Background

VEB is targeting to inhibit c-MET signaling, which plays an important role in tumorigenesis. c-MET activation results in tumor proliferation, angiogenesis, invasion, and metastasis. c-MET amplification and/or mutations have been found in various solid tumors, including NSCLC, of which MET-exon14 skipping mutations are observed in 4-7% of patients, leading to tumor resistance to TKIs like Gefitinib and Erlotinib. Vebreltinib (bozitinib, APL-101, PLB-1001, CBT-101) is a potent highly selective c-MET inhibitor.

Methods

Patients with NSCLC harboring METex14, both previously treated and treatment-naïve, showed objective response rates (ORR) of 44.0%~89.7%, respectively. (Figure 2.) The incidence of TRAEs was 77.0% (87/113), with 31.0% (35/113) experiencing TRAEs of grade 3 or above. The most common grade ≥3 TRAEs were neutropenia (4.5%), anemia (4.5%), fatigue (2.7%), and diarrhea (2.7%). No grade 5 TRAE occurred.

Results

The incidence of TRAEs was 77.0% (87/113), with 31.0% (35/113) experiencing TRAEs of grade 3 or above. The most common grade ≥3 TRAEs were neutropenia (4.5%), anemia (4.5%), fatigue (2.7%), and diarrhea (2.7%). No grade 5 TRAE occurred.

Conclusions

KUNPENG is an international multi-center, parallel single-arm, open-label Phase II clinical trial to assess the efficacy and safety profile of Vebreltinib in Chinese patients with MET-exon14 skipping mutations. The primary endpoint is ORR assessed by blinded independent review committee (BIRC) per RECIST v1.1. Secondary endpoints included investigator-assessed (INV) ORR, disease control rate (DCR), duration of response (DoR), time to progression (TTP), and overall survival (OS). The trial was conducted in 20 sites across China, including Shanghai Chest Hospital, Shanghai Jiao Tong University, Shanghai, China; Jilin Cancer Hospital, Jilin, China; Yantai Cancer Hospital, Yantai, China; Anhui Cancer Hospital, Anhui, China; Jiangsu Cancer Hospital, Nanjing, China; and 16 additional medical institutions across China. The trial was sponsored by China Medical Device Innovation Group (CMDIG) and the Chinese Anti-Cancer Association (CCCA) with support from the China National Medical Health Technology Research Fund (CMHTRF) project. This study is registered with the Chinese Clinical Trial Registry (ChiCTR-IPR-22029124). The trial is sponsored by Bioventec Biotech Co., Ltd (BVT).

Corresponding author

Ye Liang Xu

Reference