Meeting Minutes

Meeting Date:	July 8, 2025, at 12:30 PM Mountain Time
Meeting Place:	Teleconference (Remote)
Members in Attendance:	Bavaret, Tammy Ellis, Robert Helm, Allen Haltiwanger, Brett Wilson, Zachary Gord, Bradley
Members Not in Attendance:	None
Guests:	Jacquez, Andrea
Staff:	Payne, Kaylie
Institution:	Urology Associates P.C. – Lone Tree

Call to Order: The meeting was called to order at 12:30 PM. A quorum was present.

Conflicts of Interest: None declared by voting members of the IBC

Meeting Minutes: Previous meeting minutes were reviewed and approved with no requested changes.

New Business:

PI:	Bell, Brad MD
Sponsor:	CG Oncology, Inc
Protocol:	BOND-003
	A Phase 3 Study of Cretostimogene Grenadenorepvec in Patients with Non-Muscle Invasive Bladder Cancer (NMIBC) Unresponsive to Bacillus-Calmette-Guerin (BCG) Title
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: BOND-003 is a Phase III clinical trial sponsored by CG Oncology Inc. and designed to assess the safety and efficacy of a recombinant, conditionally replicating oncolytic adenovirus designed to express human granulocyte-macrophage colony-stimulating factor (GMCSF) in adults with Non-Muscle Invasive Bladder Cancer (NMIBC) that is unresponsive to standard-of-care therapy with Bacillus Calmette-Guerin (BCG).

Biosafety Containment Level per Risk Assessment: BSL-2

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, Annual Review Report, and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.
    - The Committee wanted to get confirmation about DOT requirements for transportation of the study agent to the Littleton office from a regulatory and legal standpoint. The site confirmed they will have the IP packaged according to DOT standards. The committee requested a staged photo of the packaging.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by majority vote. There were no abstentions on voting

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - The Committee would like the site to provide a photo of the shipping packaging for the study agent by 8/7/2025. The Committee agreed that resolution of this stipulation can be approved following review by the Chair

New Business:

PI:	Mazur, Daniel MD
Sponsor:	CG Oncology, Inc
Protocol:	CORE-008
	A Phase 2, Multi-Arm, Multi-Cohort, Open-Label Study to Evaluate the Safety and Efficacy of Cretostimogene Grenadenorepvec in Participants with High-Risk Non-Muscle-Invasive Bladder Cancer (NMIBC)
Review Type:	Annual Review
NIH Guidelines:	III-C

Trial Summary: CORE-008 is a multi-arm, open-label Phase II trial sponsored by CG Oncology, Inc. and designed to assess the safety and efficacy of cretostimogene grenadenorepvec in participants with high-risk non-muscle invasive bladder cancer. The study agent cretostimogene

grenadenorepvec consists of a recombinant, conditionally replicating oncolytic adenovirus

Biosafety Containment Level per Risk Assessment: BSL-2

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, Annual Review Report, and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.
    - The Committee wanted to get confirmation about DOT requirements for transportation of the study agent to the Littleton office from a regulatory and legal standpoint. The site confirmed they will have the IP packaged according to DOT standards. The committee requested a staged photo of the packaging.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by majority vote. There were no abstentions on voting

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - The Committee would like the site to provide a photo of the shipping packaging for the study agent by 8/7/2025. The Committee agreed that resolution of this stipulation can be approved following review by the Chair

New Business:

PI:	Mazur, Daniel MD
Sponsor:	Merck Sharp & Dohme LLC
Protocol:	V940-011
	A Phase 2 Open-label Randomized Study of V940 in Combination with BCG Versus BCG Monotherapy in Participants with High-risk Non-muscle Invasive Bladder Cancer (INTerpath-011)
Review Type:	Initial Review
NIH Guidelines:	III-C

Trial Summary: V940-011 is a Phase II randomized, active-controlled, open-label study sponsored by Merck Sharp & Dohme LLC designed to evaluate the efficacy and safety of the study agent V940 (also known as mRNA-4157) in combination with Bacillus Calmette Guerin (BCG) compared to BCG monotherapy in adult participants with high-risk non-muscle invasive bladder cancer (NIMBC) and have undergone transurethral resection of bladder tumor (TURBT). V940 is a novel mRNA-based individualized neoantigen therapy (INT) consisting of a single lipid encapsulated mRNA encoding up to 34 participant-specific neoantigens.

Biosafety Containment Level per Risk Assessment: BSL-1 plus Standard Precautions

Comments:

- The Committee reviewed the Sponsor's study documents and the comprehensive study-specific Risk Assessment which provided a thorough description of the recombinant or synthetic nucleic acid molecules ("investigational product [IP]") and the proposed clinical research involving the IP.
    - The Committee agreed that the potential risks and occupational exposure hazards associated with handling the IP in this clinical trial were well-described in the Risk Assessment.

- The Committee reviewed the Site's facility details, study-specific procedures and practices, training records, the PI's credentials, and other applicable information provided by the Site for the purposes of the IBC review.
    - The Site verified that the information provided by the Chair was accurate.
    - The Committee discussed the biosafety containment level for this study and agreed that BSL-1 (plus Standard Precautions) would be appropriate. The Site and Committee agreed to approve the study at BSL-2 to allow for this study to be conducted in a manner that was consistent with other clinical studies approved at the Site.

Motion: A motion of Full Approval for the study at BSL-2 was passed by majority vote. There were no abstentions on voting

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

Reminder of IBC Approval Requirements.

Adjournment: 1:13 PM

Post-Meeting Pre-Approval Note: None