

MEDIA RELEASE

ADC Therapeutics Presents Updated Data from Clinical Trials of Novel Antibody Drug Conjugates

ADCT-402 (loncastuximab tesirine) continues to demonstrate acceptable safety profile and anti-tumor activity in patients with relapsed or refractory diffuse large B-cell lymphoma; data from 183-patient study supports continued evaluation in ongoing pivotal Phase II trial

ADCT-301 (camidanlumab tesirine) achieves 86.5 percent overall response rate in heavily pretreated patients with Hodgkin lymphoma; data from 113-patient study supports further investigation in pivotal Phase II trial

Data presented at 60th American Society of Hematology (ASH) Annual Meeting

Lausanne, Switzerland, December 5, 2018 – ADC Therapeutics, an oncology drug discovery and development company that specializes in the development of proprietary antibody drug conjugates (ADCs), presented updated data from ongoing Phase I clinical trials of ADCT-402 (loncastuximab tesirine) and ADCT-301 (camidanlumab tesirine) in multiple subtypes of lymphoma during oral and poster presentations at the 60th American Society of Hematology (ASH) Annual Meeting in San Diego.

“We are encouraged by the safety profiles and strong single-agent anti-tumor activity we continue to observe in the 183-patient first-in-human clinical trial of ADCT-402 and the 113-patient trial of ADCT-301,” said Jay Feingold, MD, PhD, Chief Medical Officer and Senior Vice President of Clinical Development at ADC Therapeutics. “The updated ADCT-402 data presented at ASH support its continued evaluation in our ongoing pivotal clinical trial in patients with relapsed or refractory diffuse large B-cell lymphoma. For ADCT-301, we now have the dosing data to support further investigation in a planned pivotal Phase II trial in patients with relapsed or refractory Hodgkin lymphoma, which we look forward to initiating in 2019.”

ADCT-402 Oral and Poster Presentations at ASH

Interim Results from the First-in-Human Clinical Trial of ADCT-402 (Loncastuximab Tesirine), a Novel Pyrrolobenzodiazepine-Based Antibody Drug Conjugate, in Relapsed/Refractory Diffuse Large B-Cell Lymphoma (Abstract 398)

Oral presentation: John Radford, MD, FRCP, Manchester Academic Health Centre, The University of Manchester and The Christie NHS Foundation Trust, Manchester, UK

Data were presented from a subpopulation of 139 evaluable patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who had failed or were intolerant to established therapies. The patients had a median age of 63 years and had received a median of three previous therapies. Patients received doses of ADCT-402 ranging from 15 to 200 µg/kg every three weeks. The median number of cycles received was two and the median duration of treatment was 43 days.

Key findings from the oral presentation include:

- ADCT-402 has demonstrated manageable toxicity in patients with R/R DLBCL
- At doses ≥ 120 µg/kg, the overall response rate (ORR) was 43.3% (55/127 patients with DLBCL), comprising 23.6% complete responses and 19.7% partial responses

- At doses ≥ 120 $\mu\text{g}/\text{kg}$, after a median follow up of 5.5 months, median duration of response (DoR) was not reached in patients achieving a complete response

A pivotal Phase II study is currently enrolling patients with R/R DLBCL to evaluate the efficacy and safety of ADCT-402 at dose 150 $\mu\text{g}/\text{kg}$ every three weeks for two cycles followed by dose 75 $\mu\text{g}/\text{kg}$ every three weeks ([NCT03589469](#)).

Safety and Efficacy of ADCT-402 (Loncastuximab Tesirine), a Novel Antibody Drug Conjugate, in Relapsed/Refractory Follicular Lymphoma and Mantle Cell Lymphoma: Interim Results from the Phase I First-in-Human Study (Abstract 2874)

Poster presentation: Paolo Caimi, MD, Case Western Reserve University, University Hospitals Cleveland Medical Center, Cleveland, OH

Data were presented from a subgroup of 29 patients, including 14 patients with follicular lymphoma (FL) and 15 patients with mantle cell lymphoma (MCL). The median age of the FL patients was 60.5 years and the median age of the MCL patients was 64 years. Patients received infusions every three weeks at doses ranging from 15 to 200 $\mu\text{g}/\text{kg}$. Patients with FL and MCL received a median of three and two cycles of ADCT-402, respectively.

Key findings from the poster presentation include:

- ADCT-402 has demonstrated manageable toxicity in patients with R/R FL and R/R MCL
- In patients with FL, ORR was 78.6% (11/14) and median DoR was not reached after a median follow-up time of 11.6 months
- In patients with MCL, ORR was 46.7% (7/15) and median DoR was not reached after a median follow-up time of 8.7 months

ADCT-301 Oral and Poster Presentations at ASH

Phase I Study of ADCT-301 (Camidanlumab Tesirine), a Novel Pyrrolobenzodiazepine-Based Antibody Drug Conjugate, in Relapsed/Refractory Classical Hodgkin Lymphoma (Abstract 928)

Oral presentation: Mehdi Hamadani, MD, Division of Hematology and Oncology, Medical College of Wisconsin, Milwaukee, WI

Data were presented from 67 evaluable, heavily pretreated patients with relapsed/refractory (R/R) classical Hodgkin Lymphoma (HL) who had failed or were intolerant to any established therapy known to provide clinical benefit. The median age of the patients was 38 years and they had received a median of five prior therapies. Patients were treated with doses of ADCT-301 ranging from 5 to 300 $\mu\text{g}/\text{kg}$. They completed a median of three cycles of treatment and median treatment duration was 43 days.

