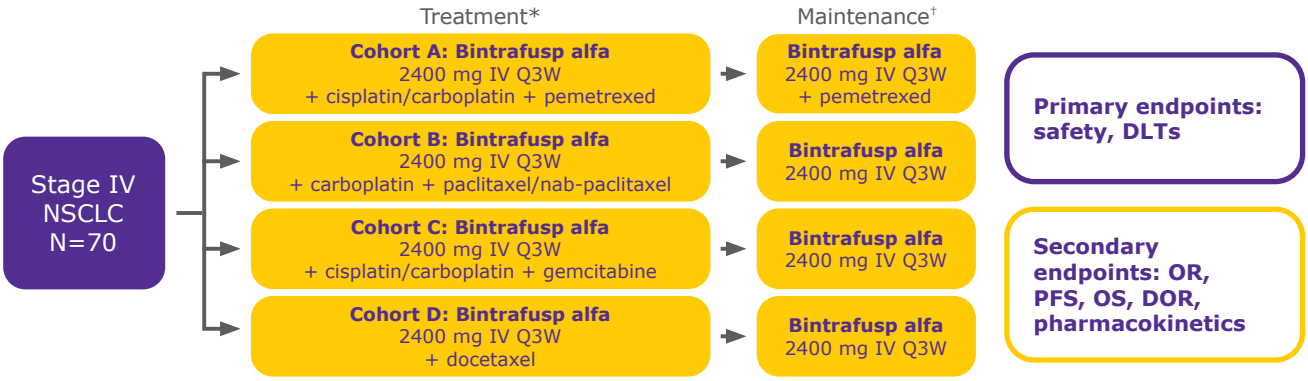
Bintrafusp alfa is under clinical investigation and has not been proven to be safe and effective. There is no guarantee that bintrafusp alfa will be approved in the sought-after indication by any health authority worldwide.

INTR@PID™ LUNG 024[1] Active, Not Recruiting

STAGE IV NSCLC | PHASE 1/2 | COMBINATION THERAPY

INTR@PID LUNG 024 (NCT03840915) is a phase 1b/2, open-label study evaluating bintrafusp alfa with chemotherapy for the treatment of patients with stage IV non-small cell lung cancer (NSCLC).

Study design | Europe and the United States



Key inclusion criteria‡

- Participants must have histologically confirmed stage IV NSCLC and an ECOG PS of 0 or 1
- Participants in cohorts A to C must not have received prior systemic therapy for stage IV NSCLC
- Participants in cohort D must have experienced disease progression on previous treatment with PD-(L)1 inhibitors in combination with platinum-containing chemotherapy§

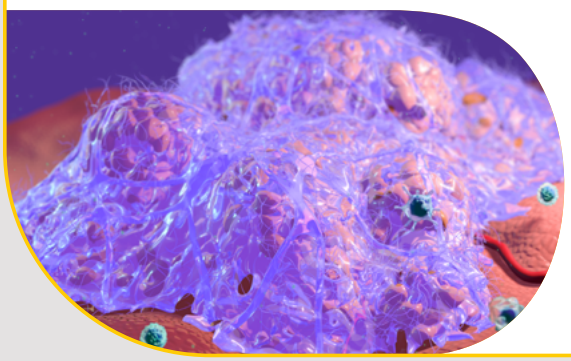
Key exclusion criteria‡

- Participants must not have mixed small cell lung cancer with NSCLC histology or, if targeted therapy is locally approved, tumors that contain an *EGFR*-sensitizing (activating) mutation, *ROS1* rearrangement, or *BRAF* V600E mutation or are *ALK* positive
- Participants in cohorts A, B, and C must not have received prior therapy targeting T-cell costimulation or checkpoint pathways

*Treatment is given for 4 cycles, each lasting 21 days. †Maintenance is given for up to 31 cycles. ‡For a full list of inclusion and exclusion criteria, please visit www.clinicaltrials.gov. §Therapy must be completed at least 28 days prior to first study intervention.

ALK, anaplastic lymphoma kinase; BRAF, B-Raf proto-oncogene, serine/threonine kinase; DLT, dose-limiting toxicity; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; EGFR, epidermal growth factor receptor; IV, intravenous; NSCLC, non-small cell lung cancer; OR, objective response; OS, overall survival; PD-L1, programmed death ligand 1; PFS, progression-free survival; Q3W, every 3 weeks; ROS1, ROS proto-oncogene 1, receptor tyrosine kinase; TGF-β, transforming growth factor β.

Reference: 1. ClinicalTrials.gov. M7824 in combination with chemotherapy in stage IV non-small cell lung cancer (NSCLC). Accessed March 11, 2021. https://clinicaltrials.gov/ct2/show/NCT03840915.



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

INTR@PID is a trademark of Merck KGaA, Darmstadt, Germany. Bintrafusp alfa is being developed in a strategic global alliance between Merck KGaA, Darmstadt, Germany, and GSK.
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