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

Oncologic Drugs Advisory Committee Meeting

March 14, 2024

DRAFT AGENDA

The Committee will discuss new drug application (NDA) 217779 for imetelstat for injection, submitted by Geron Corporation. The proposed indication for this product is for the treatment of transfusion-dependent anemia in adult patients with low- to intermediate-1 risk myelodysplastic syndromes who have failed to respond or have lost response to or are ineligible for erythropoiesis-stimulating agents.

9:30 a.m.	Call to Order	**Ravi A. Madan, MD** Chairperson, ODAC
9:35 a.m.	Introduction of Committee and Conflict of Interest Statement	**LaToya Bonner, PharmD** Acting Designated Federal Officer, ODAC
9:40 a.m.	FDA Introductory Remarks	**Lori Ehrlich, MD, PhD** Cross-disciplinary Team Leader Division of Hematologic Malignancies I (DHMI) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:00 a.m.	**APPLICANT PRESENTATIONS**	**Geron Corporation**
	Introduction	**Sharon McBain, BSc** Senior Vice President, Global Head of Regulatory Affairs Geron Corporation
	Clinical Results	**Faye Feller, MD** Chief Medical Officer Geron Corporation
	Unmet Medical Need for Treatment in Low-Risk Myelodysplastic Syndromes	**Michael Savona, MD** The Beverly and George Rawlings Director of Hematology Research Professor of Medicine and Cancer Biology Vanderbilt University School of Medicine

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Perspective	**Rami Komrokji, MD** Vice Chair, Malignant Hematology Department Lead Clinical Investigator, MDS Program H. Lee Moffitt Cancer Center & Research Institute Professor of Oncologic Sciences University of South Florida
	Conclusion	**Faye Feller, MD**
10:45 a.m.	**FDA PRESENTATIONS**	
	Imetelstat for the Treatment of Transfusion-Dependent Anemia in Patients with Lower Risk Myelodysplastic Syndromes who have Not Responded to or have Lost Response to or are Ineligible for Erythropoiesis-Stimulating Agents - Efficacy	**Nina Kim, MD** Clinical Reviewer DHM1, OOD, OND, CDER, FDA
11:30 a.m.	Clarifying Questions to the Presenters	
12:30 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**ADJOURNMENT**	