

Amgen Teleconference Minutes

February 11, 2015, Thursday 4:15-4:45pm

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Conference ID: (b) (4)

Dr. Steven Galson emailed Dr. Peter Bross requesting a brief informal communication regarding T-VEC. In return, Dr. Bross emailed Amgen contact Michelle Pernice to verify Amgen authorization to let Dr. Galson have normal communication with FDA on their behalf and was approved to do so.

Dr. Galson requested advice regarding whether Amgen should modify the proposed indication given the recent approvals and currently available therapy in the proposed indication. FDA reminded Dr. Galson that the proposed BLA indication had already been revised to reflect the population included in the Phase 3 study, subjects with injectable regionally or distantly metastatic melanoma, and that the proposed indication should reflect the submitted clinical data. Dr. Galson thanked the FDA for the advice.

FDA Attendees:

Celia Witten
Peter Bross
Wilson Bryan,
Maura O’Leary
Robert Le
Mark Davidson

Amgen Attendees:

Steven Galson
Rhian Thomas