DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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March 11, 2019

James Love
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Subject: Comments Submitted in Response to Federal Register Notice 2019-01431 (84 FR 2537), entitled "Prospective Grant of an Exclusive Patent License: Development and Commercialization of Cell Therapies for Cancer"

Dear Mr. Love:

Thank you for providing us with your comments regarding the above-referenced notice ("Notice"). As you indicated your comments were submitted on behalf of several organizations and individuals, we kindly request that you share our response with these same parties.

Prior to posting the Notice, the NCI determined that the criteria set forth in 37 CFR 404.7(a)(1)(ii(A)-iii) were satisfied and that the prospective licensee is qualified, both technically and financially, to be granted an exclusive license to the Government's intellectual property in the specified fields of use. 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. Specifically, we considered three comments you submitted in your objection.

On page two of your submission, you assert that the NIH has not explained where it will file national phase applications for all inventions subject to the Notice. At this time, the definitive list of national phase entries for all pending applications where this action remains possible is not known. Decisions regarding the filing of national phase applications are typically made a few months before the close of the relevant deadline specified in Article 22 of the Patent Cooperation Treaty.

On page four of your submission, you assert that the NIH has not provided "meaningful" information regarding how the proposed license meets the requirements specified in 35 USC §209. The determination made pursuant to 35 USC §209 is based, in part, on business confidential information provided by the prospective licensee and cannot be shared.

Also, on page four of your submission, you assert that the field(s) of use applicable to Intellectual Property Groups D and E be limited to certain targets (*e.g.*, KRAS, P53 and EGFR) and "to the use of transposon cell modification". First, as you may recall, the field of use provided in the Notice for Intellectual Property Group D does specify that the T cell therapy product be 1) reactive to P53, and 2) engineered by transposon-mediated gene transfer. Regarding Intellectual Property Group E, the applicable fields of use advertised in the Notice are supported by the prospective licensee's commercial development plan.

Finally, on pages six and seven, you provide specific terms which may be included in a license. We thank you for providing these proposals and will consider them, as appropriate, should a license be negotiated.

Sincerely,

Andrew Burke, Ph.D.
Senior Technology Transfer Manager