



## **ADC Therapeutics Doses First Patient in Pivotal Clinical Trial of ADCT-402 in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma**

*Phase II trial evaluating efficacy and safety of CD19-targeting antibody drug conjugate intended to support submission of Biologics License Application*

*Top-line data expected in third quarter of 2019*

**Lausanne, Switzerland, August 7, 2018** – 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 its Phase II clinical trial intended to support the submission of Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). The clinical trial is evaluating the efficacy and safety of ADCT-402 (loncastuximab tesirine) in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

At the 2017 American Society of Hematology (ASH) Annual Meeting, the Company presented interim Phase I data on ADCT-402 in 138 evaluable, heavily pre-treated lymphoma patients who had failed, or were intolerant to, any established therapy known to provide clinical benefit, with a median of three prior therapies. At the time, for the 49 response-evaluable patients in Part 1 of the study (dose escalation) with DLBCL who received ADCT-402 at doses greater than or equal to 120 µg/kg, the overall response rate (ORR) was 55 percent (27/49), with 18 patients achieving a complete response (37 percent) and 9 patients achieving a partial response (18 percent).

The primary endpoint of the Phase II, multi-center, open-label, single-arm trial is the ORR in patients treated with ADCT-402, as confirmed by central review. Secondary endpoints include assessments of duration of response, complete response rate, relapse-free survival, progression-free survival and overall survival, as well as safety, pharmacokinetics and health-related quality of life. The trial will enroll approximately 140 patients with relapsed or refractory DLBCL at multiple centers in the USA and Europe.

“We are pleased to have dosed the first patient in our registrational Phase II clinical trial evaluating ADCT-402 in patients with DLBCL who have relapsed and have refractory disease after two or more multi-agent treatment regimens. Our Phase I clinical trial of ADCT-402 in non-Hodgkin lymphoma showed significant activity in patients with DLBCL and an acceptable safety profile,” said Jay Feingold, MD, PhD, Chief Medical Officer and Senior Vice President of Clinical Development at ADC Therapeutics. “Unfortunately, there is no effective treatment for patients with multiple relapsed and refractory DLBCL, so we are excited about the potential to improve outcomes in these patients with ADCT-402 in a single-arm trial. We anticipate reporting results from the Phase II trial in the third quarter of 2019 and are hopeful that the data will support our submission of a BLA to the FDA.”

Alex Spira, MD, PhD, FACP, Director of Virginia Cancer Specialists Research Institute and Clinical Assistant Professor of Oncology at Johns Hopkins School of Medicine, added, “Patients with DLBCL who have relapsed or are refractory after second-line chemotherapy face a very poor prognosis. There is a

significant unmet need for an effective new treatment option for this patient population, and we believe ADCT-402 has the potential to help impact patient outcomes in this disease.”

For more information about the Phase II clinical trial, please visit [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (identifier NCT03589469).

ADC Therapeutics also plans to initiate multiple combination studies with ADCT-402 in the fourth quarter of 2018.

### **About Diffuse Large B-Cell Lymphoma (DLBCL)**

Non-Hodgkin lymphoma (NHL) is the seventh most common type of cancer in the U.S., and accounted for an estimated 4.3 percent of new cancer cases in 2017.<sup>1</sup> Diffuse large B-cell lymphoma (DLBCL) accounts for nearly one-third (32.5 percent) of NHL.<sup>2</sup> The most common initial treatment for patients with DLBCL is chemo-immunotherapy. Response to initial treatment is high, but more than half of patients do not have long-term disease control.<sup>3</sup> The current standard of care for relapsed DLBCL is additional chemotherapy, which can be followed by stem cell transplantation (SCT). The prognosis for relapsed patients is poor, especially for those with chemotherapy-refractory disease with a short interval between remission and relapse or those who relapse after high-dose therapy and SCT. There is a significant unmet need for an effective treatment for patients with relapsed or refractory DLBCL.

### **About ADCT-402**

ADCT-402 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. Preliminary data from a Phase I clinical trial in relapsed or refractory B-cell non-Hodgkin lymphoma demonstrate ADCT-402 has significant activity in patients with diffuse large B-cell lymphoma (DLBCL). ADCT-402 is also being evaluated in an ongoing Phase I clinical trial in patients with relapsed or refractory B-cell lineage acute lymphoblastic leukemia (B-ALL). The U.S. Food and Drug Administration has granted orphan drug designation to ADCT-402 for the treatment of DLBCL and mantle cell lymphoma.

### **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](http://www.adctherapeutics.com).

- 1 Siegel et al., 2017
- 2 Al-Hamadani et al., 2015
- 3 Gisselbrecht et al., 2010

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