DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

BLA 761065/S-001

SUPPLEMENT APPROVAL

Theratechnologies Inc.
Attention: Elizabeth Wishart, B.Sc., MBA
US Agent on behalf of Theratechnologies Inc.
Mapi USA, Inc.
2343 Alexandria Drive, Suite 100
Lexington, KY 40504

Dear Ms. Wishart:

Please refer to your Supplemental Biologics License Application (sBLA), dated and received May 29, 2018, submitted under section 351(a) of the Public Health Service Act for TROGARZO (ibalizumab-uiyk) injection.

This "Changes Being Effected" supplemental biologics application provides for the following changes to the US Prescribing Information:

- Section 2.2 Preparation: addition of the missing word "of" in the caption for Table 1
- Section 14 Clinical Studies: removal of the specified three classes of antiretroviral medications in the parentheses (NRTI, NNRTI, and PI) to be consistent with the respective inclusion criterion from TMB-301 study protocol

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the prescribing information, text for the patient package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in MS Word format that includes the changes approved in this supplemental application.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, please contact Elizabeth Thompson, M.S., Chief, Project Management Staff, at (301) 796-0824 or via email at elizabeth.thompson@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Director
Division of Antiviral Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

POONAM MISHRA
05/30/2018
on behalf of Debra Birnkrant, M.D.