



14 August 2019

VIA E-MAIL ONLY

James Love

Knowledge Ecology International

1621 Connecticut Ave. NW, Suite 500

Washington, DC 20009

IN RE: Prospective Grant of an Exclusive License (NIH License Application A-367-2019) to Kite Pharma, Inc., published on 12 July 2019 in *Federal Register* Vol. 84, No. 134, pages 33272

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of intent to grant a license to Kite Pharma, Inc. (Kite), by the National Cancer Institute (NCI).

Prior to posting a notice for a proposed grant of an exclusive license, the NCI determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied and that the company is qualified both technically and financially to be granted an exclusive license to the Government's intellectual property in the fields of use as specified. The notice period provides an opportunity for public comment and possible objection to the proposed license. We consider all comments prior to negotiating the proposed license.

While your comments have been given full consideration, they do not persuade us that the grant of an exclusive license to Kite for NCI technology E-205-2018-0 in the limited field of use described in the notice would be inconsistent with the regulations and, furthermore, advance public health. With respect to your concern that the license would be anticompetitive, we determined that this was not the case prior to the publication of the notice. Specifically, and as you noted in your own objection, there is already an FDA-approved alternative (Kymriah) to any therapeutic that would arise from the proposed license, said alternative being marketed by a competitor. Furthermore, there remain fields of use available within the E-205-2018-0 technology that could be licensed by other interested parties, and products from these prospective licenses could also compete with a Kite-developed therapy. Your other questions and statements have either been addressed in many previous responses to you or are not relevant to the statutory criteria for licensing.

In conclusion, NCI has determined that your objection did not raise an issue that would preclude the grant of the proposed exclusive license, and the NCI intends to proceed with the negotiation of the license.

Sincerely,
David A. Lambertson, Ph.D.
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