Article details

Title of article
Bempegaldesleukin plus nivolumab in untreated, unresectable or metastatic melanoma: Phase III, PIVOT IO 001 study design

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Trial registration number
NCT03635983

Key eligibility criteria

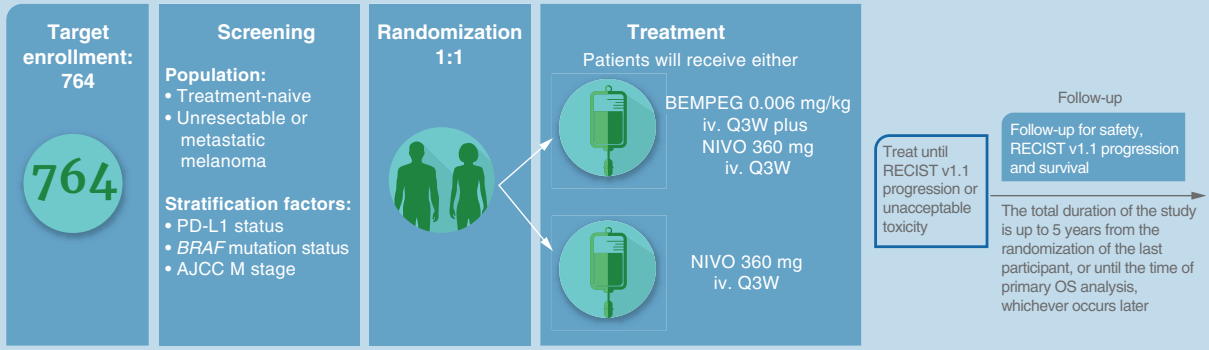
- ≥12 — 12 years of age
- Histologically confirmed unresectable or metastatic melanoma
- Treatment-naive, with the exception of prior adjuvant and/or neoadjuvant treatment
- 0 or 1 — ECOG PS 0 or 1 in adult patients; Lansky performance score of 80% (patients 12-17 years of age)
- No active brain metastases or leptomeningeal metastases; uveal melanoma; or an active, known or suspected autoimmune disease

Primary objectives/rationale

Primary objective
Compare ORR, PFS and OS of combination BEMPEG plus NIVO versus NIVO alone in patients with previously untreated, unresectable or metastatic melanoma

Secondary key objectives
- Compare safety and tolerability of combination BEMPEG plus NIVO with that of NIVO monotherapy
- Compare additional efficacy measures of combination BEMPEG plus NIVO with that of NIVO monotherapy
- Assess association between PD-L1 tumor expression on tumor cells (1% or <1%/indeterminate) and efficacy measures, including PFS, ORR and OS

Study design and treatment



Outcome measures/endpoints

Primary endpoints
ORR by BICR, PFS by BICR, OS

Secondary endpoints
CBR, DoR, TTR; ORR, PFS, OS in PD-L1 biomarker population; investigator-assessed ORR and PFS

Exploratory endpoints
PK and immunogenicity parameters, PRO

Glossary

AJCC: American Joint Committee on Cancer; BEMPEG: Bempegaldesleukin; BICR: Blinded independent central review; CBR: Clinical benefit rate; DoR: Duration of response; ECOG PS: Eastern Cooperative Oncology Group performance status; IL-2: Interleukin-2; iv.: Intravenous; LDH: Lactate dehydrogenase; M: Metastatic; NIVO: Nivolumab; ORR: Objective response rate; OS: Overall survival; PD-L1; Programmed death ligand 1; PFS; Progression-free survival; PK: Pharmacokinetic; PRO: Patient-reported outcomes; Q3W: Every 3 weeks; RECIST v1.1: Response Evaluation Criteria In Solid Tumors; TTR: Time to response