Background Enhancement of antitumor immunity through inhibition of the checkpoint PD-1 receptor has been effective in the treatment of many malignancies. AMG 404 is a monoclonal antibody (mAb) targeting PD-1. This phase 1, open-label, multicenter first-in-human study (NCT03853109) will evaluate the safety, tolerability, pharmacokinetics, and efficacy of AMG 404 monotherapy in adult patients with advanced solid tumors.

Methods The primary study endpoint is dose-limiting toxicity (DLT) and safety; key secondary endpoints include pharmacokinetic parameters, objective response rate (assessed Q8W), duration of response, and progression-free survival. Key inclusion criteria include histologically or cytologically proven malignancies; prior anti–PD-(L)1 or other checkpoint inhibitors were not allowed. Five dose-finding cohorts, including 2 expansion cohorts, ranged from 3–20 patients each. AMG 404 was given until disease progression, unacceptable toxicity, or other reasons for study discontinuation. Safety, PK, PD and efficacy data will be collected and monitored throughout the study. PD effects will be assessed by measuring modulation of tumor immune cells and TGFb pathway within the tumor microenvironment.

Results N/A

Conclusions An enrollment update will be provided.

Trial Registration NCT04291079

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