25 January 2018

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-039-2018) to Kite Pharma, Inc., published on 20 December 2017 in *Federal Register* Vol. 82, No. 243, pages 60406-7

Dear Mr. Love:

Thank you for providing us with your comments regarding the notice of the proposed 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-001-2016/0 in the limited field of use that has been advertised would be inconsistent with the regulations and, furthermore, advance public health. The reasons for this determination are set forth below:

1) With respect to your comment that it is premature to grant an exclusive license, thereby creating a monopoly, because the NIH is funding a Phase I clinical trial and may be able to fund subsequent trials depending on the outcome, the comment is not entirely accurate.
    a. First, because the field of use is limited only to specific anti-CD30 CARs using a specific antibody targeting component, a monopoly will not be created. There will remain fields of use available where another company can develop an anti-CD30 CAR using distinct targeting moieties, and these can compete with the CARs to be developed by Kite.
    b. Second, the ongoing Phase 1 clinical trial suggests that the time to license the invention is immediate. The NIH does not have the appropriate funding to conduct Phase 2 or Phase 3 clinical trials; if the Phase 1 trial ends prior to a license being executed with a company that can fund later clinical trials, there will be a significant delay in the development of the invention for public use, which is in direct contrast to the NIH mission.
2) With respect to your recommendations regarding pricing of products made by the licensee, NIH has not included pricing provisions in its licenses for many years, for reasons that have been extensively discussed in the literature, which is readily and publicly available.
3) With respect to the suggestion in your letter regarding Kite's research and development costs, etc., NCI does not have the authority to require a licensee to publicly disclose financial or business confidential information, and this would be inconsistent with the licensing regulations. We respectfully refer you to 37 C.F.R. 404.14.

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 proposed exclusive license, the terms of which have not yet been negotiated. All of the regulations and statutes governing the grant of an exclusive license have been adhered to during the evaluation of the Kite license application. If I can be of any further assistance, please let me know.

Sincerely,

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