



Our STN: BL 125646/0

**PROPRIETARY NAME ACCEPTABLE**  
**May 2, 2017**

Novartis Pharmaceuticals Corporation  
Attention: Manisha Patel, PharmD  
One Health Plaza, Bldg. 315, Office 3450B  
East Hanover, NJ 07936

Dear Dr. Patel:

We have reviewed your February 2, 2017, submission to your Biologics License Application (BLA) for tisagenlecleucel-T, requesting a proprietary name review for KYMRIAH.

In consultation with Center for Biologics Evaluation and Research's Advertising and Promotional Labeling Branch (CBER/APLB), we conclude that, under the Federal Food, Drug, and Cosmetic Act and applicable regulations, KYMRIAH is Acceptable.

If you have any questions, please contact the Regulatory Project Manager, Erica Giordano, at (240) 402 - 8298.

Sincerely yours,

Ramani Sista, PhD  
Director  
Division of Regulatory Project Management  
Office of Tissues and Advanced Therapies  
Center for Biologics Evaluation and Research