Meeting Minutes

Institution:	UC – Irvine
Meeting Date:	Wednesday, October 15, 2025
Meeting Time	9:00 AM Pacific Time
Meeting Type:	Virtual Platform Teleconference (Remote) Open to the Public

Members in Attendance:

Member	Voting	Member Type
Noriea, Nicholas	Yes	Chair: Biosafety Expert/HGT Expert
Campbell, Mark	Yes	Core Member: Biosafety Expert/HGT Expert
Rastein, Daniel	Yes	Core Member: Biosafety Expert/HGT Expert
Makmura, Linna	Yes	Local Unaffiliated Member
Zhou, Jennifer	Yes	Local Unaffiliated Member
Tafoya, Christine	Yes	Biological Safety Officer
Abegania, Judi	No	Biological Safety Officer

Guests:	None
Staff:	Stark, Casey

Call to Order: The IBC Chair called the meeting to order at 9:01 AM. 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.

Review of Prior Business: None

Previous Meeting Minutes: Minutes from 10-1-25 were approved by the IBC with no changes. There were no votes against and no abstentions.

New Business:

PI:	Lu, Stephanie MD
Sponsor:	4D Molecular Therapeutics, Inc.
Protocol:	4D-150-C003 A Phase 3, Randomized, Double-Masked, Active-Controlled Trial of a Single Intravitreal Injection of 4D-150 in Adults with Macular Neovascularization Secondary to Age-Related Macular Degeneration (4FRONT-1)
Review Type:	Change in Research Review
NIH Guidelines Section:	III-C-1

Trial Summary: 4D-150-C003 is a Phase 3 clinical trial sponsored by 4D Molecular Therapeutics, Inc., and designed to evaluate the safety and efficacy of 4D-150 in adult participants with macular neovascularization (MNV) secondary to age-related macular degeneration (nAMD). 4D-150 is a recombinant, replication-defective adeno-associated virus (rAAV) vector designed to express two anti-VEGF transgene components [miR-(VEGF-C) and coAFLB] that are designed to inhibit angiogenesis and vascular leakage in the eyes of individuals with nAMD. The investigational product (IP) is administered by intravitreal injection.

Biosafety Containment Level (BSL): The study agent 4D-150 is a replication-defective rAAV vector that does not encode a toxin molecule or potentially tumorigenic gene product and is produced in the absence of a helper virus. Therefore, 4D-150 may be classified as a Risk Group 1 (RG1) agent under the *NIH Guidelines* and Biosafety Level 1 (BSL-1) may be considered as the minimum containment level for handling the study agent.

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 reviewed the Site's facility details, relevant study-specific procedures and practices, the PI's credentials and other applicable information provided by the Site for the purposes of the IBC review.
    - The Chair noted that this is a Change in Research to change the Principal Investigator to Dr. Stephanie Lu and to add a new storage and preparation location. The Committee had no concerns with these changes.
    - 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. At the specific request of the Site, the 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 unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee: None

PI:	Uchio, Edward MD, FACS, CPI
Sponsor:	Ferring Pharmaceuticals A/S
Protocol:	ABLE-22 A phase 2, randomized, multi-centre, open label trial to evaluate the safety and efficacy of intravesical nadofaragene firadenovec alone or in combination with chemotherapy (gemcitabine and docetaxel) or immunotherapy (pembrolizumab) in subjects with high-grade Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ABLE-22 (Trial Code 000434) is a randomized, open-label Phase III clinical trial sponsored by Ferring Pharmaceuticals A/S designed to evaluate the safety and efficacy, including reinduction, of intravesical instillation of nadofaragene firadenovec in subjects with high-grade Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC). The study agent nadofaragene firadenovec is a recombinant, replication-deficient type 5 adenovirus vector containing the transgene that encodes the human interferon-α2b (IFN-α2b) gene. The investigational product (IP) is administered by intravesical instillation.

