

ADC Therapeutics Doses First Patients in Pivotal Phase 2 Clinical Trial of ADCT-301 in Patients with Relapsed or Refractory Hodgkin Lymphoma

Trial to support anticipated BLA submission in 1H 2022

Lausanne, Switzerland, October 17, 2019 – ADC Therapeutics SA, 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, today announced that the first patients have been dosed in a 100-patient pivotal Phase 2 clinical trial evaluating the efficacy and safety of ADCT-301 (camidanlumab tesirine) in patients with relapsed or refractory Hodgkin lymphoma (HL). The trial is intended to support the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA).

Alex Herrera, MD, Assistant Professor, Department of Hematology/Hematopoietic Cell Transplantation at City of Hope Medical Center and an investigator for the trial, said, “Approximately 15 to 25 percent of the 16,500 patients diagnosed with HL each year in the U.S. and Europe have relapsed or refractory HL. While advances have been made in the treatment of HL, a significant unmet medical need remains in the relapsed or refractory HL patient population, especially patients who have progressed following treatment with other novel agents. I believe ADCT-301 has the potential to fill this important medical need.”

The primary objective of the Phase 2, multi-center, open-label, single-arm clinical trial is to evaluate the efficacy of ADCT-301 in patients with relapsed or refractory HL, measured by overall response rate based on the 2014 Lugano Classification Criteria. Patients with pathologically confirmed relapsed or refractory HL who have failed three prior lines of therapy, including brentuximab vedotin and a checkpoint inhibitor approved for HL such as nivolumab or pembrolizumab, are eligible for enrollment in the clinical trial.

Jay Feingold, MD, PhD, Senior Vice President, Chief Medical Officer and Head of Oncology Clinical Development at ADC Therapeutics, said, “In our large Phase 1 clinical trial, ADCT-301 demonstrated an overall response rate of 86.5 percent in patients with HL at the dose we are using in the pivotal Phase 2 clinical trial, with more than half of those being complete responses. We look forward to continuing the evaluation of ADCT-301 in this pivotal Phase 2 trial and, if successful, submitting a BLA to the FDA for accelerated approval of ADCT-301 for the treatment of relapsed or refractory HL in patients who have failed or were intolerant to brentuximab vedotin and a checkpoint inhibitor approved for HL.”

For more information about the pivotal Phase 2 clinical trial of ADCT-301, please visit <https://clinicaltrials.gov/> (identifier NCT04052997).

About ADCT-301

ADCT-301 (camidanlumab tesirine) is an antibody drug conjugate (ADC) composed of a human 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 tumor cell, ADCT-301 is internalized into the cell where enzymes release the PBD-based warhead killing the cell with an immunogenic cell death. The intra-tumoral release of its PBD warhead may also cause bystander killing of neighboring tumor cells. The ADC also depletes CD25-positive regulatory T cells in the tumor environment. All of these properties of ADCT-301 may enhance immune-mediated anti-

tumor activity. ADCT-301 is being evaluated in a pivotal Phase 2 clinical trial in patients with relapsed or refractory Hodgkin lymphoma ([NCT04052997](#)), as well as ongoing Phase 1a/1b clinical trials in patients with relapsed or refractory Hodgkin lymphoma and non-Hodgkin lymphoma ([NCT02432235](#)) and a Phase 1b clinical trial in solid tumors ([NCT03621982](#)).

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, 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, 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://adctherapeutics.com/>.

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