DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
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September 5, 2019

Kathryn Ardizzone, Esq.

Re: Prospective Grant of an Exclusive Patent License: Development and Commercialization of CD19/CD22 Chimeric Antigen Receptor (CAR) Therapies for the Treatment of B-Cell Malignancies Federal Register / Vol. 84, No. 161 / Tuesday, August 20, 2019

Dear Kathryn,

Thank you for providing us with your comments regarding the aforementioned Federal Register notice. Prior to posting notices of the proposed grant of an exclusive commercial patent licenses, the NIH determines that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) are satisfied and that the company applying for the license is qualified both technically and financially to take on the development of a product in the proposed field based on United States Government owned intellectual property. 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 and have considered your comments.

In regards to this proposed license, pertaining to a clinical stage CAR-T therapy for B cell malignancies, we determined that the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) have been satisfied. Lyell demonstrated the scientific and financial capacity to develop CAR-T therapeutics to treat B cell malignancies. The scope of the license proposed is necessary for incentivizing the company to undertake the developmental risks to develop this type of therapy. The grant of exclusivity to the Government-owned intellectual property seeks to fulfill the Government's interest in promoting the public health and public access to therapeutics.

As it pertains to your comments on August 23, 2019, the E-106-2015 technology is being evaluated in clinical trials, while E-017-2017 is at the preclinical stage. I do not have additional information related to the costs, etc. of these clinical trials. Many of your questions relate to terms in the license which have not yet been negotiated and would be business confidential, however we can address that the world-wide territory typically pertains to the countries in which the relevant patents have been filed and ultimately issued. Patent protection for E-106-2015 is being pursued in the United States, while the E-017-2017 technology has not yet entered the national stage of patent filing . Your other questions have been answered in previous responses that apply to all proposed licenses or are not relevant to the criteria under 37 CFR 404.7(a)(1)(ii-iii) by which we evaluate an application for an exclusive license.

We have read through and considered the terms and suggestions you proffered. If your organization requests more documentation, such requests should be filed under the Freedom of Information Act. The webpage for the NIH FOIA Office provides more information on filing requests: http://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests.

Sincerely,

Jim Knabb, Ph.D.
Senior Technology Transfer Manager, NCI