77th Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee November 21, 2024 Web Conference

# **Final Meeting Roster**

# **MEMBERS**

# Tabassum (Taby) Ahsan, Ph.D. \*\*\*\*

Expertise: Biomedical Engineering Term: 05/17/2021-03/31/2026

Vice-President

Cell and Gene Therapy Operations

City of Hope Duarte, CA

# Anne-Virginie Eggimann, M.Sc. \*\*\*

Expertise: Industry Representative Term: 07/18/2024-03/31/2028 Chief Regulatory Officer Tessera Therapeutics, Inc. Somerville, MA

# Donald B. Kohn, M.D.

Expertise: Gene Therapies for Blood Diseases Term: 08/23/2022-03/31/2025
Distinguished Professor
Departments of Microbiology, Immunology and Molecular Genetics, Pediatrics,
Molecular and Medical Pharmacology
David Geffen School of Medicine at UCLA
University of California, Los Angeles
Los Angeles, CA

#### Christopher K. Breuer, M.D.+

Expertise: General Surgery and Pediatric

Surgery

Term: 06/07/2018-03/31/2026

Director of Tissue Engineering Program and

Surgical Research

Director, Center for Regenerative Medicine

Nationwide Children's Hospital

Columbus, OH

# Melissa A. Greenwald, M.D., CAPT USPHS (Ret.) ~+

Expertise: Alternate Industry Representative

Term: 07/18/2024-03/31/2028 Medical, Scientific, and Regulatory

Consultant

MA Greenwald Consulting, LLC

Chicago, IL

# Wendy B. London, Ph.D.

Expertise: Biostatistics, Clinical Trial Design

Oncology

Term: 04/01/2023-03/31/2027 Associate Professor of Pediatrics

Boston Children's Hospital/Dana-Farber

Cancer Institute

Harvard Medical School

Boston, MA

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# MEMBERS (CONT'D)

# Troy Lund, Ph.D., M.D.

Expertise: Gene Therapy, Biomedical Sciences, Stem Cell Biology
Term: 08/30/2024-03/31/2028
Associate Director Metabolic Program
Pediatric Blood and Marrow Transplant
Division of Pediatric Blood and Marrow
Transplantation and Cellular Therapy
University of Minnesota Medical Center
Minneapolis, MN

# Kathleen O'Sullivan-Fortin, Esq. \*\*

Expertise: Consumer Representative Term: 08/23/2022-03/31/2025 Founder, ALD Connect, Inc. Middleton, MA

#### Nirali N. Shah M.D., M.H.Sc. +

Expertise: Hematology and Oncology Term: 02/04/2022-03/31/2026 Head, Hematologic Malignancies Section Pediatric Oncology Branch Lasker Clinical Research Scholar National Cancer Institute Bethesda, MD

### Sean J. Morrison, Ph.D.

Expertise: Stem Cell Biology
Term: 06/07/2018-03/31/2026
Director
Children's Medical Center Research Institute
University of Texas Southwestern Medical
Center
Dallas, TX

#### Melanie Ott, M.D., Ph.D.

Expertise: Virology and Immunology Term: 04/01/2022-03/31/2026 Director, Senior Investigator, Gladstone Institute of Virology Senior Vice President, Gladstone Institutes University of California, San Francisco San Francisco, CA

# Evan Y. Snyder, M.D., Ph.D.

Expertise: Neurobiology, Cell Biology Pediatric Neurology Term: 08/30/2024-03/31/2028 Director, Center for Stem Cells and Regenerative Medicine Professor, Human Genetics Program Sanford Burnham Prebys Medical Discovery Institute La Jolla, CA

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# MEMBERS (CONT'D)

# Cynthia J. Tifft, M.D., Ph.D.

Expertise: Gene Therapy, Pediatrics Lysosomal Storage Disorders Term: 08/30/2024-03/31/2028 Deputy Clinical Director and Senior Clinician

Director, Pediatric Undiagnosed Diseases

Program

National Human Genome Research Institute

National Institutes of Health

Bethesda, MD

#### Gil I. Wolfe, M.D., F.A.A.N.

Expertise: Neurology

Term: 02/04/2022-03/31/2026 SUNY Distinguished Professor

Neurology Chief of Service, Kaleida Health

Department of Neurology

Jacobs School of Medicine and Biomedical Sciences University at Buffalo/SUNY

Buffalo, NY

# Joseph Wu, M.D., Ph.D.

Expertise: Cardiology and Radiology Term: 11/28/2016-03/31/2025 Director, Stanford Cardiovascular Institute Professor of Medicine and Radiology Stanford University Stanford, CA

# **TEMPORARY VOTING MEMBERS (TVMs)**

#### Sanjay P. Ahuja, M.D., M.Sc., M.B.A.

Expertise: Pediatric Hematology, Bleeding

Disorders

Chief Medical & Informatics Officer

Innovative Hematology, Inc.

Indiana Hemophilia and Thrombosis Center Inc.

Indianapolis, IN

#### Andrei L. Kindzelski, M.D., Ph.D.

Expertise: Hematology

Chief, Translational Blood Science and

Resources Branch

Division of Blood Diseases and Resources National Heart, Lung, and Blood Institute

National Institutes of Health

Bethesda, MD

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# TEMPORARY VOTING MEMBERS (TVMs) (CONT'D)

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Expertise: Vascular Neurology

Director

National Institute of Neurological Disorders

and Stroke

National Institutes of Health

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Joseph P. O'Brien, M.B.A.

Expertise: Patient Representative President and Chief Executive Officer

National Scoliosis Foundation, Inc.

Stoughton, MA

Thomas L. Ortel, M.D., Ph.D.

Expertise: Hematology

Chief, Division of Hematology

Professor of Medicine & Pathology

Medical Director, Clinical Coagulation

Laboratory

Duke University Medical Center

Durham, NC

Rajiv Ratan, M.D., Ph.D.

Expertise: Neurology Chief Executive Officer

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Associate Dean Weill Cornell Medicine

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#### FDA PARTICIPANTS

Peter W. Marks, M.D., Ph.D.

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CBER, FDA

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Office of Therapeutic Products (OTP)

CBER, FDA

Lola Fashovin-Aje, M.D., M.P.H.

Director

Office of Clinical Evaluation (Cell, Tissue,

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Lin Huo, Ph.D.

Lead Mathematical Statistician

Division of Biostatistics

Office of Biostatistics and Pharmacovigilance

CBER, FDA

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# FDA PARTICIPANTS (CONT'D)

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Medical Officer Mathematical Statistician
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OTP, CBER, FDA CBER, FDA

# FDA ADMINISTRATIVE STAFF

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Committee Management Officer

Joanna Malsch Tonica Burke, B.S.

Division of Scientific Advisors and

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CBER, FDA

+ Not Attending

\*\* Consumer Representative

\*\*\* Industry Representative

~Alternate Industry Representative

\*\*\*\* Chairperson

Committee Management Specialist