ADC Therapeutics Receives FDA Clearance to Begin Clinical Studies for its Second Novel Antibody Conjugate ADCT-402 against Lymphomas and Leukemia

4 December 2015

Lausanne, Switzerland, London, UK and Murray Hill, New Jersey, US – 4 December 2015 — ADC Therapeutics SA (ADCT or the “Company”), the oncology drug development company focused on Antibody Drug Conjugates (ADCs), today announced that it has received clearance from the US Food and Drug Administration (FDA) to begin clinical trials with ADCT-402, a novel antibody drug conjugate targeting CD19, a cell-surface antigen, which is over-expressed in many patients with B-cell non-Hodgkin Lymphoma (NHL) and B-cell Acute Lymphoblastic Leukemia (ALL). ADCT plans to initiate Phase I clinical trials in both NHL and ALL.

ADCT-402 combines a humanized monoclonal antibody targeting CD19 with a pyrrolobenzodiazepine (PBD) warhead. In preclinical in vivo models, ADCT-402 exhibited strong dose-dependent anti-tumor activity against CD19-positive leukemic and lymphoma cell lines at low single doses, and it outperformed other CD19 targeted ADCs currently in clinical development.

The first of the Phase I clinical trials for patients with B-cell NHL will commence at eight leading oncology centres in the USA and two centres in the United Kingdom. The initial study will evaluate the tolerability, safety, pharmacokinetics and antitumor activity of ADCT-402 in patients with relapsed or refractory B-cell NHL. Subject to study results, ADCT intends to rapidly expand the numbers of patients in the trial and expand the number of participating clinical centres.

Dr. Owen O’Connor, Professor of Medicine and Experimental Therapeutics, and the Director of the Center for Lymphoid Malignancies, and Co-Program Director of the Lymphoid Development and Malignancy Program in the Herbert Irving Comprehensive Cancer Center at Columbia University Medical Center, is the Principal Investigator for this Phase I study.

Dr. O’Connor said: “There is significant unmet medical need for patients with relapsed or refractory disease in B-cell NHL. An ADC targeting CD19 with a potent PBD warhead, is a sensible approach in this difficult to treat population. We are delighted to be working with ADC Therapeutics to bring this potential treatment to patients.”

The second study, a Phase 1 trial for patients with relapsed or refractory B-cell ALL will commence simultaneously at 10 centres in the USA and EU to evaluate the tolerability, safety, pharmacokinetics and anti-tumor activity of ADCT-402 in this patient population. Dr. Nitin Jain, Assistant Professor in the Leukemia Department at MD Anderson Cancer Center in Houston, Texas, is the Principal Investigator for
this Phase 1 study said: “We have made significant strides treating patients with B-Cell ALL but we are still seeking new treatment modalities to improve the prognosis for patients. We are excited to working with ADC Therapeutics on this program.”

Dr. Jay M. Feingold, Senior Vice President and Chief Medical Officer at ADC Therapeutics said: “This is the second ADC we have advanced into clinical development in the past eight months. Preclinical data suggests that ADCT-402 may have significant activity against B-cell NHL and ALL and we are pleased to progress our pipeline by beginning these two clinical studies and, hopefully, to bring significant benefit to patients with these diseases.”

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About ADC Therapeutics (www.adctherapeutics.com)

ADC Therapeutics SA (ADCT) is an oncology drug development company that specializes in the development of proprietary ADCs targeting major solid and hematological cancers. The Company’s ADCs are highly targeted drug constructs which combine monoclonal antibodies specific to surface antigens present on particular tumor cells with a novel class of highly potent pyrrolobenzodiazepine (PBD)-based warheads. The Company has access to warhead and linker chemistries via agreements with Spirogen (a wholly-owned subsidiary of AstraZeneca's MedImmune). It is progressing eleven ADC programs, two of these under a joint development agreement with MedImmune. Its lead program, ADCT-301 for lymphoma and leukemia entered Phase I in 2015.

ADC Therapeutics has its head office in Lausanne, Switzerland and through subsidiaries has its R&D laboratories in London, UK, its clinical development team in New Jersey, USA, and its manufacturing team based in San Francisco, USA. With its industry leading management team and board of directors, ADC Therapeutics is a leader in the development of PBD-based ADCs.

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