



MEMORANDUM

From: Kimberly Benton, Ph.D., Deputy Director, Division of Cellular & Gene Therapies
Raj Puri, M.D., Ph.D., Director, Division of Cellular & Gene Therapies, OCTGT, CBER

Date: October 16, 2015

BLA/ STN#: 125518

Applicant Name: Amgen

Date of Submission: July 28, 2014, major amendment November 28, 2014

Action Goal Date: October 27, 2015

Proprietary Name/ Established Name: Imlygic

Proper (Non-Proprietary name): talimogene laherparepvec

Indication: For the local treatment of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery

Product Reviewers: Ramjay Vatsan, Ph.D. (chair)
Robert Aksamit, Ph.D.
Andrew Byrnes, Ph.D.
Michael Havert, Ph.D.

Branch Chief: Denise Gavin, Ph.D.

Material Reviewed/Consulted:

CMC Review of Original Submission dated October 15, 2015

I agree with the recommendation for approval as stated in the CMC review memo dated October 15, 2015, and have no additional comments.

Kimberly Benton, Ph.D.

Raj K. Puri, M.D., Ph.D.