Meeting Minutes

Institution:	New York Oncology Hematology, P.C.
Meeting Date:	October 29, 2026
Meeting Time	4:00 PM Eastern Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public
Members in Attendance:	**Member** / **Voting** / **Member Type** Bavaret, Tammy / Yes / Chair: Biosafety Expert/HGT Expert Rastein, Daniel / Yes / Core Member: Biosafety Expert/HGT Expert Ellis, Robert / Yes / Core Member: Biosafety Expert/HGT Expert Shakerley, Nicole / Yes / Local Unaffiliated Member
Invited Members Not in Attendance:	**Member** / **Voting** / **Member Type** Morgan, Trokon / No / Site Contact Tabe, Ebot / Yes / Local Unaffiliated Member
Guests:	Duprey, Danielle (Site representative); Mays, Jessica; Abbasi, Husn; Hickman, Talia; Faruol, Josephine; Pikus, MaryClare; Cicchinelli, Ambri; Raval, Mihir
Staff:	Smith, Jennifer

Call to Order: The IBC Chair called the meeting to order at 4:01 PM. A quorum was present as defined in the Sabai IBC Charter.

Conflicts of Interest: The IBC Chair reminded all members present to identify any conflicts of interest (COI). No COI was declared by any voting member of the IBC for any of the items on the agenda.

Public Comments: No public comments were made prior to or at the meeting.

Meeting Minutes

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 10/11/24 were approved by the IBC with no changes.

New Business:

PI:	Raval, Mihir
Sponsor:	AstraZeneca AB
Protocol:	D8312C00002 A Phase III Open-Label, Randomised, Multicentre Study of Consolidation with a Single Administration of AZD0120, a Dual-Targeting Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy Directed Against BCMA and CD19, Compared with Continuous Standard Therapy in Participants with NDMM Who Are Ineligible to Receive ASCT as Initial Therapy (DURGA-5)
Review Type:	Initial Review
NIH Guidelines Section:	III-C-1

Trial Summary: D8312C00002 is a multicenter, randomized, controlled, open-label, Phase III trial sponsored by AstraZeneca AB and designed to assess the efficacy and safety of AZD0120 versus standard regimens in adult participants with newly diagnosed multiple myeloma (NDMM) who are ineligible to receive autologous stem cell transplantation (ASCT) as initial therapy. AZD0120 is composed of autologous T cells genetically engineered with a replication-deficient, recombinant lentiviral vector to express dual-targeting chimeric antigen receptors (CARs) against CD19 and B-cell maturation antigen (BCMA). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent AZD0120 consists of primary human cells transduced with a recombinant Risk Group 3 lentiviral vector; therefore, BSL2 containment is considered the minimum biocontainment level under the *NIH Guidelines*.

Risk Assessment and Discussion:

- The Committee reviewed the clinical trial Sponsor's study documents and the Sabai-generated comprehensive study-specific Risk Assessment which collectively provided a thorough description of the recombinant or synthetic nucleic acid molecules (investigational product/s) and the proposed clinical research activities involving the IP.
    - In summary, the primary risks in this clinical trial include potential occupational exposure from accidental spills or splashes of the IP during preparation and/or administration procedures and needlesticks due to the use of needles during preparation and/or administration. These potential risks are mitigated through a combination of relevant staff training, safe clinical practices (including Standard Precautions and sharps safety) and use of appropriate PPE (as prescribed in the Risk Assessment and documented in the IBC submission package).

- The Site confirmed that only study personnel who have been educated on the potential biohazards and the precautions to be taken when working with the IP will handle the IP or any materials contaminated by the IP.
- The Site confirmed that study personnel are sufficiently trained in the practices and techniques required to safely work with the IP.
- The Site confirmed that staff members receive Bloodborne Pathogens training.
- Occupational Health Recommendations: None
- The Committee had no additional significant comments or recommendations regarding the description of the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial, or the proposed mitigation strategies, as detailed in the Risk Assessment.

- The Committee discussed the Site's facility details but did not have enough information to review the site and the meeting was tabled. No vote was taken.

Motion: A motion of Tabled for the study. No vote was taken.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 5:00 PM.

Post-Meeting Pre-Approval Note: None