ADAPT-001 IN ADVANCED SOFT-TISSUE SARCOMA (BETA PRIME): A MULTICENTER, OPEN-LABEL, PHASE 1 CLINICAL TRIAL

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Background The prognosis for adult patients with advanced soft tissue sarcomas (STS) is poor and new therapies that improve overall survival are needed. Chemotherapy and targeted therapies offer short-lived disease palliation and control, and the role of checkpoint inhibitors in STS is unclear. We assessed AdAPT-001, an immunotherapy that delivers a TGF-β trap, which binds to and neutralizes the immunosuppressive and profibrotic cytokine, TGF-β, for safety and activity in an ‘all comers, all failed’ population, the majority of which were patients with advanced soft-tissue sarcoma.

Methods In this multicenter, open-label, phase 1 study, we enrolled patients with superficially accessible, relapsed/refractory solid tumors. AdAPT-001 was administered by intratumoral injection at 1x10^{12} viral particles (VPs) once every 2 weeks until progression. Efficacy was evaluated by response (RECIST 1.1). This trial is registered with ClinicalTrials.gov, number NCT04673942.

Results AdAPT-001 was well tolerated with local inflammation, fever, and fatigue as the main side effects. No dose limiting or autoimmune toxicities, grade 4 toxicities, or treatment-related serious adverse events (SAEs) were seen. Out of 25 enrolled patients, 12 had STS. The sarcoma types were leiomyosarcoma (n = 4), chondrosarcoma (n = 1), Mullerian carcinomas (n = 1), chordoma (n = 6). 2 of these STS patients, a chordoma and a leiomyosarcoma, demonstrated durable stable disease (SD) of ≥ 6 months and 1 of the patients with chordoma that was rechallenged with a checkpoint inhibitor after AdAPT-001 objectively responded. Another of the chordoma patients was successfully downstaged and underwent surgical resection. In the leiomyosarcoma patient with durable SD, the injected lesion shrank by 72.2% and evidence of abscopal activity in the non-injected lesions was observed.

Conclusions AdAPT-001 showed encouraging activity in patients with STS. Enrollment to the Phase 2 portion of the study in combination with a checkpoint inhibitor is ongoing.

Trial Registration ClinicalTrials.gov Identifier: NCT04673942

Ethics Approval This study obtained WIRB ethics approval, under Protocol approval #20203029, and participants gave informed consent before taking part

Consent Written informed consent was obtained from the patient for publication of this abstract and any accompanying images. A copy of the written consent is available for review by the Editor of this journal

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