BLA 125518 (Amgen; talimogene laherparepvec for treatment of melanoma)

Telecon

Date: 3/13/2015
Time: 11:00 – 11:30 a.m.
(b) (4) Conference ID: (b) (4)

This telecon was requested by Amgen.

Amgen Participants

Peter Feldman, MBA	Global Product General Manager
Greg Friberg, MD	Executive Director, Global Development
Jennifer Gansert, MD, PhD	Executive Director, Global Development
Michelle Pernice, PharmD	Manager, Global Regulatory Affairs
Lisa Shamon, PhD	Director, Global Regulatory Affairs
Mark Taisey	Vice President, Global Regulatory Affairs
Rhian Thomas, BSc	Executive Director, Global Regulatory Affairs
Michael Wolf, MS	Director, Biostatistics

FDA Participants

Mark Davidson, RHIA,	Consumer Safety Officer, Regulatory Management Staff
Abigail Luo, PhD,	Mathematical Statistics, Office of Biostatistics
Shiowjen Lee, PhD	Lead Mathematical Statistics, Office of Biostatistics
Boguang Zhen PhD,	Branch Chief, Office of Biostatistics
Maura O'Leary,MD,	Medical Officer, OCTGT/DCEPT
Ramjay Vatsan, PhD,	Chemist, OCTGT / DCGT
Wilson, Bryan, MD,	Director/DCEPT
Peter Bross, MD,	Medical Officer / DCEPT
Ke Liu, MD, PhD,	Branch Chief /DCEPT
Meghna Alimchandani, PhD	OBE/ Epidemiology

Proceedings

FDA expressed appreciation for the follow-up data on survival on three of the ten subjects with potentially informative censoring. There was brief discussion of a new sensitivity analysis proposed by Amgen. FDA did not endorse the analysis, but stated that Amgen should conduct whatever analyses they think will be informative. Amgen expressed their intention to submit the analysis to the BLA and to present this sensitivity analysis to the Advisory Committee. At FDA's request, Amgen agreed to submit sufficient details of the sensitivity analyses so that they may be reproducible. At this time, FDA does not intend to reproduce these analyses.

Action Items: None