

ADC Therapeutics Announces First Patient Dosed in Phase I Clinical Trial of ADCT-402 (loncastuximab tesirine) and IMFINZI® (durvalumab) in Multiple Types of Advanced Non-Hodgkin Lymphoma

Combination of antibody drug conjugate and checkpoint inhibitor being evaluated for treatment of relapsed or refractory diffuse large B-cell, mantle cell and follicular lymphomas

Lausanne, Switzerland, February 13, 2019 – ADC Therapeutics, an oncology drug discovery and development company that specializes in the development of proprietary antibody drug conjugates (ADCs), today announced that the first patient has been dosed in a Phase I clinical trial evaluating the safety, tolerability, pharmacokinetics and anti-tumor activity of ADCT-402 (loncastuximab tesirine) plus AstraZeneca’s IMFINZI® (durvalumab) in patients with advanced diffuse large B-cell lymphoma (DLBCL), mantle cell lymphoma (MCL) or follicular lymphoma (FL).

ADCT-402, an ADC designed to target and kill CD19-expressing malignant B-cells, is also being evaluated in an ongoing pivotal Phase II clinical trial in patients with relapsed or refractory (R/R) DLBCL. Durvalumab is a human monoclonal antibody that binds to PD-L1 and blocks the interaction of PD-L1 with PD-1 and CD80, countering the tumor’s immune-evading tactics and releasing the inhibition of immune responses.

Jay Feingold, MD, PhD, Chief Medical Officer and Senior Vice President of Clinical Development at ADC Therapeutics, said, “Data from our 183-patient first-in-human clinical trial of ADCT-402, which were presented at the 60th American Society of Hematology (ASH) Annual Meeting, demonstrated its acceptable safety profile and promising anti-tumor activity as a single agent in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. We are now excited to explore the possible impact of ADCT-402 plus durvalumab in patient populations that would greatly benefit from new treatment options.”

Craig Moskowitz, MD, Physician in Chief for the Cancer Service Line of the Sylvester Comprehensive Cancer Center, Professor of Medicine in the Miller School of Medicine at University of Miami Health System, and an investigator for the trial, said, “While the majority of patients with non-Hodgkin lymphoma typically respond to initial treatment, many patients relapse and face a poor prognosis. I look forward to evaluating this combination therapy of ADCT-402 and a PD-L1 blocker to determine its safety and potential anti-tumor activity in patients with relapsed or refractory diffuse large B-cell lymphoma, mantle cell lymphoma and follicular lymphoma who have failed or are intolerant to established therapies, or who don’t have other available treatment options.”

The open-label, single-arm trial will include a dose-escalation part, followed by a dose-expansion part. The dose-expansion part will consist of up to three expansion cohorts – one for DLBCL, one for MCL and one for FL – to obtain additional safety and preliminary anti-tumor activity information at the maximum tolerated dose. Approximately 75 patients will be enrolled in the trial. For more information, please visit www.clinicaltrials.gov (identifier NCT03685344).

ADCT-402 Interim First-in-Human Data

Updated data from the ongoing 183-patient Phase I clinical trial of ADCT-402 were presented at the 60th American Society of Hematology (ASH) Annual Meeting. In a subpopulation of 139 evaluable patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) who had failed or were intolerant to established therapies, ADCT-402 demonstrated manageable toxicity. At doses >120 µg/kg, the overall response rate (ORR) was 43.3 percent (55/127 patients with DLBCL), comprising 23.6 percent complete responses and 19.7 percent partial responses. In a subgroup of 15 patients with R/R mantle cell lymphoma (MCL) and 14 patients with R/R follicular lymphoma (FL), ADCT-402 demonstrated manageable toxicity. In MCL patients, ORR was 46.7 percent (7/15) and median duration of response (DoR) was not reached after a median follow-up time of 8.7 months. In FL patients, ORR was 78.6 percent (11/14) and median DoR was not reached after a median follow-up time of 11.6 months.

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 (R/R) diffuse large B-cell lymphoma (DLBCL) ([NCT03589469](https://clinicaltrials.gov/ct2/show/study/NCT03589469)) and a Phase I clinical trial in combination with IMFINZI® (durvalumab) in patients with R/R DLBCL, mantle cell lymphoma or follicular lymphoma ([NCT03685344](https://clinicaltrials.gov/ct2/show/study/NCT03685344)). The U.S. Food and Drug Administration granted orphan drug designation to ADCT-402 for the treatment of DLBCL and MCL.

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 five PBD-based ADCs in ongoing clinical trials, ranging from first in human to pivotal Phase II, 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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