Key findings from the oral presentation include:

- ADCT-301 has demonstrated manageable toxicity in patients with R/R HL
- The most common Grade 3 or 4 treatment-emergent adverse events occurring in at least 5 percent of patients, regardless of attribution, at the 45 $\mu\text{g}/\text{kg}$ dose in 37 patients were: maculopapular rash (18.9 percent), elevated gamma-glutamyltransferase (8.1 percent), elevated alanine aminotransferase (8.1 percent), elevated aspartate aminotransferase (2.7 percent), anemia (8.1 percent), Guillain-Barré syndrome / radiculopathy (8.1 percent) and increased lipase (8.1 percent)

- In patients with R/R HL, therapy with ADCT-301 achieved an overall response rate (ORR) of 86.5% in the 37 patients in the 45 µg/kg dose group who had received and failed prior brentuximab vedotin and most of whom had failed prior checkpoint inhibitor treatment
- These data support further investigation of the 45 µg/kg dose of ADCT-301 in a planned pivotal Phase II study anticipated to commence in 2019

ADCT-301 (Camidanlumab Tesirine), a Novel Pyrrolobenzodiazepine-Based CD25-Targeting Antibody Drug Conjugate, in a Phase I Study of Relapsed/Refractory Non-Hodgkin Lymphoma Shows Activity in T-Cell Lymphoma (Abstract 1658)

Poster presentation: Graham P. Collins, MB, BS, DPhil, Oxford University Hospitals, NHS Trust, Oxford, UK

Data were presented from 44 patients with R/R non-Hodgkin lymphoma (NHL) with a median age of 65.5 years who had received a median number of four previous systemic therapies (including prior stem cell transplant). Of those, 22 patients were in a T-cell lymphoma subgroup. Patients were treated with doses of ADCT-301 ranging from 3 to 150 µg/kg and received a median number of two cycles. Median treatment duration was 22 days.

Key findings from the poster presentation include:

- ADCT-301 demonstrated an acceptable safety profile during dose-escalation
- Overall, in patients with R/R NHL, therapy with ADCT-301 achieved an ORR of 31.7% (13/41) at doses ≥ 60 µg/kg
- In the R/R T-cell lymphoma subgroup, therapy with ADCT-301 achieved an ORR of 53.8% (7/13) in the 60 and 80 µg/kg dose groups
- These data support further investigation of ADCT-301 in T-cell lymphoma

About ADCT-402

ADCT-402 (loncastuximab tesirine) is an antibody drug conjugate (ADC) composed of a humanized monoclonal antibody that binds to human CD19, conjugated through a linker to a pyrrolobenzodiazepine (PBD) dimer toxin. Once bound to a CD19-expressing cell, ADCT-402 is internalized into the cell where enzymes release the PBD-based warhead. CD19 is a clinically validated target for the treatment of B-cell malignancies. The PBD-based warhead has the ability to form highly cytotoxic DNA interstrand cross-links, blocking cell division and resulting in cell death. ADCT-402 is being evaluated in a pivotal Phase II clinical trial in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) ([NCT03589469](#)). The U.S. Food and Drug Administration granted orphan drug designation to ADCT-402 for the treatment of DLBCL and mantle cell lymphoma.

About ADCT-301

ADCT-301 (camidanlumab tesirine) is an antibody drug conjugate (ADC) composed of a monoclonal antibody that binds to CD25 (HuMax[®]-TAC, licensed from Genmab A/S), conjugated to the pyrrolobenzodiazepine (PBD) dimer payload tesirine. Once bound to a CD25-expressing cell, ADCT-301 is internalized into the cell where enzymes release the PBD-based warhead. The intra-tumor release of its PBD warhead may cause bystander killing of neighboring tumor cells. In addition, the PBD warhead will trigger immunogenic cell death, which in turn will strengthen the immune response against tumor cells. ADCT-301 is being evaluated in ongoing Phase Ia/Ib clinical trials in patients with relapsed or refractory Hodgkin lymphoma and non-Hodgkin lymphoma ([NCT02432235](#)), as well as a Phase Ib clinical trial in solid tumors ([NCT03621982](#)).

About ADC Therapeutics

ADC Therapeutics SA is an oncology drug discovery and development company that specializes in the development of proprietary antibody drug conjugates (ADCs) targeting major hematological malignancies and solid tumors. The Company's ADCs are highly targeted biopharmaceutical drugs that combine monoclonal antibodies specific to surface antigens present on particular tumor cells with a novel class of highly potent pyrrolobenzodiazepine (PBD)-based warheads via a chemical linker. The Company has multiple PBD-based ADCs in ongoing clinical trials in the USA and Europe, and a deep pipeline of other preclinical ADCs in development. ADC Therapeutics has world-class partners, including AstraZeneca and its global biologics research and development arm, MedImmune. The Company is based in Lausanne (Biopôle), Switzerland and has operations in London, San Francisco and New Jersey. For more information, visit www.adctherapeutics.com.

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