

# **PUBLIC VERSION**

## **Document 10**



GRANT –  
BREAKTHROUGH THERAPY DESIGNATION

Merck Sharp and Dohme Corp.  
Attention: Nahid Latif  
Executive Director  
351 North Sumneytown Pike  
UG 2CD 48  
P.O. Box 1000  
North Wales, PA 19454

Dear Ms. Latif:

[REDACTED]

[REDACTED]

[REDACTED] For

further information regarding Breakthrough Therapy designation and FDA actions to expedite development of a designated product, please refer to section 902 of the Food and Drug Administration Safety and Innovation Act (FDASIA) and the *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics*.<sup>1</sup>

When Breakthrough Therapy designation is granted, sponsors are asked to submit a Type B meeting request for a multidisciplinary comprehensive discussion of the drug development program, including planned clinical trials and plans for expediting the manufacturing development strategy. Please refer to MAPP 6025.6 - *Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics*, Attachment 1, for potential topics for

<sup>1</sup> <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf>

discussion at this initial Breakthrough Therapy meeting<sup>2</sup>. [REDACTED]

If the Breakthrough Therapy designation for pembrolizumab for the treatment of patients with unresectable or metastatic non-colorectal MSI-H-positive cancers who have progressed on or who have no satisfactory alternative treatments is rescinded, submission of portions of the sBLA will not be permitted under this program. However, if you have Fast Track designation you will be able to submit portions of your application under the Fast Track program.

If you have any questions, please contact Ms. Sharon Sickafuse, Senior Regulatory Health Project Manager, at (301) 796-2320.

Sincerely,

*{See appended electronic signature page}*

Martha Donoghue, M.D.  
Associate Director (Acting)  
Division of Oncology Products 2  
Office of Hematology and Oncology Products  
Center for Drug Evaluation and Research

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<sup>2</sup>

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/default.htm>.

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/s/

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MARTHA B DONOGHUE  
