ADC Therapeutics Announces Positive Results from Pivotal Phase 2 Clinical Trial of Single Agent Loncastuximab Tesirine (ADCT-402) in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Exceeded primary endpoint target with 45.5% overall response rate, including 20% complete response rate, in 145-patient trial

On track for Biologics License Application (BLA) submission in 3Q 2020

Lausanne, Switzerland, January 9, 2020 – ADC Therapeutics SA, a clinical-stage oncology-focused biotechnology company pioneering the development and commercialization of highly potent antibody drug conjugates (ADCs) for patients suffering from hematological malignancies and solid tumors, today announced positive results from the pivotal 145-patient Phase 2 clinical trial of loncastuximab tesirine (ADCT-402) for the treatment of relapsed or refractory diffuse large B-cell lymphoma (DLBCL).

To date, loncastuximab tesirine has achieved an overall response rate (ORR) of 45.5% (66/145 patients), including 20% complete responses and 25.5% partial responses, across a broad population of relapsed or refractory DLBCL patients, even those who are difficult to treat. Comparably, the ORR in the 183-patient Phase 1 clinical trial of loncastuximab tesirine at the initial dose used in Phase 2 was 41.4% (29/70 patients), including 21.4% complete responses and 20% partial responses. Loncastuximab tesirine has demonstrated manageable toxicity in patients with relapsed or refractory DLBCL. The most common grade ≥3 treatment-emergent adverse events in the Phase 2 clinical trial were neutropenia, thrombocytopenia and increased gamma-glutamyltransferase.

Jay Feingold, MD, PhD, Senior Vice President and Chief Medical Officer at ADC Therapeutics, said, "These data exceeded our primary endpoint target and reinforce the significant single-agent anti-tumor activity and manageable toxicity profile of loncastuximab tesirine in patients with relapsed or refractory DLBCL who have failed established therapies. Loncastuximab tesirine has demonstrated its potential to fill a critical unmet need for a new therapy and become a key part of the treatment paradigm for all heavily pretreated patients with DLBCL. We plan to present final data from the pivotal Phase 2 clinical trial at a future scientific meeting."

Chris Martin, Chief Executive Officer of ADC Therapeutics, said, "We look forward to submitting a BLA to the U.S. Food and Drug Administration for accelerated approval of loncastuximab tesirine for the treatment of relapsed or refractory DLBCL patients who have failed two or more treatment regimens later this year and we are building our commercial organization in anticipation of a launch in the second quarter of 2021."

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

About Loncastuximab Tesirine

Loncastuximab tesirine (formerly ADCT-402) 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, 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. 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 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 and commercialization 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. Loncastuximab tesirine (formerly 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, mantle cell lymphoma and follicular 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 targeting CD25 / regulatory T cells, 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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