

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
75th Meeting of the Cellular, Tissue, and Gene Therapies
Advisory Committee (CTGTAC)
September 27, 2023
FINAL AGENDA

Meeting Topic: *The committee will meet in open session to discuss and make recommendations on biologics license application (BLA) 125782 from BrainStorm Cell Therapeutics, Inc. for debamestrocel (autologous bone marrow-derived mesenchymal stromal cells induced to secrete neurotrophic factors [MSC-NTF], NurOwn). The applicant has requested an indication for the treatment of mild to moderate amyotrophic lateral sclerosis (ALS).*

EDT	Presentation/Presenter
10:00 a.m.	<p><u>Opening Remarks: Call to Order and Welcome</u> (5 min.)</p> <ul style="list-style-type: none"> • Taby Ahsan, Ph.D. Acting Chair, CTGTAC Vice President, Cell Therapy Operations City of Hope Duarte, CA <p><u>Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement</u> (20 min.)</p> <ul style="list-style-type: none"> • Marie DeGregorio Designated Federal Officer Division of Scientific Advisors and Consultants Center for Biologics Evaluation and Research (CBER), FDA
10:25 a.m.	<p><u>FDA Introduction</u> (25 min. including Q&A)</p> <p>Opening Remarks (5 min.)</p> <ul style="list-style-type: none"> • Celia Witten, Ph.D., M.D. Deputy Director, CBER, FDA <p>FDA Overview of BLA 125782, debamestrocel (MSC-NTF) for Treatment of Amyotrophic Lateral Sclerosis (ALS) (15 min.)</p> <ul style="list-style-type: none"> • Rosa Sherafat-Kazemzadeh, M.D. Clinical Team Leader Office of Clinical Evaluation (OCE), Division of Clinical Evaluation General Medicine (DCEGM) Office of Therapeutic Products (OTP)/CBER/FDA <p>Q&A (5 min.)</p>

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	<p>Supportive Biomarker Evidence</p> <p>Robert Bowser, Ph.D. Chief Scientific Officer, Chair, Department of Translational Neuroscience Barrow Neurological Institute</p> <p>Safety</p> <p>Kirk Taylor, M.D. Executive Vice President, Chief Medical Officer BrainStorm Cell Therapeutics</p> <p>Benefit/Risk – Clinical Perspective</p> <p>Anthony J. Windebank, M.D. Judith and Jean Pape Adams Professor and Faculty Development Chair Department of Neurology, Mayo Clinic</p> <p>Q&A (15 min.)</p>
1:05 p.m.	LUNCH (35 min.)
1:40 p.m.	<u>Open Public Hearing</u> (60 min.)
2:40 p.m.	BREAK (10 min.)
2:50 p.m.	<p><u>FDA Presentation</u> (85 min. including Q&A)</p> <p>BLA 125782, Application for debamestrocel (MSC-NTF) for Treatment of Amyotrophic Lateral Sclerosis (ALS)</p> <p>Tom Finn, Ph.D. BLA Chair and Chemistry, Manufacturing, and Controls (CMC) Reviewer Office of Cellular Therapy and Human Tissue CMC, Division of Cell Therapy OTP/CBER/FDA</p> <p>Gumei Liu, M.D., Ph.D. Clinical Reviewer OCE, DCEGM OTP/CBER/FDA</p>

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	<p>Xue (Mary) Lin, Ph.D. Statistical Reviewer Office of Biostatistics and Pharmacovigilance, Division of Biostatistics CBER/FDA</p> <p>Xiaofei Wang, Ph.D. Clinical Pharmacology Reviewer OCE, DCEGM OTP/CBER/FDA</p> <p>Q&A (15 min.)</p>
4:15 p.m.	<u>Committee Discussion, Voting, and Vote Explanation</u> (100 min.)
5:55 p.m.	<p><u>Closing Remarks</u> (5 min.)</p> <ul style="list-style-type: none"> • Celia Witten, Ph.D., M.D. Deputy Director, CBER, FDA
6:00 p.m.	<p><u>ADJOURNMENT</u></p> <ul style="list-style-type: none"> • Marie DeGregorio Designated Federal Officer, CTGTAC