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Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Tue, Sep 10, 2019 at 3:59 PM

To: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>, James Love <james.love@keionline.org>

Dear Ms. Ardizzone,

Answers to your questions are provided below.

Regards,

Andy

Andrew R. Burke, Ph.D.

Senior Technology Transfer Manager

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From: kathryn ardizzone <kathryn.ardizzone@keionline.org>

Sent: Monday, September 9, 2019 12:30 PM

To: Burke, Andy (NIH/NCI) [E] <andy.burke@nih.gov>

Cc: Luis Gil Abinader <luis.gil.abinader@keionline.org>; James Love <james.love@keionline.org>

Subject: Questions Re: Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy

Dear Dr. Burke:

Please answer the following questions related to Federal Register notice 84 FR 45503 regarding, "Prospective Grant of an Exclusive Patent License: Genetically-Modified Lymphocytes for Cancer Therapy."

1. At what stage of development are the inventions listed? **Answer: Preclinical**
 - a. If there has been a clinical trial, please list any NCT clinical trial numbers.
2. If the government has provided funding:
 0. How much has been spent by the government on these trials? **Answer: The technologies are preclinical.**
 - a. Please identify any NIH grant numbers.
 - b. Please confirm whether grants 5R21CA216652-02 and 1R21CA216652-01A1 are associated. **Answer: Please direct this question to the University of Minnesota or consult NIH Reporter.**
3. Please confirm or deny whether the license will "extend to the expiration of the last to expire of the Licensed Patent Rights" as provided in the **NIH Model Exclusive Patent License Agreement** **Answer: This has not yet been determined.**
 0. If you deny #4, please state the duration of exclusivity.
4. Has the NIH sought advice from the Attorney General (as is required under **40 USC § 559**)?
5. According to the Federal Register notice, Intima Bioscience is "headquartered in New York." According to the PCT applications PCT/US2016/044856, PCT/US2016/044858 and PCT/US2017/058615, Intima Bioscience has an address at 3 Columbus Circle New York, New York 10019. However, a search for the entity name "Intima Bioscience" using the NYS Department of State Division of Corporations database does not return any company with that name. A search for the entity name "Intima Capital" using the NYS Department of State Division of Corporations database does return a registered company with addresses in 3 Columbus Circle New York, New York 10019. Please confirm whether the prospective licensee is "Intima Bioscience" or "Intima Capital." **Answer: The applicant is Intima Bioscience, Inc.**
6. Is the prospective licensee in this case the same company listed in the Federal Register notice 80 FR 59790, titled "Prospective Grant of Exclusive License: Development of Non-viral Adoptive Cell Transfer-based Immunotherapies (ACT) for the Treatment and Prophylaxis of Patients With Metastatic Cancer"? **Answer: Yes, the applicant is the same.**
 0. Was the exclusive license described in 80 FR 59790 executed? **Answer: No**
 - a. If so, what is the rationale for granted additional exclusive rights to Intima Bioscience in a field of use that also relates to cancer?
7. How did the NIH determine that Intima Bioscience is an appropriate licensee? Who are the principals of the company? **Answer: The preliminary determination was based on a review of the commercial development plan and supporting information submitted by the company in their application for license.**
8. Does Intima Bioscience has a website? If so, please provide a link to their website. **Answer: I am not aware of a website for Intima Bioscience, Inc.**
 0. Note that "Intima Capital," a company located in **3 Columbus Circle New York, New York** and registered to do business there, does seem to have a website: <http://intimacapital.com/>
 - a. Note also that a study performed by University of Minnesota Scientists Branden Moriarity and RS Ivor (co-inventors on the patent listed) in "Gene Engineering for Cancer Therapy" was funded by Intima Capital LLC.
 - b. If Intima Capital and Intima Bioscience are related, what is the relationship? **Answer: Please direct this question to the company.**
9. Please confirm whether the following CRADA is associated with the licensed technology:
 0. CRADA No. C-058-2015/0, *Development and Evaluation of Intima Bioscience Proprietary Non-Viral Vectors for the Integration of Genes Encoding Mutation Specific T Cell Receptors that Have Been Identified Using NCI Proprietary Methods for the Identification of Lymphocytes and Receptors Specific for Mutated Cancer Antigens Expressed by the Autologous Cancer* **Answer: The patents and patent applications listed in 84 FR 45503 are not Subject Inventions of this or any NCI CRADA.**
 - a. If your answer to No. 6 is "No," please identify any CRADAs associated with any of the subject inventions.
10. Did the NIH previously post this technology in the Federal Register under "Government Inventions available for licensing" or on the NIH's OTT Website's "Licensing Opportunities"? **Answer: No**

0. If "Yes," please provide a citation for the listing(s).

11. According to the Federal Register notice Intima Bioscience, Inc. is a co-owner of the listed patent documents. Why is the NIH proposing to license rights in patents/patent applications that are already co-owned by the prospective licensee? Why is the rationale for this? **Answer: Because NIH wishes to grant an exclusive license to improve the chances that the technologies will be made available to the public.**
12. How has NIH ensured that the grant and scope of exclusivity are no greater than reasonably necessary to incentivize Intima Bioscience to commercialize the licensed technology? **Answer: As 37 CFR 404.7(a)(1)(ii) makes clear, consideration of any written objection(s) timely received in response to the notice provided in 84 FR 45503 is a necessary component of the determination required by 37 CFR 404.7(a)(1)(ii)(C). Since the 15-day notice period for this proposed license remains open, the final determination that 37 CFR 404.7(a)(1)(ii)(C) is satisfied has not been made.**

Thank you in advance for your assistance in this matter.

Sincerely,

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