

**FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)**

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
June 20, 2019

AGENDA

During the morning session, the particular matter for this meeting will be review and discussion of the FDA Reauthorization Act of 2017 (FDARA) mandated Relevant Pediatric Molecular Target List now posted on the FDA website: <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OCE/ucm544641.htm>. FDA is required by statute to review and update the previously approved and published lists. The focus of the discussion will be limited to two target “classes” included in the Relevant Pediatric Molecular Target List: (1) targets linked to cell lineage and (2) targets on normal immune cells and cells in the tumor microenvironment. Planned introductory presentations will be on: (1) cell-based therapy approaches to childhood cancer and (2) novel membrane antigen determinants in pediatric tumors.

During the afternoon session, information will be presented to gauge investigator interest in exploring potential pediatric development plans for a product in development for adult cancer indications. The subcommittee will consider and discuss issues concerning diseases to be studied, patient populations to be included, and possible study designs in the development of this product for pediatric use. The discussion will also provide information to the Agency pertinent to the formulation of written requests for pediatric studies, if appropriate. The product under consideration is ONC201, presentation by Oncoceutics Inc.

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| 9:00 a.m. | Call to Order and Introduction of Subcommittee | Alberto S. Pappo, MD
Chairperson, pedsODAC |
| 9:05 a.m. | Conflict of Interest Statement | Lauren Tesh Hotaki, PharmD, BCPS
Designated Federal Officer, ODAC |
| 9:10 a.m. | Introductory Remarks:
Relevant Molecular Targets for Cancer Drug
Development for Children | Gregory H. Reaman, MD
Associate Director for Pediatric Oncology
Oncology Center of Excellence
Office of the Commissioner
Associate Director for Oncology Sciences
Office of Hematology and Oncology Products
Office of New Drugs, CDER, FDA |
| 9:15 a.m. | GUEST SPEAKER PRESENTATION

Immunotherapies for Pediatric Cancer:
Current Status and Future Prospects (with an
emphasis on Targets) | Crystal L. Mackall, MD
Ernest and Amelia Gallo Family Professor of
Pediatrics and Medicine
Director, Stanford Center for Cancer Cell Therapy
Director, Parker Institute for Cancer
Immunotherapy at Stanford
Associate Director, Stanford Cancer Institute
Stanford University |
| 9:45 a.m. | Clarifying Questions | |

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AGENDA (cont.)

9:55 a.m. **GUEST SPEAKER PRESENTATION**

Immunogenomic Approaches to More Effective
Childhood Cancer Therapies

Kris Bosse, MD

Assistant Professor of Pediatrics
Perelman School of Medicine at the University of
Pennsylvania
Evan Lindberg Neuroblastoma Research Scholar
Attending Physician, Division of Oncology
Children's Hospital of Philadelphia

10:25 a.m. Clarifying Questions

10:35 a.m. **BREAK**

10:50 a.m. **OPEN PUBLIC HEARING**

11:20 a.m. Questions to the Subcommittee and
Subcommittee Discussion

12:00 p.m. **LUNCH**

1:00 p.m. Call to Order and Introduction of Subcommittee

Alberto S. Pappo, MD

Chairperson, pedsODAC

1:10 p.m. Conflict of Interest Statement

Lauren Tesh Hotaki, Pharm.D, BCPS

Designated Federal Officer, ODAC

1:15 p.m. Introductory Remarks

Gregory H. Reaman, MD

1:20 p.m. **INDUSTRY PRESENTATION - ONC201**

Oncoceutics Inc.

ONC201: The First Imipridone for the
Treatment of H3 K27M-mutant High Grade
Glioma

Wolfgang Oster, MD, PhD

Chief Executive Officer, Oncoceutics Inc.

Josh Allen, PhD

Senior Vice President of R&D, Oncoceutics Inc.

Patrick Wen, MD

Professor, Neurology, Harvard Medical School
Director, Center For Neuro-Oncology
Dana-Farber Cancer Institute

Sabine Mueller, MD, PhD

Assistant Professor of Clinical Neurology
University of California at San Francisco Hellen
Diller Family Comprehensive Cancer Center

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AGENDA (cont.)

1:40 p.m. Clarifying Questions

1:50 p.m. **OPEN PUBLIC HEARING**

2:20 p.m. Questions to the Subcommittee and
Subcommittee Discussion

3:20 p.m. FDA Closing Remarks

Gregory H. Reaman, MD

3:30 p.m. **ADJOURNMENT**