Phase 1 study of DCC-3014, an oral inhibitor of CSF1R, to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics in patients with advanced solid tumors, including diffuse-type tenosynovial giant cell tumor

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INTRODUCTION

Colony stimulating factor 1 (CSF1) is a growth factor that stimulates tumor-associated macrophages (TAMs) through interaction with the CSF1R receptor. DCC-3014 is a selective, oral inhibitor of CSF1R, which has been shown to cause shrinkage of melanoma and soft tissue sarcoma xenografts in mice.

METHODS

This phase 1 trial is a modified 3+3 dose escalation study with a starting dose of 20 mg once a week for cycle 1 and 20 mg twice a week for cycles 2–7. Eligible patients included both chemotherapy-naïve and chemotherapy-experienced patients with advanced solid tumors, including diffuse-type tenosynovial giant cell tumor (TGCT).

RESULTS

In total, 43 patients were enrolled and treated, of which 97.2% patients discontinued study treatment (TEAEs) regardless of relatedness were recorded. The most frequent diagnoses (≥10%) were colorectal cancer, pancreatic cancer; and ovarian cancer and most grade ≥3 events were related to fatigue (12.5%) and anemia (6.9%). DCC-3014 has ≥100-fold selectivity for CSF1R relative to closely-related other kinases.

CONCLUSIONS

Dose escalation evaluation is ongoing to determine the recommended phase 2 dose for patients with advanced solid tumors and diffuse-type TGCT. Results from DCC-3014 were generally good and tolerable in patients with advanced solid tumors and diffuse-type TGCT. The preliminary results from initial phase 1 dose patients will be presented at the American Society for Clinical Oncology/Hematology Annual Meeting (Abstract #3241734, November 13–15, 2019, Tokyo, Japan).