

Food and Drug Administration
Center for Biologics Evaluation and Research
Summary Minutes
66th Cellular, Tissue and Gene Therapies Advisory Committee Meeting
September 7, 2016

OPEN Session

Committee Members

Timothy Cripe, M.D., Ph.D., Chair
Dale Ando, M.D.#
David Bartlett, M.D.
Catherine Bollard, MBChB, M.D., FRACP
William Bugbee, M.D.
Barry Byrne, M.D., Ph.D.
Ole Isacson, M.D., Ph.D.+
G. Elizabeth Pluhar, D.V.M., Ph.D., Diplomate ACVS
Jan Stegemann, Ph.D.
Janet Wittes, Ph.D.
Ann Zovein, M.D.

Temporary Voting Member

Stephen Rose, Ph.D.*

FDA Participants

Carolyn Wilson, Ph.D.
Raj Puri, M.D., Ph.D.
Suzanne Epstein, Ph.D.
Andrew Byrnes, Ph.D.
Jakob Reiser, Ph.D.
Graeme Price, Ph.D.
Zhili Xu, Ph.D.

Designated Federal Officer

Janie Kim, Pharm.D.

Committee Management Specialists

Denise Royster
Joanne Lipkind

+ Did not participate in the meeting
Industry Representative
* Temporary Consumer Representative
(Consumer Representative Position is Vacant)

These summary minutes for the September 7, 2016 meeting of the Cellular, Tissue and Gene Therapies Advisory Committee were approved on _____.

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I certify that I participated in the September 7, 2016 meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) meeting and that these minutes accurately reflect what transpired.

/s/

Janie Kim, Pharm.D.
Designated Federal Officer, CTGTAC

Timothy Cripe, M.D., Ph.D.
Chair, CTGTAC

On September 7, 2016 at 1:00 p.m. Eastern Standard Time (EST), Timothy Cripe, M.D., Ph.D. (Chair) called to order the 66th meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC). The partially closed meeting was held at the Food and Drug Administration (FDA) Conference Center, 10903 New Hampshire Avenue, Building 31, White Oak Campus, Silver Spring, Maryland. The meeting began with a session open to members of the Public. CTGTAC members participated via teleconference for the open and closed sessions. The topic of the open session was the overview of the intramural research programs of the Gene Transfer and Immunogenicity Branch, Division of Cellular and Gene Therapies (DCGT), Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Drug Evaluation and Research (CDER).

The DFO made some administrative remarks before making a roll call and reading the conflict of interest statement for the public record. Members on the phone were asked to introduce themselves during the roll call.

Open Session

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

- Overview of CDER research programs by Dr. Carolyn Wilson, Associate Director for Research, CDER.
- 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, CDER.
- Summary of research programs in the Gene Transfer and Immunogenicity Branch (GTIB) by the Branch Chief Dr. Andrew Byrnes.

Time was allotted after the presentations for public comment. However, no individuals from the public requested time at the meeting to address the Committee. The open session adjourned at 3:00 pm.

For more detailed information concerning the open session presentations and committee discussions summarized above, please refer to the meeting transcripts available on the FDA website. Please submit all external requests to the FDA Freedom of Information Office.