**Background**

Sunvozertinib (DZD9008) is a rationally designed, irreversible EGFR inhibitor targeting EGFR mutations with wild-type EGFR selectivity. Primary analysis of two ongoing pivotal studies (WU-KONG1 [NCT03974022] and WU-KONG6 [NCT05712902 & CTR20211009]) have demonstrated promising efficacy and safety of sunvozertinib in advanced NSCLC patients with EGFR Exon20 insertion mutations (exon20ins) in ≥ 2nd line settings. Herein, we reported preliminary results of sunvozertinib in treatment naïve EGFR exon20ins NSCLC.

**Methods**

NSCLC patients with EGFR exon20ins who did not receive prior systemic anti-cancer therapy were enrolled into two ongoing studies: WU-KONG1, a multinational phase I/II study; and WU-KONG15 (NCT05559645), a phase II investigator-initiated study. Sunvozertinib was administered orally at 200 mg or 300 mg QD until discontinuation criteria were met. Efficacy analysis included patients with at least one post-treatment tumor assessment according to RECIST 1.1 by independent review committee (IRC).

**Results**

As of February 21, 2023, a total of 28 patients were included in the efficacy analysis (200 mg, n = 19; 300 mg, n = 9). Median age was 67 years, and 75.0% (21/28) were female. Baseline ECOG PS was 0 or 1. Majority of patients (96.4%, 27/28) had metastatic diseases at study entry, with 21.4% (6/28) having > 3 metastatic sites and 32.1% (9/28) having baseline brain metastasis (BM). The most frequent mutation subtypes included 769_ASV (39.3%, 11/28), 770_SVD (10.7%, 3/28) and others. By IRC, 20 patients achieved tumor response, with a best objective response rate (ORR) of 71.4% (200 mg, 68.4%; 300 mg, 77.8%). Median duration of response has not been reached. Safety findings were consistent with results of previous sunvozertinib studies. The most common TEAEs included diarrhea, CPK increase, and skin rash. Majority of the AEs were of CTCAE grade 1 or 2, and clinically manageable.

**Conclusions**

In the 1st line setting, sunvozertinib as monotherapy demonstrated promising anti-tumor efficacy and acceptable safety profile in NSCLC patients with EGFR exon20ins. A phase III, multinational, randomized study (WU-KONG28, NCT05668988) is ongoing to compare sunvozertinib to chemotherapy as 1st line treatment for EGFR exon20ins NSCLC.

**Clinical trial identification**

NCT03974022, NCT05559645.
Legal entity responsible for the study
Dizal Pharmaceutical.

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Disclosure
All authors have declared no conflicts of interest.

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