

## **ADC Therapeutics Announces Oral Presentation of Interim Efficacy Data from Pivotal Phase 2 Clinical Trial of ADCT-402 (Loncastuximab Tesirine) in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma at 61<sup>st</sup> ASH Annual Meeting**

*Data on 52 patients in the 145-patient clinical trial highlight ADCT-402 (loncastuximab tesirine) continues to demonstrate anti-tumor activity and manageable toxicity in heavily pretreated patients*

*Biologics License Application submission planned for 2H 2020*

**Lausanne, Switzerland, December 9, 2019** – ADC Therapeutics SA, a clinical-stage oncology-focused biotechnology company pioneering the development of highly potent antibody drug conjugates (ADCs) for patients suffering from hematological malignancies and solid tumors, today announced interim efficacy and safety data on 52 patients in the ongoing pivotal 145-patient Phase 2 clinical trial of ADCT-402 (loncastuximab tesirine), demonstrating its potential as a single agent for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL). Carmelo Carlo-Stella, MD, Section Chief, Lymphoid Malignancies and Cancer Therapeutics, Humanitas Cancer Center, Humanitas University, and an investigator for the trial, presented the data today during an oral session at the 61<sup>st</sup> American Society of Hematology (ASH) Annual Meeting in Orlando, FL.

“The data continue to reinforce the significant single-agent, anti-tumor activity and manageable toxicity profile of ADCT-402 in patients with relapsed or refractory DLBCL, even in difficult-to-treat patients. Based on the encouraging data seen with this agent today, I believe ADCT-402 has the potential to be an integral part of the treatment paradigm for patients with DLBCL,” said Dr. Carlo-Stella. “DLBCL is a common and aggressive cancer that can be challenging to treat due to its frequent resistance to available treatments. Patients who have failed established therapies are limited in their treatment options, creating a critical need for a new therapy.”

“We are pleased that the data from our oral presentation at ASH support the potential of ADCT-402 to be an important treatment option for heavily pretreated patients with DLBCL,” said Jay Feingold, MD, PhD, Senior Vice President, Chief Medical Officer and Head of Oncology Clinical Development at ADC Therapeutics. “We look forward to completing the pivotal Phase 2 clinical trial and submitting a Biologics License Application to the U.S. Food and Drug Administration for accelerated approval of ADCT-402 for the treatment of relapsed or refractory DLBCL patients who have failed two or more treatment regimens in the second half of 2020.”

The oral presentation included data, as of October 4, 2019, on 52 patients from the pivotal Phase 2 clinical trial of ADCT-402 (loncastuximab tesirine) who were a median age of 63 years (range 24-84) and had received a median of three previous therapies. Key data include:

- The overall response rate (ORR) was 46.2% (24/52 patients), comprising 19.2% complete responses and 26.9% partial responses. Comparably, the ORR in the Phase 1 trial of ADCT-402 (loncastuximab tesirine) at the initial dose used in Phase 2 was 41.4% (29/70 patients), comprising 21.4% complete responses and 20% partial responses. The primary endpoint in the pivotal Phase 2 clinical trial is ORR.

- For complete responders, the median duration of response has not yet been reached. For complete and partial responders, the preliminary median duration of response is 5.7 months.
- Stable disease was attained in 19.2% of patients.
- ADCT-402 (loncastuximab tesirine) demonstrated manageable toxicity in patients with relapsed or refractory DLBCL. The most common grade  $\geq 3$  treatment-emergent adverse events in at least 5% of patients were: gamma-glutamyltransferase increased (25%), hypokalemia (5.8%), platelet count decreased (21.2%), neutrophil count decreased (32.7%) and anemia (11.5%).

The ongoing single-arm, multi-center, open-label Phase 2 clinical trial is evaluating the safety, efficacy and pharmacokinetics of ADCT-402 (loncastuximab tesirine) as a monotherapy in patients with relapsed or refractory DLBCL. Patients received 30-minute intravenous infusions of ADCT-402 (loncastuximab tesirine) once every three weeks at a dose of 150  $\mu\text{g}/\text{kg}$  for the first two cycles, followed by 75  $\mu\text{g}/\text{kg}$  for subsequent cycles for up to one year or until disease progression, unacceptable toxicity, or other discontinuation criteria, whichever occurred first.

The presentation will be available on the [Posters and Presentations](#) page and a video of the investor event ADC Therapeutics hosted on Sunday, December 8 will be available on the [Videos](#) page of the Company's website: <https://adcttherapeutics.com/>.

### **About ADCT-402 (loncastuximab tesirine)**

ADCT-402 (loncastuximab tesirine) is an antibody drug conjugate (ADC) composed of a humanized monoclonal antibody directed against human CD19 and conjugated through a linker to a pyrrolobenzodiazepine (PBD) dimer cytotoxin. Once bound to a CD19-expressing cell, ADCT-402 (loncastuximab tesirine) is designed to be internalized by the cell, following which the warhead is released. The warhead is designed to bind irreversibly to DNA to create highly potent interstrand cross-links that block DNA strand separation, thus disrupting essential DNA metabolic processes such as replication and ultimately resulting in cell death. CD19 is a clinically validated target for the treatment of B-cell malignancies. ADCT-402 (loncastuximab tesirine) is being evaluated in a pivotal Phase 2 clinical trial in patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) ([NCT03589469](#)), a Phase 1b trial in combination with ibrutinib in patients with R/R DLBCL or mantle cell lymphoma (MCL) ([NCT03684694](#)) and a Phase 1b trial in combination with durvalumab in patients with R/R DLBCL, MCL or follicular lymphoma ([NCT03685344](#)). The U.S. Food and Drug Administration granted orphan drug designation to ADCT-402 (loncastuximab tesirine) for the treatment of R/R DLBCL and MCL.

### **About ADC Therapeutics**

ADC Therapeutics SA is a clinical-stage oncology-focused biotechnology company pioneering the development of highly potent and targeted antibody drug conjugates (ADCs) for patients suffering from hematological malignancies and solid tumors. The Company develops ADCs by applying its decades of experience in this field and using next-generation pyrrolobenzodiazepine (PBD) technology to which ADC Therapeutics has proprietary rights for its targets. Strategic target selection for PBD-based ADCs and substantial investment in early clinical development have enabled ADC Therapeutics to build a deep clinical and research pipeline of therapies for the treatment of hematological and solid tumor cancers with significant unmet need. The Company has multiple PBD-based ADCs in ongoing clinical trials, ranging from first in human to pivotal Phase 2 clinical trials, in the USA and Europe, and numerous preclinical ADCs in development. ADCT-402 (loncastuximab tesirine), the Company's lead product candidate, has demonstrated significant single-agent clinical activity across a broad population of patients with relapsed or refractory diffuse large B-cell

lymphoma, including difficult-to-treat patients. ADCT-301 (camidanlumab tesirine), the Company's second lead product candidate, has demonstrated clinical activity in heavily pretreated patients with Hodgkin lymphoma and, based on its mechanism of action, also has potential for the treatment of solid tumors. ADC Therapeutics is based in Lausanne (Biopôle), Switzerland and has operations in London, the San Francisco Bay Area and New Jersey. For more information, please visit <https://adcttherapeutics.com/>.

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