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

Pediatric 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 28 - 29, 2016

DRAFT AGENDA

On June 28, 2016, information will be presented for expert assessments related to exploring potential pediatric development plans for four products in various stages of 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 these products 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 products under consideration are: (1) venetoclax, presentation by AbbVie, Inc. (2) tazemetostat, presentation by Epizyme, Inc., and (3) atezolizumab, presentation by Roche/Genentech.

8:00 a.m.	Call to Order Introduction of Subcommittee	**Alberto Pappo, MD** Chairperson, Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC)
8:10 a.m.	FDA Introductory Remarks/Presentation	**Gregory Reaman,MD** Associate Director for Oncology Sciences Office of Hematology and Oncology Products (OHOP), Office of New Drugs (OND) CDER, FDA
8:15 a.m.	**Topic 1: ABT-199 (Venetoclax) – AbbVie, Inc.**	
	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**
8:20 a.m.	**INDUSTRY PRESENTATION**	**AbbVie, Inc.**
	Venetoclax for the Treatment of Pediatric Patients with Relapsed/Refractory Cancers	**Su Young Kim, MD, PhD** Medical Director, Oncology Development AbbVie, Inc.
8:40 a.m.	Clarifying Questions from Subcommittee	
8:50 a.m.	**OPEN PUBLIC HEARING**	
9:10 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
10:10 a.m.	**BREAK**	
10:25 a.m.	**Topic 2: Tazemetostat – Epizyme, Inc.**	
	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**

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10:30 a.m.	**INDUSTRY PRESENTATION**	**Epizyme, Inc.**
	Tazemetostat for the Treatment of Pediatric Subjects with Malignant Rhabdoid Tumors and Other INI1-Negative Tumors	**Peter Ho, MD, PhD** Chief Medical Officer Epizyme, Inc.
10:50 a.m.	Clarifying Questions from Subcommittee	
11:00 a.m.	**OPEN PUBLIC HEARING**	
11:20 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
12:20 pm.	**LUNCH**	
1:20p.m.	**Topic 3: Atezolizumab- Roche/Genentech**	
	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**
1:25 p.m.	**INDUSTRY PRESENTATION**	**Roche/Genentech**
	Atezolizumab Oncology Development	**Raphaël Rousseau, MD, PhD** Global Head, Pediatric Oncology Drug Development Group Genentech, a member of the Roche Group
1:45 p.m.	Clarifying Questions from Subcommittee	
1:55 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:15 p.m.	**ADJOURNMENT**	

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DRAFT AGENDA (cont.)

On June 29, 2016, during the morning session, information will be presented for expert assessments related to exploring potential pediatric development plans for two products in various stages of 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 these products 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 products under consideration are: (1) LOXO-101, presentation by Loxo Oncology, Inc., and (2) entrectinib, presentation by Ignyta, Inc.

During the afternoon session, information will be presented on the current unmet clinical need in the nearly uniformly fatal brain tumor, diffuse intrinsic pontine glioma (DIPG) which occurs predominantly in the pediatric age group. The diagnosis of DIPG is typically based on characteristic radiographic and clinical features in lieu of brain biopsy, and histological confirmation. Recent data has demonstrated that the biology and pathophysiology of these tumors differ. There are no approved drugs for this disease. Clinical investigators seek to exploit precision medicine approaches to DIPG and use potentially predictive information from the genomic signature of tumors at either diagnosis or relapse. This information can be used to select specific molecularly targeted drugs based on the genetic aberrations of an individual patient's tumor. The Agency will seek the input of the subcommittee, including an assessment of benefit/risk given the potential for an adverse event associated with a surgical intervention in the brainstem.

8:00 a.m.	Call to Order Introduction of Subcommittee	**Alberto Pappo, MD** Chairperson, Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (ODAC)
8:10 a.m.	FDA Introductory Remarks/Presentation	**Gregory Reaman, MD** Associate Director for Oncology Sciences, Office of Hematology and Oncology Products (OHOP), Office of New Drugs (OND) CDER, FDA
8:15 a.m.	**Topic 1: LOXO-101- Loxo Oncology, Inc.**	
	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS** Designated Federal Officer, ODAC
8:20 a.m.	**INDUSTRY PRESENTATION**	**Loxo Oncology, Inc.**
	Developing LOXO-101 in Children with NTRK Gene Fusion Cancers	**Josh Bilenker, MD** Chief Executive Officer Loxo Oncology, Inc.
8:40 a.m.	Clarifying Questions from Subcommittee	
8:50 a.m.	**OPEN PUBLIC HEARING**	

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9:10 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
10:10 a.m.	**BREAK**	
10:20 a.m.	**Topic 2: Entrectinib – Ignyta, Inc.**	
	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**
10:25 a.m.	**INDUSTRY PRESENTATION**	**Ignyta, Inc.**
	Entrectinib	**Pratik S. Multani, MD, MS** Chief Medical Officer at Ignyta, Inc.
10:45 a.m.	Clarifying Questions from Subcommittee	
10:55 a.m.	**OPEN PUBLIC HEARING**	
11:15 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
12:15 pm.	**LUNCH**	
1:15 p.m.	**Topic 3: Diffuse Intrinsic Pontine Glioma (DIPG)**	
	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS**
1:20 p.m	FDA Introductory Remarks	**Joohee Sul, PhD** Medical Officer Division of Oncology Products II (DOPII) OHOP, OND, CDER, FDA
1:25 p.m.	**FDA PRESENTATIONS**	
	To Biopsy or Not to Biopsy – That is the Question.	**Robert (Skip) Nelson, MD** Deputy Director and Senior Pediatric Ethicist Office of Pediatric Therapeutics Office of the Commissioner, FDA
	Biopsy Risks for Investigational in vitro Diagnostic Devices	**Jeffrey D. Seidman, MD** Medical Officer/Pathologist Molecular Pathology and Cytology Branch Division of Molecular Genetics and Pathology Office of In Vitro Diagnostics and Radiological Health Center for Devices and Radiological Health FDA

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2:10 p.m.	**SPEAKER PRESENTATION**	
	Treatment Opportunities in Diffuse Intrinsic Pontine Glioma (DIPG)	**Mark W. Kieran, MD, PhD** Director, Pediatric Medical Neuro-Oncology Dana-Farber Cancer Institute/Boston Children's Hospital Director, Pediatric Brain Tumor Clinic Dana-Farber Cancer Institute/Boston Children's Hospital Associate Professor of Pediatrics Harvard Medical School
2:25 p.m.	**GUEST SPEAKER PRESENTATIONS**	
	Surgical Experience with Biopsy of Brainstem Tumors	**Nalin Gupta, MD, PhD** Professor in Residence of Neurological Surgery and Pediatrics Dennis Bruce Dettmer Endowed Chair in Pediatric Neurosurgery Director, Pediatric Neurological Surgery Program Principal Investigator, Brain Tumor Research Center University of California, San Francisco
	DIPG: The Role of Neurosurgery	**Jeffrey R. Leonard, MD** Pediatric Neurosurgeon Chief of Neurosurgery Nationwide Children's Hospital Professor, Department of Neurological Surgery The Ohio State University
	Clarifying Questions from Subcommittee	
2:50 p.m.	**BREAK**	
3:05 p.m.	**OPEN PUBLIC HEARING**	
3:25 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
4:25p.m.	Closing Remarks	**Gregory Reaman, MD**
4:30 p.m.	**ADJOURNMENT**	