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

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting
June 17 - 18, 2020

AGENDA

On June 17, 2020, information will be presented regarding pediatric development plans for two products that are in early development for an oncology indication. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of written requests for pediatric studies, if appropriate. The two products under consideration are: (1) SP 2577, presentation by Salarius Pharmaceuticals, Inc. and (2) Marizomib, presentation by Celgene International II Sàrl, a wholly owned subsidiary of Bristol-Myers Squibb.

10:00 a.m.	Call to Order Introduction of Subcommittee	**Alberto S. Pappo, MD** Chairperson, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC)
10:10 a.m.	Introductory Remarks	**Gregory Reaman, MD** Associate Director for Pediatric Oncology Oncology Center of Excellence Office of the Commissioner Associate Director for Oncology Sciences Office of Oncologic Diseases Office of New Drugs, CDER, FDA
10:15 a.m.	**Topic 1: SP-2577 – Salarius Pharmaceuticals, Inc.**	
	Conflict of Interest Statement	**CDR LaToya Bonner, PharmD** Acting Designated Federal Officer, pedsODAC
10:20 a.m.	**INDUSTRY PRESENTATIONS**	**Salarius Pharmaceuticals, Inc.**
	Introduction	**David Arthur** Chief Executive Officer Salarius Pharmaceuticals, Inc.
	SP-2577 (Seclidemstat): Mechanism of Action, Designs Rationale, and Preclinical Data	**Bruce McCreedy, PhD** Chief Scientific Officer Salarius Pharmaceuticals, Inc.
	Relapsed Ewing Sarcoma Lacks a Standard of Care	**Damon Reed, MD** Associate Professor Moffitt Cancer Center
	Seclidemstat Clinical Trials	**Margaret Dugan, MD** Consulting Sr. Medical Advisor

10:40 a.m.	Clarifying Questions from Subcommittee	
10:50 a.m.	**OPEN PUBLIC HEARING**	
11:20 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
12:20 p.m.	**LUNCH**	
1:20 p.m.	**Topic 2: Marizomib – Celgene International II Sàrl, a wholly owned subsidiary of Bristol-Myers Squibb**	
	Call to Order Introduction of Subcommittee	**Alberto S. Pappo, MD**
	Conflict of Interest Statement	**CDR LaToya Bonner, PharmD**
1:25 p.m.	**INDUSTRY PRESENTATIONS**	**Celgene International II Sàrl, a wholly owned subsidiary of Bristol-Myers Squibb**
	Introduction	**Deborah Tady, PharmD, RAC** Executive Director, Global Regulatory Strategy Celgene, a Bristol-Myers Squibb Company
	Pediatric Research Commitment/ Marizomib Development	**Sherry A. Leonard, BSc, RAC** Director, Global Regulatory Strategy Celgene, a Bristol-Myers Squibb Company
	Regulatory History & Key Activities for Pediatric Development	
	Molecular Mechanism of Action	**Mark W. Kieran, MD, PhD** Senior Director, Pediatric Oncology Bristol-Myers Squibb
	Clinical Trial Experience in Adults	
	Ongoing and Planned Clinical Trials in Pediatrics	

AGENDA (cont.)

1:45 p.m.	Clarifying Questions from Subcommittee	
1:55 p.m.	**OPEN PUBLIC HEARING**	
2:25 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:25 p.m.	Closing Remarks	**Gregory Reaman, MD**
3:30 p.m.	**ADJOURNMENT**	

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AGENDA (cont.)

On June 18, 2020, information will be presented regarding pediatric development plans for two products that are in early development for an oncology indication. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of written requests for pediatric studies, if appropriate. The two products under consideration are: (1) CD30.CAR-T, presentation by Tessa Therapeutics and (2) SNDX-5613, presentation by Syndax Pharmaceuticals, Inc.

10:00 a.m.	Call to Order Introduction of Subcommittee	**Alberto S. Pappo, MD** Chairperson, Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC)
10:10 a.m.	Introductory Remarks	**Gregory Reaman, MD** Associate Director for Pediatric Oncology Oncology Center of Excellence Office of the Commissioner Associate Director for Oncology Sciences Office of Oncologic Diseases Office of New Drugs, CDER, FDA
10:15 a.m.	**Topic 1: CD30.CAR-T – Tessa Therapeutics**	
	Conflict of Interest Statement	**CDR LaToya Bonner, PharmD** Acting Designated Federal Officer, pedsODAC
10:20 a.m.	**INDUSTRY PRESENTATION**	**Tessa Therapeutics**
	CD30.CAR-T for Treatment of Patients with Relapsed or Refractory CD30-positive Classical Hodgkin Lymphoma	**Ivan Horak, MD** President of Research and Development Tessa Therapeutics
10:40 a.m.	Clarifying Questions from Subcommittee	
10:50 a.m.	**OPEN PUBLIC HEARING**	
11:20 a.m.	Questions to the Subcommittee and Subcommittee Discussion	
12:20 p.m.	**LUNCH**	

AGENDA (cont.)

1:20 p.m.	**Topic 2: SNDX-5613 – Syndax Pharmaceuticals, Inc.**	
	Call to Order Introduction of Subcommittee	**Alberto S. Pappo, MD**
	Conflict of Interest Statement	**CDR LaToya Bonner, PharmD**
1:25 p.m.	**INDUSTRY PRESENTATION**	**Syndax Pharmaceuticals, Inc.**
	SNDX-5613 for the Treatment of Pediatric MLL-r Acute Leukemias	**Michael Meyers, MD, PhD** Chief Medical Officer Syndax Pharmaceuticals, Inc.
1:45 p.m.	Clarifying Questions from Subcommittee	
1:55 p.m.	**OPEN PUBLIC HEARING**	
2:25 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:25 p.m.	Closing Remarks	**Gregory Reaman, MD**
3:30 p.m.	**ADJOURNMENT**	