ADC Therapeutics Doses First Patient in a Phase I Clinical Trial of ADCT-402 for Patients with B-cell lineage Acute Lymphoblastic Leukemia

- Trial to provide data on safety, tolerability, dosing and efficacy
- ADCT-402 also being investigated in a Phase I clinical trial in B-cell lineage non-Hodgkin lymphoma

Lausanne, Switzerland, April 12, 2016 – ADC Therapeutics (ADCT), the Swiss-based oncology drug development company, announces that the first patient has been dosed in a Phase I clinical trial to evaluate its antibody drug conjugate (ADC) ADCT-402 in patients with relapsed/refractory B-cell lineage acute lymphoblastic leukemia (B-ALL). ADCT-402 combines a humanized monoclonal antibody targeting CD19 with a highly potent pyrrolobenzodiazepine (PBD)-based warhead.

The two stage, open-label Phase Ia / Ib clinical trial is designed to evaluate the tolerability, safety and pharmacokinetics of ADCT-402, and is also expected to provide preliminary efficacy data in patients with relapsed or refractory B-ALL. The first stage (Phase Ia) is a dose escalation study which is planned to recruit up to 30 patients over ten clinical sites across the US and EU and will seek to determine the recommended dose of ADCT-402. The second stage (Phase Ib), which is planned to begin once an appropriate dose is identified, has the objective to confirm the safety, preliminary efficacy and tolerability profile at the selected dose.

Dr. Jay Feingold, Chief Medical Officer and Senior Vice President of Clinical Development at ADCT, said: “This is our second Phase I clinical trial with ADCT-402. Our ADCT-402 Phase Ia study in B-cell lineage relapsed/refractory non-Hodgkin lymphoma began earlier last month. Dosing the first patient in this trial in a different indication is an important milestone for us and could pave the way for a better treatment regimen for patients with B-ALL. The trial is expected to give us data on safety, tolerability and dosing.”

In preclinical in vitro studies ADCT-402 was shown to bind to and selectively inhibit the growth of a panel of CD19-expressing human cell lines, while its cytotoxicity was strongly reduced in CD19-negative cell lines, illustrating the specificity of ADCT-402. In preclinical in vivo studies ADCT-402 induced complete responses in xenograft models following single low dose administration.

Dr. Nitin Jain, Principal Investigator for the study and Assistant Professor of the Leukemia Department of the MD Anderson Cancer Center, said: “While advances have been made in treating patients with B-ALL, a common type of ALL, there are few options for relapsed/refractory patients and their prognosis remains poor. Having seen the effects of other ADCs in ALL, we are hopeful that ADCT-402 will show positive activity in patients with B-ALL.”

ADC Therapeutics now has four ongoing Phase Ia/Ib clinical trials for ADCT-402 and one other product candidate ADCT-301 in sub-types of lymphoma and leukemia and is actively recruiting patients for all four trials.

About Acute Lymphoblastic Leukemia
Leukemia is a cancer of the bone marrow and blood and is classified according to cell type and rate of growth into four main groups: acute lymphoblastic (ALL), chronic lymphocytic (CLL), acute myeloid (AML) and chronic myeloid (CML). Acute lymphoblastic leukemia is a rapidly progressing cancer of the white blood cells, which accounts for approximately 20% of adult leukemia and for more than 80% of childhood leukemia cases. ALL is responsible for more than one quarter of all cancer in children. It develops rapidly, within a few days or a few weeks of the first symptoms. Relapsed and refractory ALL remains difficult to treat, with minimal improvement in
outcomes seen despite advances in upfront therapy and improved survival for de novo ALL. According to cancer statistics, 6,250 new cases of ALL have been diagnosed in 2015 and 1,450 deaths occurred from ALL in the U.S.¹

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)-based warhead. 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 certain CD19-expressing 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 Ia/Ib clinical trials in patients with relapsed or refractory B-cell lineage non-Hodgkin lymphoma and relapsed or refractory B-cell lineage acute lymphoblastic leukemia.

About ADC Therapeutics
ADC Therapeutics SA (ADCT) is an oncology drug 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. Its lead programs, ADCT301 and ADCT402, are in four Phase I clinical trials for certain subtypes of lymphoma and leukemia. ADCT has strong relationships with world class partners, including Astrazeneca/MedImmune, Genmab, and Cancer Research Technology. The Company is based in Lausanne, Switzerland.

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¹ Cancer statistics from the National Cancer Institute, U.S.