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

Oncologic Drugs Advisory Committee (ODAC) Meeting
Sheraton College Park North Hotel, Chesapeake Ballroom
4095 Powder Mill Road, Beltsville, Maryland
March 29, 2017

AGENDA

The committee will discuss biologics license application (BLA) 761064, rituximab/hyaluronidase injection for subcutaneous use, submitted by Genentech, Inc. The proposed indications (uses) for this product are for: (1) The treatment of patients with relapsed or refractory, follicular lymphoma as a single agent; (2) previously untreated follicular lymphoma in combination with first line chemotherapy and, in patients achieving a complete or partial response to rituximab/hyaluronidase for subcutaneous injection in combination with chemotherapy, as single-agent maintenance therapy; (3) non-progressing (including stable disease), follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy; (4) the treatment of patients with previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, prednisolone (CHOP) or other anthracycline based chemotherapy regimens; and (5) in combination with fludarabine and cyclophosphamide (FC), for the treatment of patients with previously untreated and previously treated chronic lymphocytic leukemia (CLL).

8:00 a.m.	Call to Order and Introduction of Committee	**Bruce J. Roth, MD** Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS** Designated Federal Officer, ODAC
8:10 a.m.	Opening Remarks	**R. Angelo de Claro, MD** Medical Team Leader Division of Hematology Products (DHP) Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Genentech, Inc.**
	Rituximab SC Development Rationale	**Nancy Valente, MD** Head of Global Hematology Development Genentech
	Rituximab SC Clinical Perspective	**Andrew Davies, BM PhD** Associate Professor in Medical Oncology University of Southampton
	Rituximab SC Clinical Pharmacology	**Peter Morcos, PharmD** Clinical Pharmacologist Genentech
	Rituximab SC Clinical Development Concluding Remarks	**Axel Boehnke, MD** Global Development Team Leader Genentech

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AGENDA (cont.)

9:00 a.m.	**FDA PRESENTATIONS**	
	Rituximab and Hyaluronidase - BLA 761064	
	Clinical Pharmacology	**Lanre Okusanya, PharmD, MS** Clinical Pharmacologist Division of Clinical Pharmacology V (DCPV) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
	Efficacy	**Jingjing Ye, PhD** Mathematical Statistician Division of Biometrics V (DBV) Office of Biometrics (OB), OTS, CDER, FDA
	Safety	**Alexandria Schwarsin, MD** Medical Officer DHP, OHOP, OND, CDER, FDA
	Patient Preference and Patient Reported Outcomes	**Vishal Bhatnagar, MD** Medical Officer DHP, OHOP, OND, CDER, FDA
9:45 a.m.	Clarifying Questions to the Presenters	
10:15 a.m.	**BREAK**	
10:30 a.m.	Open Public Hearing	
11:30 a.m.	Questions to the Committee/Committee Discussion	
12:30 p.m.	**ADJOURNMENT**	