

Food and Drug Administration
Center for Biologics Evaluation and Research
Open Session Summary Minutes
71st Cellular, Tissue and Gene Therapies Advisory Committee Meeting
March 10, 2022

OPEN SESSION

Committee Members

Lisa Butterfield, Ph.D. (Chair)
Tabassum Ahsan Ph.D.+
Kenneth Berns, M.D., Ph.D.
Christopher Breuer, M.D.
Bernard Fox, Ph.D.
Jeannette Yen Lee, Ph.D.
Sean Morrison, Ph.D.+
Nirali Shah, M.D., MHSc
Mark Walters, M.D. +
Joseph Wu, M.D., Ph.D.
John Zaia, M.D.
Gil Wolfe, M.D., F.A.A.N.

FDA Speakers

Andrew Byrnes, Ph.D.
Karen Elkins, Ph.D.
Steven Oh, Ph.D.

FDA Participants

Rachael Anatol, Ph.D.
Wilson Bryan, M.D.
Leila Hann +
Chava Kimchi-Sarfaty, Ph.D.
Peter Marks, M.D., Ph.D.
Steven Oh, Ph.D.
Celia Witten, Ph.D., M.D. +

Industry Representative

Goefrey Nichol, M., M.D., M.B.A.***
Eric Crombez, M.D. < +

Designated Federal Officers (DFO)

Christina Vert, M.S.

Consumer Representative

Randy Hawkins, M.D. **

Committee Management Specialist(s)

Joanne Lipkind, M.S.
Tonica Burke, B.S.

**Consumer Representative

***Industry Representative

<Alternate Industry Representative

+Not in attendance

Director

Prabhakara Atreya, Ph.D.

These summary minutes for the March 10, 2022, meeting of the Cellular, Tissue and Gene Therapies Advisory Committee were approved on March 28, 2022.

I certify that I participated in the March 10, 2022, meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) meeting and that these minutes accurately reflect what transpired.

/S/
Christina Vert, M.S.
Designated Federal Officer

/S/
Lisa H. Butterfield, Ph.D.
Chair

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On March 10, 2022, at 10:00 a.m. Eastern Standard Time (EST), Lisa Butterfield, Ph.D., (Chair) called to order the 71st Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee. The partially closed meeting was held virtually by an Adobe Connect web conferencing platform. The Designated Federal Official (DFO), Christina Vert, made administrative remarks, conducted roll call, and invited members to introduce themselves, and read into the official record the conflicts of interest (COI) statement. Given that the topics of this meeting were determined to be a Non-Particular Matters, no COI screening was needed or conducted for this meeting. It was stated that no conflicts of interest waivers were issued under 18 U.S. Code 208 in connection with the meeting.

The topic of the meeting included:

Overview of the research programs of the Gene Transfer and Immunogenicity Branch (GTIB), Division of Cellular and Gene Therapies (DCGT), Office of Tissues and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER)

In open session, the Committee heard presentations on the following:

- Overview of CBER Research Programs
by Dr. Karen Elkins, Ph.D. Associate Director for Science, CBER
- Overview of OTAT and DCGT Research Programs
by Steven Oh, Ph.D., Deputy Director, DCGT, OTAT, CBER
- Overview of GTIB Research Programs
by Andrew Byrnes, Ph.D., Chief, GTIB, DCGT, OTAT, CBER

After the FDA speaker presentations, the Committee then proceeded with the Open Public Hearing. There were no open public hearing speakers, therefore the open session adjourned at 11:40 a.m. EST. Following the Open session, the Committee met in closed session to proceed with the Site Visit report discussion followed by the vote. Dr. Lisa Butterfield handed the meeting over to the DFO who adjourned the meeting March 10, 2022, at 12:45 p.m. EST.

Additional information and details may be obtained from the transcript and the recordings of the webcast of the meeting that may be viewed at:

<https://www.fda.gov/advisory-committees/advisory-committee-calendar/cellular-tissue-and-gene-therapies-advisory-committee-march-10-2022-meeting-announcement-03102022>

Direct Link to Recording of the Open Session: https://youtu.be/silb2C_Ro8I