FOOD AND DRUG ADMINISTRATION (FDA)
Center for Biologics Evaluation and Research (CBER)
77th Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC)
November 21, 2024
DRAFT AGENDA

The committee will meet in open session to discuss and make recommendations on supplemental biologics license application (sBLA) 125586/546 from Astra Zeneca to confirm clinical benefit of Andexxa (coagulation factor Xa (recombinant), inactivated -zhzo) for patients treated with rivaroxaban or apixaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Time EDT	Presentation/Presenter
10:00 a.m.	**Opening Remarks: Call to Order and Welcome (5 Min)** Tabassum (Taby) Ahsan, Ph.D., Chairperson, CTGTAC Vice President, Cell Therapy Operations City of Hope, Duarte, CA **Administrative Announcements, Roll Call, Introduction of Committee, Conflict of Interest Statement (20 Min)** Cicely Reese, Pharm.D., LCDR, USPHS, Designated Federal Officer Division of Scientific Advisors and Consultants, Office of Management CBER, FDA
10:25 a.m.	**FDA Introduction (5 Min)** **Introductory Remarks** • **Nicole Verdun, M.D.** Super Office Director Office of Therapeutic Products (OTP), CBER, FDA
10:30 a.m.	**Applicant Presentations (60 Min including Q & A)** Introduction — **Jeffy John, M.B.A.** Director, Regulatory Affairs AstraZeneca BioPharmaceuticals Burden of Life-Threatening Bleeds Related to FXa Inhibitors and Need For Effective Reversal Agents — **Paul A. Nyquist, M.D., M.P.H.** Professor of Neurology Co-Director, Johns Hopkins Bayview Neurocritical Unit, Johns Hopkins School of Medicine Andexanet Efficacy — **Per Ladenvall, M.D., Ph.D.** Global Clinical Head, AstraZeneca BioPharmaceuticals

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	Andexanet Safety	**Rohit Narayan, M.B.Ch.B.** Patient Safety Physician AstraZeneca BioPharmaceuticals
	Clinical Perspective	**Ashkan Shoamanesh, M.D., F.R.C.P.C.** Associate Professor of Medicine (Neurology) Director, Hemorrhagic Stroke Research Program Mart and Owen Boris Chair in Stroke Research and Care, McMaster University/Population Health Research Institute
	Benefit: Risk Considerations – Conclusions	**Matthew Roe, M.D., M.H.S.** Cardiologist, Adjunct Professor of Medicine Duke University Medical Center, Vice President Head of Early CVRM Clinical Development AstraZeneca BioPharmaceuticals
	Q & A (15 Min)	
11:30 a.m.	**<u>FDA Presentations</u> (60 Min including Q & A)**	
	sBLA 125586/546	**Christine Knoll, M.D. and Karl Kasamon, M.D.** Medical Officers Division of Clinical Evaluation and Hematology Office of Clinical Evaluation OTP, CBER, FDA
	Q & A (15 Min)	
12:30 p.m.	**LUNCH (40 Min)**	
1:10 p.m.	**<u>Open Public Hearing</u> (60 Min)**	
2:10 p.m.	**BREAK (10 Min)**	
2:20 p.m.	**<u>Committee Discussion</u> (95 min)**	
3:55 p.m.	**<u>Closing Remarks</u> (5 Min)** • **Nicole Verdun**	
4:00 p.m.	**ADJOURNMENT**	