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Updated results from a phase I/II study of gocatamig for small cell lung cancer (SCLC) and other neuroendocrine cancers

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Background

Delta-like ligand 3 (DLL3) is highly expressed in neuroendocrine carcinomas (NEC) including SCLC. Gocatamig (MK-6070; HPN328) is a DLL3-targeting T-cell engager. Early results of the phase I/II open-label study 6070-001 (NCT04471727) showed that gocatamig monotherapy at target doses had encouraging antitumor activity with manageable safety in participants (pts) with ES-SCLC, neuroendocrine prostate cancer, and other NEC. Here, we report updated results of pts with ES-SCLC and other NEC treated in gocatamig monotherapy cohorts of 12 mg or 24 mg.

Methods

Pts with relapsed/refractory, metastatic ES-SCLC or DLL3-expressing NEC received gocatamig at target doses of 12 mg (after initial 1-mg priming dose) QW or Q2W or 24 mg (after initial 1-mg priming dose + 12-mg step-up dose) QW or Q2W. Primary objectives are safety, tolerability, and pharmacokinetics. Secondary objectives are efficacy as assessed by overall response rate per RECIST 1.1 and immunogenicity.

Results

As of data cutoff on 28FEB2025, 73 pts with ES-SCLC (n=39, 53%) or NEC (n=34, 47%) were enrolled in the 12 mg QW (n=11), 12 mg Q2W (n=25), 24 mg QW (n=12), and 24 mg Q2W (n=25) cohorts. 69 (95%) pts had prior platinum-based chemotherapy. Treatment is ongoing for 22 (30%) pts. No pts had a dose-limiting toxicity. 21 pts (29%) had grade 3-5 treatment-related AEs, including 1 (1%) who died of pneumonitis (as previously reported). 40 (55%) pts developed cytokine release syndrome (39 with grade 1-2; 1 with grade 4). 5 (7%) pts had immune effector cell-associated neurotoxicity syndrome (all grade 1-2; all recovered). The confirmed objective response rate (ORR) was 44% (95% CI 32%-56%), including 2 complete responses; disease control rate (DCR) was 66% (95% CI 54%-76%). Among 33 pts who received at least one 24-mg target dose, confirmed ORR was 55% (95% CI 36%-72%) and DCR was 79% (95% CI 61%-91%).

Conclusions

Gocatamig monotherapy at target doses of 12 mg and 24 mg QW or Q2W continues to show promising antitumor activity in pts with relapsed/refractory ES-SCLC and other NEC. There were no new or unexpected safety findings as of this data cutoff. Investigations of gocatamig at other monotherapy dosing schedules and in combination with other cancer therapies are ongoing.

Clinical trial identification

NCT04471727.

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Legal entity responsible for the study

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Disclosure

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