Biosafety Containment Level (BSL): The study agent nadofaragene firadenovec is based on a recombinant Risk Group 2 adenovirus containing more than two-thirds of the native genome, requiring the use of BSL-2 containment 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: The Sponsor indicates that immunocompromised persons, including those receiving immunosuppressant therapy, maybe at risk for disseminated adenovirus infection because of the possible presence of low levels of replication-competent adenovirus in nadofaragene firadenovec. Thus, individuals who are immunosuppressed or immune-deficient should not prepare, administer, or come into contact with the study agent.
    - 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 reviewed the Site's facility details, relevant study-specific procedures and practices, the 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 noted that one of the biosafety cabinet's (BSC) certification in the preparation area expired in September; however, the other two BSCs certification is complaint until November. The Committee stipulated that the Site provide an updated certification report for the expired BSC or confirm that the expired BSC will not be used for human gene transfer (HGT) agents until it is recertified.
    - The Committee discussed the occupational precautions and how the precautions are communicated to institutional staff. The Site clarified that study nurses and pharmacy staff receive notification and additional training for specific study agents requiring additional precautions. The Site indicated that they would discuss with pharmacy staff about updating the biohazard sign to include language regarding how occupational precautions are communicated to institutional staff. The Committee had no additional concerns.
    - The Committee noted that the Facility Details report notes that disinfectants vary by location and questioned if the disinfectants are verified to be efficacious. The Site confirmed that tuberculocidal disinfectants are widely used across the institution. The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution.
    - The Chair noted that the representative Site photos of the Chao Clinic Exam Rooms do not show a biohazard waste container in the room. The Committee stipulated that the Site provide confirmation that a biohazard waste container is present in the exam room, and if possible, provide an updated photo.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
  - The Committee stipulated that the Site provide an updated certification report for the expired BSC or confirm that the expired BSC will not be used for human gene transfer (HGT) agents until it is recertified by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site provide confirmation that a biohazard waste container is present in the exam room, and if possible, provide an updated photo by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Uchio, Edward MD, FACS, CPI
Sponsor:	Ferring Pharmaceuticals A/S
Protocol:	ABLE-32 A Phase 3b, Randomized, Controlled Trial of Nadofaragene Firadenovec vs. Observation in Subjects with Intermediate Risk (IR) Non-Muscle Invasive Bladder Cancer (NMIBC)
Review Type:	Annual Review
NIH Guidelines Section:	III-C-1

Trial Summary: ABLE-32 (Trial Code 000423) is a randomized, open-label Phase IIIb clinical trial sponsored by Ferring Pharmaceuticals A/S designed to evaluate the safety and efficacy of nadofaragene firadenovec versus observation in adults with intermediate risk (IR) Non-Muscle Invasive Bladder Cancer (NMIBC). The study agent nadofaragene firadenovec is a recombinant, replication-deficient type 5 adenovirus vector containing the human interferon-α2b (IFN-α2b) gene and the excipient Syn3NODA. The investigational product (IP) is administered by intravesical instillation.

Biosafety Containment Level (BSL): The study agent nadofaragene firadenovec is based on a recombinant Risk Group 2 adenovirus containing more than two-thirds of the native genome, requiring the use of BSL-2 containment 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: The Sponsor indicates that immunocompromised persons, including those receiving immunosuppressant therapy, maybe at risk for disseminated adenovirus infection because of the possible presence of low levels of replication-competent adenovirus in nadofaragene firadenovec. Thus, individuals who are immunosuppressed or immune-deficient should not prepare, administer, or come into contact with the study agent
- 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 reviewed the Site's facility details, relevant study-specific procedures and practices, the 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 noted that one of the biosafety cabinet's (BSC) certification in the preparation area expired in September; however, the other two BSCs certification is complaint until November. The Committee stipulated that the Site provide an updated certification report for the expired BSC or confirm that the expired BSC will not be used for human gene transfer (HGT) agents until it is recertified.
    - The Committee discussed the occupational precautions and how the precautions are communicated to institutional staff. The Site clarified that study nurses and pharmacy staff receive notification and additional training for specific study agents requiring additional precautions. The Site indicated that they would discuss with pharmacy staff about updating the biohazard sign to include language regarding how occupational precautions are communicated to institutional staff. The Committee had no additional concerns.

- The Committee noted that the Facility Details report notes that disinfectants vary by location and questioned if the disinfectants are verified to be efficacious. The Site confirmed that tuberculocidal disinfectants are widely used across the institution. The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
  - The Committee stipulated that the Site provide an updated certification report for the expired BSC or confirm that the expired BSC will not be used for human gene transfer (HGT) agents until it is recertified by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.
  - The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP.

