Institutional Conflict of Interest Management and Monitoring Plan: Oral Cladribine

The University of Texas MD Anderson (MD Anderson) has established this Conflict of Interest Management & Monitoring Plan (Plan) for managing and monitoring MD Anderson's institutional conflicts of interest with respect to research studies to be conducted by MD Anderson related to the use of oral cladribine in leukemia (Studies). While use of oral cladribine in leukemia has not been licensed to a commercial partner, MD Anderson's Institutional Conflict of Interest Committee has determined that the likelihood of such a license, and the institutional financial interests that will come with it, are sufficiently likely in the near future so as to warrant the management of the Studies as a potential Institutional Conflict of Interest. Furthermore, any future license of oral cladribine in leukemia to another party will be considered an Institutional Conflict of Interest to be managed by this Plan as well

Under the Agreement, Dr. Hagop Kantarjian, Chair of the Department of Leukemia, and his co-inventors are entitled to 50% of any license income that may stem from the license of oral cladribine in leukemia under the MD Anderson Intellectual Property Policy # ADM0345.

Dr. Kantarjian is an Institutional Decision Maker under the Institutional Conflict of Interest Policy for The University of Texas MD Anderson Cancer Center and its Institutional Decision Makers, UTMDACC Institutional Policy, #ADM1273. Upon such a license for this technology, the potential financial interest will necessitate a personal Conflict of Interest Management Plan approved by the MD Anderson Conflict of Interest Committee.

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.

Prohibitive measures in the Plan include:

- Dr. Kantarjian will not be involved in any negotiations involving any entity licensing the technology covered by this Plan or its known affiliates with respect to sponsored research agreements, purchasing decisions or any other type of agreement.
- Dr. Kantarjian will not be involved in the approval or execution of contracts or agreements involving any entity licensing the technology covered by this plan on behalf of MD Anderson.
- Dr. Kantarjian will not be involved in any relevant discussions at any entity licensing the technology covered by this Plan and at MD Anderson, and except as specifically invited by MD Anderson as a content expert.
- Dr. Kantarjian will not supervise anyone participating in discussions involving any existing or proposed business relationships or research collaboration involving any entity licensing the technology covered by this Plan and at MD Anderson.

The Plan requirements include:

- MD Anderson employees who have a financial interest in any entity licensing the technology covered by this Plan and will be involved in the conduct of the Studies will have, as required by institutional policy and MD Anderson's Conflict of Interest Committee, personal conflict of interest management plans covering their involvement in the Studies.
- Altered reporting structure for (1) individuals directly supervised by or in the line of reporting of Dr. Kantarjian in those instances where such individuals' institutional responsibilities include negotiations or decisions involving any entity licensing the technology covered by this Plan or (2) for any individual supervised by Dr. Kantarjian who is also the Principal Investigator of a research study for oral cladribine in leukemia.
- Altered reporting structure when Dr. Kantarjian directly supervises or is in the line of reporting of someone who also has a financial interest in or a financial relationship with any entity licensing the technology covered by this Plan.
- Upon licensing the technology covered by this Plan, disclosure of Dr. Kantarjian financial conflict of interest, the Plan, and personal conflict of interest management plan (in general terms) to all individuals who report directly or are in the line of reporting to Dr. Kantarjian.

- Prompt disclosure by Dr. Kantarjian to the MD Anderson Conflict of Interest Committee with respect to existing business relationships or research collaborations involving any entity licensing the technology covered by this plan and MD Anderson so that conflict of management steps can be taken, if necessary and as appropriate.
- Disclosure of MD Anderson's financial interest to participants in the 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 or Dr. Kantarjian's compliance with the Plan, or its financial conflict of interest, to The University of Texas System.
- Recusal of any MD Anderson Institutional Decision Maker who has a financial relationship with any entity licensing the technology covered by this Plan and at MD Anderson or its known affiliates from negotiations with respect to any agreements or purchasing decisions.
- For any Clinical Trials, no creator of the licensed technology may serve as a Principal Investigator or Co-Investigator, nor may they enroll patients on said Clinical Trials.
- Third party monitoring of the eligibility criteria and safety and efficacy data for any Clinical Trial.
- 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.
- 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 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 principal investigator for Studies that are Phase III or Phase II clinical trials 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 IND-enabling preclinical studies.
- Review and revision of the Plan as necessary with any amendments requiring EVC approval.
- Annual review of MD Anderson's compliance with the Plan by MD Anderson's Institutional Conflict of Interest Committee and MD Anderson Institutional Compliance, with a report of such review provided to The University of Texas System Ethics Officer.

Prepared November 8, 2024