

**Food and Drug Administration**  
**Center for Biologics Evaluation and Research**  
**Summary Minutes**  
**68<sup>th</sup> Cellular, Tissue and Gene Therapies Advisory Committee Meeting**  
**May 8, 2020**

**OPEN Session**

**Committee Members**

Lisa Butterfield, Ph.D. (Chair)  
Kenneth Berns, M.D., Ph.D.  
Christopher Breur, M.D.  
Bernard Fox, Ph.D.  
Randy Hawkins, M.D. <sup>\*\*+</sup>  
Sean Morrison, Ph.D.  
Raymond Roos, M.D.  
Jan Stegemann, Ph.D.  
Michael Streiff, M.D.  
Mark Walters, M.D.  
Joseph Wu, M.D., Ph.D.  
Jeannette Yen Lee, Ph.D.  
John Zaia, M.D.

**Industry Representative**

Geoffrey Martin Nichol, MB ChB <sup>\*\*\*</sup>

**Temporary Consumer Representative**

Sheldon Toubman, J.D. &

+Not Attending

\*\*Consumer Representative

\*\*\* Industry Representative

& Temporary Consumer Representative

**FDA Speakers**

Carolyn Wilson, Ph.D.

Topic I

Raj Puri, M.D., Ph.D.

Topic II

Steven Bauer, Ph.D.

**FDA Participants**

Rachael Anatol, Ph.D.  
Wilson Bryan, M.D.  
Suzanne Epstein, Ph.D.  
Chava Kimchi-Sarfaty, Ph.D.  
Steven Oh, Ph.D.

**Designated Federal Officer (DFO)**

Christina Vert, M.S.  
Kathleen Hayes, M.P.H

**Committee Management Specialist(s)**

Joanne Lipkind, M.S.  
Monique Hill, M.H.A.

**Director**

Prabhakara Atreya, Ph.D.

These summary minutes for the May 8, 2020 meeting of the Cellular, Tissue and Gene Therapies Advisory Committee were approved on May 27, 2020.

I certify that I participated in the May 8, 2020 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 Official

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

**Food and Drug Administration**  
**Center for Biologics Evaluation and Research**  
**Summary Minutes**  
**68<sup>th</sup> Cellular, Tissue and Gene Therapies Advisory Committee Meeting**  
**May 8, 2020**

**OPEN Session**

On May 8, 2020 at 1:05 p.m. Eastern Standard Time (EST), Lisa Butterfield, M.D., Ph.D. (Chair) called to order the 68<sup>th</sup> meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC). The partially closed meeting was held virtually by an Adobe Connect web conferencing platform. During the open session, CTGTAC members, FDA speakers and staff, and the public all participated via the Adobe Connect web conference. The closed session was also held 100% virtually by the Adobe Connect web conferencing, however, only attended by members and appropriate FDA staff. The meeting began with a session open to members of the Public.

The topics of the open session included the overview of the intramural research programs of the Tumor Vaccines and Biotechnology Branch (TVBB) and Cellular and Tissue Therapy Branch (CTTB), in the Division of Cellular and Gene Therapies (DCGT), Office of Tissue and Advanced Therapies (OTAT), Center for Biologics Evaluation and Research (CBER).

The DFO Ms. Vert took a roll call, made some administrative remarks and read the conflict of interest statement for the public record. Members were asked to introduce themselves during the roll call. Given that the topics of this meeting were determined to be a Non-Particular Matters, no conflict of interest screening was needed or conducted for this meeting.

**Open Session**

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

- Overview of CBER research programs by Dr. Carolyn Wilson, Associate Director for Research, CBER.
- Overview of research and regulatory activities in the Office of Cellular, Tissue and Gene Therapies (OCTGT) by Dr. Raj Puri, Director, Division of Cellular and Gene Therapies, OCTGT, CBER.
- Summary of research programs in the Tumor Vaccines and Biotechnology Branch (TVBB) by the Branch Chief Dr. Raj Puri.
- Summary of research programs in the Cellular and Tissue Therapy Branch (CTTB) by the Branch Chief Dr. Steven Bauer.

After the FDA speaker presentations, the Committee then proceeded with the Open Public Hearing. There was one speaker, Dr. Leslie Meltzer, Ph.D., Vice President and Head of Global Medical Affairs, Orchard Therapeutics, who gave a presentation on “Hematopoietic Stem & Progenitor Cell Gene Therapy Approach Addressing Unmet Medical Needs in Monogenic Diseases, including Neurometabolic Diseases.” The open session adjourned at 3:25 pm EST.

Following the OPH session, the Committee held a 15-minute break. Following the break, the Committee met in closed session to proceed with Site Visit report discussions followed by a vote.

**Food and Drug Administration**  
**Center for Biologics Evaluation and Research**  
**Summary Minutes**  
**68<sup>th</sup> Cellular, Tissue and Gene Therapies Advisory Committee Meeting**  
**May 8, 2020**

**OPEN Session**

The meeting was then adjourned on May 8, 2020 at 4:46 pm EST.

Additional information and details may be obtained from the transcript and the recording of the Adobe Connect meeting that may be viewed at:

<https://www.fda.gov/advisory-committees/advisory-committee-calendar/cellular-tissue-and-gene-therapies-advisory-committee-may-8-2020-meeting-announcement-05082020>

Direct Link to Recording of Open Session: <https://collaboration.fda.gov/p97zq9yv66l1/>