FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Cellular, Tissue and Gene Therapies (CTGT)
Advisory Committee Meeting
April 15, 2021

FINAL AGENDA

TOPIC SUMMARY

On April 15, 2021, the committee will discuss biologics license application (BLA) 125734 for donislecel (purified allogeneic deceased donor pancreas derived Islets of Langerhans). The applicant, CellTrans, Inc., has requested an indication for the "treatment of brittle Type I diabetes mellitus (TlD)". The morning session will discuss issues related to the characterization and critical quality attributes of donislecel as they relate to product comparability in the context of consistent product quality and clinical effectiveness. The afternoon session will discuss results from the clinical trials included in BLA 125734.

10:00 a.m.	Opening Remarks: Call to Order and Welcome	**Chairperson, Lisa Butterfield, Ph.D. (5 min)** Vice-President, PICI Research Center University of California, San Francisco
	Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement	**Jarrod Collier, M.S. (15 min)** Designated Federal Officer
10:20 a.m.	FDA Opening Remarks	**Wilson W. Bryan, M.D. (5 min)** Director Office of Tissues and Advanced Therapies (OTAT), CBER
10:25 a.m.	Assessment of Islet Quality Pre-Transplant	**Klearchos Papas, Ph.D. (25 min)** Director Institute for Cellular Transplantation University of Arizona
	Q and A (15 min)	
Islet Cell – Chemistry, Manufacturing, and Control (CMC)		
11:05 a.m.	**APPLICANT PRESENTATIONS**	**CellTrans, Inc. (20 min)**
	Introduction and Manufacturing Process	**James McGarrigle, Ph.D.**
	Potency and Purity Assays and Relationships to Clinical Outcomes	**José Oberholzer, M.D., M.H.C.M., F.A.C.S.**

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Cellular, Tissue and Gene Therapies (CTGT)
Advisory Committee Meeting
April 15, 2021

FINAL AGENDA

11:25 a.m.	**FDA PRESENTATION** AM Session Product Characterization, BLA 125734, Donislecel	**Sukhanya Jayachandra, Ph.D (20 min)** Cell Therapy Branch Division of Cellular and Gene Therapies (DCGT) OTAT, CBER
11:45 a.m.	CMC Clarifying Questions to Presenters	**(15 min)**
12:00 p.m.	CMC Questions to the Committee/Committee Discussion	**(60 min)**
1:00 p.m.	**LUNCH BREAK**	**(45 min)**
1:45 p.m.	**OPEN PUBLIC HEARING**	**(60 min)**
Clinical		
2:45 p.m.	FDA Clinical Introductory Remarks	**Elizabeth Hart, M.D. (5 min)** Branch Chief Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT) OTAT, CBER
2:50 p.m.	**APPLICANT PRESENTATION**	**CellTrans, Inc. (45 min)**
	Introduction, Agenda, Executive Summary	**José Oberholzer, M.D., M.H.C.M., F.A.C.S.**
	Introduction to Diabetes and Unmet Clinical Need	**Betul Hatipoglu, M.D.**
	Introduction to Islet Cell Transplantation	**James Shapiro, M.D., Ph.D., F.R.C.S.(Eng), F.R.C.S.C., M.S.M., F.C.A.H.S.**
	Efficacy, Safety, and Risk-Benefit Assessment	**José Oberholzer, M.D., M.H.C.M., F.A.C.S.**
3:35 p.m.	**BREAK**	**(10 min)**

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Tissues and Advanced Therapies (OTAT)
Cellular, Tissue and Gene Therapies (CTGT)
Advisory Committee Meeting
April 15, 2021

FINAL AGENDA

3:45 p.m.	**FDA PRESENTATION** Clinical Considerations	**Patricia Beaston, M.D., Ph.D. (45 min)** Medical Officer DCEPT, OTAT, CBER
4:30 p.m.	Clarifying Questions to Presenters	**(30 min)**
5:00 p.m.	Questions to the Committee/Committee Discussion/Voting/Member Remarks	**(60 min)**
6:00 p.m.	**CLOSING REMARKS**	**Dr. Peter Marks** Director, CBER
	ADJOURNMENT	**Jarrod Collier, M.S.** Designated Federal Officer