PI:	Desai, Sheetal MD
Sponsor:	Fate Therapeutics, Inc.
Protocol:	FT819-102 A Phase 1 Study of FT819 in B-cell Mediated Autoimmune Diseases
Review Type:	Annual Review and Change in Research
NIH Guidelines Section:	III-C-1

Trial Summary: FT819-102 is a Phase I open-label study sponsored by Fate Therapeutics, Inc., and designed to evaluate the safety, tolerability, and recommended phase 2 dose (RP2D) of FT819 in participants ≥12 and ≤ 70 years of age with B-cell mediated autoimmune diseases including systemic lupus erythematosus (SLE), antineutrophilic cytoplasmic antibody (ANCA)- associated vasculitis (AAV), idiopathic inflammatory myositis (IIM), and systemic sclerosis (SSc). The investigational product FT819 consists of allogeneic T cells that express a CD19- targeted chimeric antigen receptor (CAR). The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent FT819 consists of primary human cells engineered with a DNA plasmid, BSL-2 is the recommended 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. 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 reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
  - The Chair noted that this study proposes adding a new storage and preparation location that has been previously reviewed by the Committee. The Committee had no concerns with this addition.
  - The Site verified that the information provided by the Chair was accurate.
  - The Committee noted that the Facility Details report notes that disinfectants vary by location and questioned if the disinfectants are verified to be efficacious. The Site confirmed that virucidal disinfectants are widely used across the institution. The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP

PI:	Habib, Ali MD
Sponsor:	Nkarta, Inc.
Protocol:	NKX019-101 A Phase 1 Study of NKX019, a CD19 Chimeric Antigen Receptor Natural Killer (CAR NK) Cell Therapy, in Subjects with B-cell Malignancies.
Review Type:	Annual Review and Change in Research
NIH Guidelines Section:	III-C-1

Trial Summary: NKX019-101 is a Phase I clinical trial sponsored by Nkarta, Inc. and is designed to assess the safety, tolerability, and maximum tolerated dose of allogeneic natural killer (NK) cells genetically engineered to treat cancers derived from B-cell lineages. The study agent NKX019 consists of donor-derived NK cells engineered to express a chimeric antigen receptor (CAR) targeting CD19 and a membrane-bound form of the cytokine IL-15 (mbIL-15). CD19 is a therapeutic target for patients with B-cell malignancies while mbIL-15 enhances NKX019 cell survival and persistence. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): Because the study agent NKX019 contains recombinant Risk-Group 2 gammaretrovirus, BSL-2 containment is considered the default 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 reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
    - The Chair noted that this study proposes adding a new storage and preparation location that has been previously reviewed by the Committee. The Committee had no concerns with this addition.
    - The Site verified that the information provided by the Chair was accurate.
    - The Committee noted that the Facility Details report notes that disinfectants vary by location and questioned if the disinfectants are verified to be efficacious. The Site confirmed that virucidal disinfectants are widely used across the institution. The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP

PI:	Mozaffar, Tahseen MD
Sponsor:	Nkarta, Inc.
Protocol:	NKX019-103 A Phase 1 Study of NKX019, a CD19 Chimeric Antigen Receptor Natural Killer (CAR NK) Cell Therapy, in Subjects with Immune-Mediated Diseases.
Review Type:	Annual Review and Change in Research
NIH Guidelines Section:	III-C-1

Trial Summary: NKX019-103 (Ntrust02) is an open-label, multi-cohort, Phase I dose escalation and dose expansion study sponsored by Nkarta, Inc. designed to assess the safety, tolerability, and preliminary efficacy of NKX019 in subjects with various immune-mediated diseases (IMDs). NKX019 consists of donor-derived (allogeneic) natural killer (NK) cells genetically engineered to express a chimeric antigen receptor (CAR) targeting CD19 which is highly expressed on the surface of autoantibody-producing plasmablasts. The investigational product (IP) is administered by intravenous infusion.

Biosafety Containment Level (BSL): The study agent NKX019 contains primary human cells that have been transduced with a recombinant amphotropic gammaretrovirus, therefore BSL-2 containment is the recommended 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 reviewed the Site's facility details, relevant study-specific procedures and practices, the Annual Review Report and other applicable information provided by the Site for the purposes of the IBC review.
    - The Chair noted that this study proposes adding a new storage and preparation location that has been previously reviewed by the Committee. The Committee had no concerns with this addition.
    - The Site verified that the information provided by the Chair was accurate.
    - The Committee noted that the Facility Details report notes that disinfectants vary by location and questioned if the disinfectants are verified to be efficacious. The Site confirmed that virucidal disinfectants are widely used across the institution. The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution.

Motion: A motion of Approval with Stipulations for the study at BSL-2 was passed by unanimous vote. There were no votes against and no abstentions.

- Contingencies stated by the Committee: None

- Stipulations stated by the Committee:
    - The Committee stipulated that the Site provide confirmation of the disinfectants used at the institution by 11/15/2025. The Committee agreed that resolution of this stipulation can be approved following review by the AP

Review of Incidents: Nothing to report.

IBC Training: Nothing to report.

Reminder of IBC Approval Requirements.

Adjournment: The IBC Chair adjourned the meeting at 10:21 AM

Post-Meeting Pre-Approval Note: None