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Abstract CT206: ICAM-1 directed chimeric antigen receptor (CAR) T cells (AIC100) in patients with advanced thyroid cancers: Clinical and translational data from the phase 1 dose escalation study FREE

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Abstract

Background:

Patients with newly diagnosed or relapsed/refractory (R/R) anaplastic thyroid cancer (ATC) and R/R poorly differentiated thyroid cancer (PDTC) have limited treatment options and an overall poor prognosis. ICAM-1, a cell surface glycoprotein also known as CD54 overexpressed in a variety of cancers including thyroid cancers, is known to play a key role in tumorigenesis. AIC100 is a 3rd generation ICAM-1 directed CAR T-cell product engineered with affinity-tuned technology to selectively bind and kill tumor cells to improve safety. Another unique feature for AIC100 is co-expression of somatostatin receptor 2 to allow CAR T-cell monitoring with DOTATATE PET scan. We present here updated results from phase 1 dose-escalation clinical trial NCT04420754.

Methods:

The multicenter study was designed to explore 3 dose levels (DLs) of AIC100 at 1x 10^7, 1 x 10^8, and 5 x 10^8, respectively. An additional DL4 (7.5 x 10^8) was explored since no dose-limiting toxicities (DLTs) were observed previously. Key eligibility included adult patients (≥18 years) with newly diagnosed or R/R ATC or R/R PDTC, who had measurable disease, and with ECOG status 0-2. AIC100 was infused intravenously 48 hours after completing lymphodepletion (Fludarabine/Cyclophosphamide x 3 days). Primary objectives included safety assessment/DLTs within 30 days of AIC100 infusion and to determine the recommended phase 2 dose (RP2D).

Results:

As of 12-Dec-2024, 24 patients were enrolled and 15 (8 ATC; 7 PDTC) with a median age of 59 (range, 47-69) years were infused with AIC100 at 4 DLs. Patients were predominantly male (N = 11), with a median of 2 (range, 1-4) prior lines of systemic therapies. No DLTs were observed in the originally planned DLs 1-3. Two patients in the exploratory DL4 developed grade 3 pneumonitis. 10 (66.7%) patients developed grade 1/2 CRS. No ICANS or other SAEs related to AIC100 occurred at DLs 1-3. 11 patients were evaluable for efficacy in DLs 1-3 at day 42 after infusion; responses were assessed per study site. No responses were observed in DL1. For evaluable patients in DL 2 and 3 (n = 9), the objective response rate (ORR) and disease control rate (DCR, defined as ORR + stable disease (SD)) were 22% and 56%, respectively. For ATC patients at DL2-DL3 (N=4), the ORR was 50% [1 each with partial response (PR) and complete response (CR) in DL 2 and 3, respectively]. In PDTC at DL2-DL3 (N=5), DCR was 60%. AIC100 expansion was observed in all patients. Additional transaltional data will be presented at the meeting. Based on safety and efficacy, 5 x 108 (DL3) was declared as RP2D.

Conclusions:

AIC100, a first-in-human ICAM-1 directed CAR T-cell therapy, demonstrated an acceptable safety profile in patients with relapsed/refractory ATC and PDTCs. The observed durable responses in DL2 and DL3 are encouraging and provide a proof of concept for potential role of AIC100 in aggressive thyroid cancer patients and other advanced cancers. DL3 is determined as the RP2D. Cohort expansion at RP2D will be initiated in Q2 2025 in 2 indications; ATC and PDTC.

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