ADC Therapeutics Doses First Patient in a Phase I Clinical Trial of ADCT-502 in Patients with Advanced Solid Tumors with HER2 Expression

- Trial to provide data on safety, tolerability, pharmacokinetics and efficacy
- ADCT-502 represents ADC Therapeutic’s fourth ADC program in clinical trials

Lausanne, Switzerland, May 19, 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 that the first patient has been dosed in a Phase I clinical trial to evaluate its antibody drug conjugate (ADC) ADCT-502 in patients with advanced solid tumors with HER2 expression.

The two stage, open-label Phase Ia / Ib clinical trial will evaluate the safety, tolerability, pharmacokinetics and efficacy of ADCT-502 in patients with advanced solid tumors with HER2 expression. The first stage (Phase Ia) is a dose escalation phase which will recruit patients at leading clinical centres across the US and EU, and will seek to determine the recommended dose of ADCT-502. The second consecutive stage (Phase Ib), has the objective to confirm the safety and efficacy profile for ADCT-502 in expanded patient cohorts in multiple potential cancer indications.

ADCT-502 combines a humanized monoclonal antibody targeting the protein HER2 with a pyrrolobenzodiazepine (PBD) warhead. The HER2 surface protein is expressed at high or low levels in a variety of different tumor types, including breast cancer, gastric and gastroesophageal cancers. In preclinical studies, ADCT-502 exhibited strong dose-dependent anti-tumor activity at low single doses against both low and high HER2 expressing tumors. Given the substantial prevalence of HER2 expression in a range of cancers, ADCT-502 will be evaluated in patients with non-small cell lung cancer (NSCLC), bladder, biliary tract, and ovarian cancer, for which HER2 targeted therapies are not yet approved.

Dr. Jay Feingold, Chief Medical Officer and Senior Vice President of Clinical Development at ADCT said: “This is the fourth ADC we have put into the clinic in just over two years. Dosing the first patient in this trial with ADCT-502 is an important milestone for us and could pave the way for a better treatment regimen for patients. The trial will give us vital data on safety, tolerability and dosing. Our preclinical studies suggest ADCT-502 may provide significant clinical benefit for patients suffering from a variety of tumor types which are known to express HER2 in a significant proportion of patients. We are exploring this potential in lung, bladder and biliary tract cancers further within this study as well as in the more established indications of breast and gastric cancer.”

Dr. Kyriakos Papadopoulos, Senior Clinical Investigator of START and one of the investigators of the study said: “Tremendous advances have been made in the treatment of HER2 expressing cancers, particularly gastroesophageal and breast cancers, in the past 20 years. However, a significant portion of this patient population still fail to respond or relapse with currently available therapies. Having seen the effects of other pyrrolobenzodiazepine ADCs in various tumour types in recent years, we eagerly anticipate the results of this study.”

ADC Therapeutics has four PBD-based antibody drug conjugates in six ongoing Phase I clinical trials in the USA and in Europe.
**About ADCT-502**

ADCT-502 is an investigational antibody drug conjugate (ADC) composed of the humanized monoclonal antibody trastuzumab directed against the human epidermal growth factor receptor 2 (HER2). The antibody is site-specifically conjugated to the PBD-based linker-drug tesirine. Once bound to the HER2 receptor on the cell surface, ADCT-502 is internalized into the cell where enzymes release the PBD-based warhead. HER2 is a well-established, clinically validated target expressed in a wide variety of solid tumors, including breast, gastric, esophageal, bladder and lung cancer. ADCT-502 is being evaluated in an ongoing Phase I clinical trial in patients with advanced solid tumors with HER2 expression.

**About ADC Therapeutics**

Founded in 2012, 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 three lead programs, ADCT-301, ADCT-402, and ADCT-502 are in five Phase I clinical trials in the USA and in Europe. 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, Switzerland and has operations in London, San Francisco and New Jersey (www.adctherapeutics.com).

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