Food and Drug Administration
Center for Biologics Evaluation and Research

Summary Minutes
65th Cellular, Tissue and Gene Therapies Advisory Committee Meeting
OPEN Session

July 26, 2016

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.
Grace 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.*
Leisha Emens, M.D., Ph.D.

FDA Participants
Steven Kozlowski, M.D.
Edward Max, M.D., Ph.D.
Serge Beaucage, Ph.D.
Kathleen Clouse, Ph.D.
Gibbes Johnson, Ph.D.
Wendy Weinberg, Ph.D.
Wen Jin Wu, M.D., Ph.D.
Baolin Zhang, Ph.D.

Designated Federal Officer
Janie Kim, Pharm.D.

Committee Management Specialist
Denise Royster

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

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These summary minutes for the July 26, 2016 meeting of the Cellular, Tissue and Gene Therapies Advisory Committee were approved on ***8/17/16***.

I certify that I participated in the July 26, 2016 meeting of the Cellular, Tissue and Gene Therapies Advisory Committee (CTGTAC) meeting and that these minutes accurately reflect what transpired.

/s/	/s/
Janie Kim, Pharm.D.	Timothy Cripe, M.D., Ph.D.
Designated Federal Officer, CTGTAC	Chair, CTGTAC

On July 26, 2016 at 1:00 p.m. Eastern Standard Time (EST), the Designated Federal Officer (DFO) called to order the 65th 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 Laboratory of Molecular Oncology and the Laboratory of Biological Chemistry, Division of Biotechnology Review and Research (DBRR-1 and 4), Office of Biotechnology Products (OBP), Center for Drug Evaluation and Research (CDER).

The DFO called the meeting to order and made some administrative remarks before reading the conflict of interest statement for the public record. Dr. Timothy Cripe, the CTGTAC chair, asked members on the phone for introductions before the start of the presentations.

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

- Overview of research and regulatory activities in the Office of Biotechnology Products (OBP), Center for Drug Evaluation and Research (CDER) by Dr. Steven Kozlowski, Director of OBP and Dr. Edward Max, Associate Director for Research, OBP.
- Research Program Summaries in the Laboratory of Molecular Oncology by the Laboratory Chief Dr. Wendy Weinberg
- Research Program Summaries in the Laboratory of Biological Chemistry by the Laboratory Chief Dr. Serge Beaucage

Time was allotted after the presentations for public comment. No individuals from the public requested time at the meeting to address the Committee. The open session was adjourned at 2:41 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.