Institutional Conflict of Interest Management and Monitoring Plan: ADC Therapeutics SA

The University of Texas MD Anderson (MD Anderson) and ADC Therapeutics SA (ADCT) are parties to a Clinical Trial Agreement (Agreement) pursuant to which MD Anderson and ADCT are collaborating on the conduct of a clinical study titled "A Phase I/II Study to Evaluate the Safety and Anti-tumor Activity of ADCT 602 targeting CD22 in Patients with Relapsed or Refractory B-cell Acute Lymphoblastic Leukemia" (Study).

Under the Agreement, ADCT will pay MD Anderson for research staff compensation, laboratory costs, and IND related costs. MD Anderson will also receive milestone payments and annual royalty payments on net sales of ADCT-602 or a onetime lump-sum payment that will substitute remaining royalty payments. ADCT will supply their drug, ADCT-602, at no cost to MD Anderson for the Study. Because of MD Anderson's financial interest in the success of ADCT-602, MD Anderson has a conflict of interest in regards to its conduct of the Study and any future research using ADCT-602 (Studies).

Because MD Anderson is committed to the protection of human subjects and the effective management of its financial conflict of interest in relation to its research activities, MD Anderson has implemented an Institutional Conflict of Interest Management and Monitoring Plan (Plan) to manage and monitor the conflict of interest with respect to MD Anderson's conduct of the Studies. The Plan has been approved by the President of MD Anderson and the Executive Vice Chancellor for Health Affairs for The University of Texas System (EVC) and has been implemented by MD Anderson.

The Plan requirements include:

- Oversight of Studies by an external Institutional Review Board (External IRB), including reporting to the External IRB by MD Anderson's Investigational New Drug (IND) Office when applicable,
- Disclosure of MD Anderson's financial interest to participants of Studies, to all members of the research teams who will work on the Studies, and in all publications and oral presentations concerning the Studies,
- Posting of this summary on MD Anderson's public website,
- Referral of any concerns/complaints related to MD Anderson's compliance with the Plan, or its financial conflict of interest, to The University of Texas System,
- Engagement of a non-MD Anderson ethicist (External Ethicist) to address any questions or concerns that participants in the Studies may have pertaining to the MD Anderson financial interest and conflict of interest,
- Supply of a copy of the Plan to the External IRB and External Ethicist,
- Review of safety and efficacy data of Studies that are clinical trials by an external and independent Data Safety Monitoring Board (External DSMB),
- Use of multi-institutional trials with a non-MD Anderson lead PI for Studies that are a Phase III or Phase II clinical trial aimed at gaining FDA approval under a new drug or biological license application,
- Monitoring activities related to the manufacture of Investigational Agents if required for the Studies by MD Anderson's IND Office,
- Reporting to the EVC by an External Contract Research Organization on Studies that are INDenabling preclinical studies,
- Review and revision of the Plan as necessary with any amendments requiring EVC approval, and
- Annual review of MD Anderson's compliance with the Plan by The University of Texas Systemwide Compliance Officer, with a written report of the review from the External DSMB to be provided to the EVC.