

## Meeting Minutes



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|-------------------------------------------|--------------------------------------------------|--|
| <b>Meeting Date:</b>                      | Thursday, July 31, 2025 at 12:30 PM Central Time |  |
| <b>Meeting Place:</b>                     | Teleconference (Remote)<br>Open to the Public    |  |
| <b>Members in Attendance:</b>             | Bavaret, Tammy                                   |  |
|                                           | Campbell, Mark                                   |  |
|                                           | Rastein, Daniel                                  |  |
|                                           | Holden, Letitia                                  |  |
|                                           | Levin, Patricia                                  |  |
|                                           | Goldin, Stephanie                                |  |
| <b>Invited Members Not in Attendance:</b> | Runkle, Chelsea                                  |  |
| <b>Guests:</b>                            | None                                             |  |
| <b>Staff:</b>                             | Stark, Casey                                     |  |
| <b>Institution:</b>                       | St. David's South Austin Medical Center          |  |

**Call to Order:** The meeting was called to order at 12:31 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:

|                        |                                                                                                                                                                                             |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PI:</b>             | Ramakrishnan, Aravind MD                                                                                                                                                                    |
| <b>Sponsor:</b>        | Janssen Research & Development, LLC                                                                                                                                                         |
| <b>Protocol:</b>       | 90014496LYM1001<br>A Phase 1b Multicenter, Open-label, Study of JNJ-90014496, an Autologous CD19/CD20 Bi-specific CAR-T Cell Therapy in Adult Participants with B-cell Non-Hodgkin Lymphoma |
| <b>Review Type:</b>    | Annual Review                                                                                                                                                                               |
| <b>NIH Guidelines:</b> | III-C                                                                                                                                                                                       |

**Trial Summary:** 90014496LYM1001 (formerly CCAR039L1101) is a Phase 1b/2 multicenter, open-label study sponsored by Janssen Research and Development, LLC and designed to assess the safety and tolerability of JNJ-90014496, an autologous bi-specific chimeric antigen receptor (CAR) T cell product targeting CD19 and CD20 in adult participants with relapsed/refractory or frontline high-risk B-cell non-Hodgkin lymphoma (B-NHL). The study agent JNJ-90014496 (formerly known as C-CAR039) consists of autologous T lymphocytes transduced with a recombinant, replication-defective lentiviral vector designed to express a novel 2nd generation bi-specific CAR-T construct targeting both CD19 and CD20.

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 Site confirmed that any penetration or manipulations of the infusion bag outside of the normal thaw and preparation procedure will take place within the biosafety cabinet. The Committee had no concerns.

**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

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|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PI:</b>             | Ramakrishnan, Aravind MD                                                                                                                     |
| <b>Sponsor:</b>        | Novartis                                                                                                                                     |
| <b>Protocol:</b>       | CADPT07A12101<br>Phase I, open label, study of B-cell Maturation Antigen (BCMA)-directed CAR-T cells in adult patients with multiple myeloma |
| <b>Review Type:</b>    | Annual Review                                                                                                                                |
| <b>NIH Guidelines:</b> | III-C                                                                                                                                        |

**Trial Summary:** CADPT07A12101 is a randomized, open-label, multi-center Phase I trial sponsored by Novartis, Inc., and designed to assess the safety and tolerability of PHE885, a novel autologous anti-BCMA CAR-T therapy in adult participants with relapsed or refractory multiple myeloma (r/r MM) or newly diagnosed MM (NDMM). The study agent PHE885 consists of the participant's own (autologous) T cells that have been transduced with a recombinant lentiviral vector expressing a chimeric antigen receptor (CAR) targeting the tumor antigen B-cell maturation antigen (BCMA).

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- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

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|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PI:</b>             | Ahmed, Faheem MD                                                                                                                                                                                                    |
| <b>Sponsor:</b>        | Kite Pharma, Inc.                                                                                                                                                                                                   |
| <b>Protocol:</b>       | KT-US-679-0788<br>A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma |
| <b>Review Type:</b>    | Annual Review                                                                                                                                                                                                       |
| <b>NIH Guidelines:</b> | III-C                                                                                                                                                                                                               |

**Trial Summary:** KT-US-679-0788 is a randomized, open-label, Phase III study sponsored by Kite Pharma, Inc. and designed to assess the efficacy and safety of the study agent anitocabtagene autoleucel, an autologous T cell product expressing a chimeric antigen receptor (CAR) against B-cell Maturation Antigen (BCMA), in participants with relapsed/refractory Multiple Myeloma (RRMM). The study agent anitocabtagene autoleucel (formerly CART-ddBCMA) consists of autologous T cells modified *ex vivo* with a recombinant replication-defective third-generation lentiviral vector to express a chimeric antigen receptor (CAR) targeting BCMA.

## Meeting Minutes



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- Contingencies stated by the Committee: None
- Stipulations stated by the Committee: None

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|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>PI:</b>             | Ramakrishnan, Aravind MD                                                                                                                                                                                                            |
| <b>Sponsor:</b>        | Collectis S.A.                                                                                                                                                                                                                      |
| <b>Protocol:</b>       | UCART20x22_01<br>Open-label dose-finding and dose-expansion study to evaluate the safety, expansion, persistence, and clinical activity of UCART20x22 in subjects with relapsed or refractory B-Cell Non-Hodgkin's Lymphoma (B-NHL) |
| <b>Review Type:</b>    | Annual Review                                                                                                                                                                                                                       |
| <b>NIH Guidelines:</b> | III-C                                                                                                                                                                                                                               |

**Trial Summary:** UCART20x22\_01 (NatHaLi-01) is an Open-Label Phase 1/2a study sponsored by Collectis S.A. and designed to assess the safety and tolerability of the investigational cell product UCART20x22 in subjects with relapsed/refractory (R/R) mature B-Cell Non-Hodgkin's Lymphoma (B-NHL). UCART20x22 is a first-in-class allogeneic, non-alloreactive, human CAR T-cell product transduced with an integrated self-inactivating (SIN) recombinant lentiviral vector with dual CAR expression, targeting both CD20 and CD22 antigens.

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  - 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.

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- Stipulations stated by the Committee: None

**Reminder of IBC Approval Requirements.**

**Adjournment:** 1:27 PM

**Post-Meeting Pre-Approval Note:** None