ADC Therapeutics Presents Interim Phase I Data from its Novel Antibody-Drug Conjugate ADCT-402

Presented at ASH Annual Meeting

Lausanne, Switzerland, December 11, 2017 – ADC Therapeutics (ADCT), an oncology drug discovery and development company that specializes in the development of proprietary Antibody Drug Conjugates (ADCs) targeting major cancers, today announced clinical data from two ongoing Phase I clinical trials evaluating ADCT-402 (loncastuximab tesirine or “Lonca-T”) in important subtypes of lymphoma and leukemia. The data were presented at the 59th American Society of Hematology (ASH) Annual Meeting in Atlanta, USA.

1. Interim results of a Phase I open label, single agent, dose-escalating study of ADCT-402 evaluating tolerability, safety, pharmacokinetics and efficacy in patients with relapsed or refractory B-cell Non-Hodgkin Lymphoma

Dr. Brad Kahl, M.D., Professor for Medical Oncology at the Washington University School of Medicine in St. Louis, said: “A significant number of Diffuse Large B-Cell Lymphoma (DLBCL) patients become relapsed or refractory to existing therapies and have no approved treatment options. As a result, we are very excited about the 60 percent overall response rate (ORR) of Lonca-T at 120 µg/kg or higher, including a 35 percent complete response rate, in this difficult-to-treat patient population. Although the data are still maturing, we are also very encouraged by a median duration of response so far of approximately 5 months. Overall, these results justify the rapid development of the Lonca-T clinical program to address this unmet need.”

Data were presented from 138 evaluable, heavily pre-treated, patients who had failed, or were intolerant to, any established therapy known to provide clinical benefit. The median age of patients was 64 years, and they had a median of 3 prior therapies. Data were reported from Part 1 and Part 2 of the Phase I study as of November 1, 2017. In Part 1 (dose escalation), 88 patients were treated at dose ranges from 15-200 µg/kg. In Part 2 (dose expansion), 50 patients were treated in two cohorts at either 120 or 150 µg/kg.

Key findings presented at an oral presentation included:

- For the 68 response-evaluable patients in Part 1 at doses greater than or equal to 120 µg/kg, the ORR was 60 percent (41/68) with 24 patients achieving a complete response (35 percent) and 17 patients achieving a partial response (25 percent).

- For the 49 response-evaluable patients in Part 1 with Diffuse Large B-Cell Lymphoma at doses greater than or equal to 120 µg/kg the ORR was 55 percent (27/49) with 18 patients achieving a complete response (37 percent) and 9 patients achieving a partial response (18 percent).
• ADCT-402 has been reasonably well tolerated.

• The most common treatment-emergent adverse events of any grade occurring in at least 20 percent of patients in Part 1 and Part 2 were fatigue (44 percent), nausea (28 percent), elevated gamma-glutamyltransferase (27 percent), anemia (25 percent), and peripheral edema (25 percent). The most common Grade 3 or 4 adverse events occurring in at least 5 percent of patients, regardless of attribution, were reduced neutrophil count (15 percent), elevated gamma-glutamyltransferase (15 percent), anemia (12 percent), reduced platelet count (12 percent), neutropenia (12 percent), thrombocytopenia (9 percent), elevated blood alkaline phosphatase (5 percent), fatigue (5 percent), reduced lymphocyte count (5 percent), and reduced white blood cell count (5 percent).

• Dose expansion in Part 2 of the Phase I study may continue using the recommended doses from Part 1 (i.e. 120 or 150 µg/kg).

2. **Elucidating Exposure-Response (Safety and Efficacy) of ADCT-402 (Loncastuximab Tesirine), a Novel Pyrrolobenzodiazepine-containing Antibody Drug Conjugate, for Recommended Phase 2 Dose Determination in Patients with Relapsed or Refractory Non-Hodgkin Lymphoma**

This poster presented pharmacokinetic (PK) data elucidating the relationship between drug exposure and response in terms of safety and efficacy.

3. **Interim results of a Phase I open label, single agent, dose-escalating study of ADCT-402 evaluating tolerability, safety, pharmacokinetics and efficacy in patients with relapsed or refractory B-cell acute lymphoblastic leukemia**

Data were presented from 29 evaluable, heavily pre-treated, patients who had failed, or were intolerant to, any established therapy known to provide clinical benefit. The median age of patients was 50 years, and they had a median of 2 prior therapies. Data were reported from Part 1 of the Phase I study as of November 1, 2017. In Part 1 (dose escalation), patients were treated at dose ranges from 15-150 µg/kg every three weeks, or at a dose of 50 µg/kg once weekly.

Key findings presented at a poster session included:

• Four patients achieved a complete bone marrow response.

• ADCT-402 has been reasonably well tolerated.

• The most common treatment-emergent adverse events of any grade occurring in at least 20 percent of patients were nausea (31 percent), fatigue (24 percent), febrile neutropenia (24 percent), and headache (24 percent). The most common Grade 3 or 4 adverse events occurring in at least 10 percent of patients, regardless of attribution, were febrile neutropenia (24 percent), reduced neutrophil count (14 percent), bacteremia (10 percent), abdominal pain (10 percent), lung infection (10 percent), and sepsis (10 percent).
Dose escalation will continue using weekly dosing.

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. ADCT-402 is being evaluated in two ongoing Phase I clinical trials in patients with relapsed or refractory B-cell lineage non-Hodgkin lymphoma and relapsed or refractory B-cell lineage acute lymphoblastic leukemia. (www.adct-402.com)

About ADC Therapeutics
ADC Therapeutics SA (ADCT) is an oncology drug discovery and development company that specializes in the development of proprietary antibody drug conjugates (ADCs) targeting major types of 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 four PBD-based antibody drug conjugates in six ongoing Phase Ia and Ib clinical trials in the USA and in Europe, and a deep pipeline of other preclinical ADCs in development. ADCT enjoys strong relationships with 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. (www.adctherapeutics.com).

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