October 7, 2021

Debyani Chakravarty, Ph.D.
Lead Scientist and Database Administrator
Marie-Josée and Henry R. Kravis Center for Molecular Oncology
Memorial Sloan Kettering Cancer Center
1275 York Avenue Box 20,
New York, NY 10065

Re: Q191007
OncoKB
Dated: May 24, 2019
Received: March 28, 2019

Dear Dr. Chakravarty:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your application for Recognition of OncoKB. We are pleased to inform you that the "FDA-Recognized Content" within the OncoKB database is recognized with the following scope:

> *Tumor-specific somatic alterations in solid neoplasms and associated clinical evidence limited to reporting "FDA Level 2" which are defined as "cancer mutations with evidence of clinical significance" and "FDA Level 3" which are defined as "cancer mutations with potential clinical significance".*

This recognition does not constitute marketing clearance or approval of this product as a medical device, and does not affect a previous clearance or approval of a device.

Data from FDA-recognized genetic variant databases would generally constitute valid scientific evidence that can be used in a premarket submission to support the clinical validity of the genotype-phenotype relationships embodied in the assertions that are provided from such databases. Under this policy, FDA expects that test developers will be able to use FDA-recognized genetic variant databases to establish, at least in part, the clinical validity of their test, provided that the evidence supports the intended use of the test. For premarket submissions that rely upon genetic variant databases recognized by FDA, the Agency may determine that submission of additional valid scientific evidence for certain variant assertions is necessary, depending on the sufficiency of the evidence for these assertions to support the intended use.

CDRH will notify the public of its decision to recognize a portion of the OncoKB database (i.e., the "FDA-Recognized Content"). You have provided consent for FDA to make public certain information regarding this recognition, and further you have committed to make documents publicly accessible on the genetic variant database's website at the time of FDA recognition.

You may request that CDRH incrementally expand or otherwise modify the recognized portion of your genetic variant database by submitting a new recognition package. If you do, please include a reference to the submission number shown at the top of this letter. CDRH also intends to reconsider recognition decisions as appropriate. For example, if the genetic variant database is not maintained according to the specifications under which it was recognized, FDA may withdraw recognition.

This notification is being sent in lieu of a formal written letter. If you have any questions, please contact Oscar Cano, M.D. at (240) 402-9092 or Oscar.Cano@fda.hhs.gov.

Sincerely yours,

Donna M. Roscoe -S

For Reena Philip, Ph.D.
Director
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health