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Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov> Tue, Jul 16, 2019 at 7:09 AM
To: Claire Cassedy <claire.cassedy@keionline.org>

Ms. Cassedy,

Thank you for your inquiry. Below you will find my response to questions # 6, 8 and 9. The other questions either have been answered previously or are not related to the criteria set forth in 37 CFR 404.7(a)(1)(ii-iii) regarding a decision by a federal agency to grant an exclusive license.

Question 6- The technology under this proposed license is generally related to at least one previous license in that they are both directed to a method of treating hematological malignancies with a chimeric antigen receptor. It differs from the previous one in having the potential as an adjunct or alternative therapy for certain cancer patients.

Question 8- The E-205-2018-0 technology has been advertised as available for licensing since November 2018.

Question 9- Since the technology was advertised, this question is not applicable.

Regards,

David A. Lambertson, Ph.D.

Senior Technology Transfer Manager

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From: Claire Cassedy <claire.cassedy@keionline.org>
Sent: Friday, July 12, 2019 2:04 PM
To: Lambertson, David (NIH/NCI) [E] <david.lambertson@nih.gov>
Subject: Inquiry re: Proposed Exclusive Licenses on CD19 and CD20-related therapies to Kite

Dear Dr. Lambertson,

I am writing in reference to the Federal Register notices 84 FR 33272 and 84 FR 33270 regarding,"Prospective Grant of an Exclusive Patent License: Autologus Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20" and "Prospective Grant of an Exclusive Patent License: Allogeneic Therapy Using Bicistronic Chimeric Antigen Receptors Targeting CD19 and CD20," for which you are listed as the contact for inquiries. I was hoping you could provide me with some further information regarding the status of the technologies.

1. At what stage of development are the inventions listed?
2. Has the government funded any clinical trials relevant to these technologies?
3. If the government has provided funding, how much has been spent by the government on these trials? Can you provide NCT numbers?
4. Is the term in the proposed licenses to be life of patent or less than life of patent?
5. In working towards executing this license, has the NIH sought advice from the Attorney General (as is required under 40 USC § 559) to determine if the “disposal to a private interest would tend to create or maintain a situation inconsistent with antitrust law”?
6. Considering the NIH has previously licensed CAR T technologies to Kite Pharma/Gilead, are the technologies identified in the current Federal Register notice related in any way to the previously executed licenses? (*List of previously noticed exclusive licenses on CAR T technologies to Kite Pharma follows below this email*)
7. Is there a Cooperative Research and Development Agreement associated with this technology?
8. Did the NIH previously post this technology in the Federal Register under “Government Inventions available for licensing”? And/or was it announced on any other platform that these technologies were available for licensing?
9. If not, how was it determined that Kite would enter into this proposed exclusive license, particularly considering the technology is currently under a provisional patent application?
10. Considering Kite/Gilead currently has CAR T therapy Yescarta (axicabtagene ciloleucel) on the

market at a price of $373,000, has/will the NIH seek license terms that will ensure the resultant therapy is available to patients on reasonable terms?

Thank you in advance for your assistance in this matter.

Sincerely,

Claire Cassedy

Previously noticed exclusive licenses on CAR T technologies to Kite Pharma:
Prospective Grant of Exclusive License: Development of T Cell Receptors and Chimeric Antigen Receptors Into Therapeutics for Adoptive Transfer in Humans To Treat Cancer
https://www.federalregister.gov/documents/2012/01/24/2012-1383/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-and-chimeric-antigen

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans to Treat Cancer
https://www.federalregister.gov/documents/2014/03/25/2014-06412/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-for-adoptive-transfer-in

Prospective Grant of Exclusive License: Development of T Cell Receptors for Adoptive Transfer in Humans To Treat Cancer
https://www.federalregister.gov/documents/2014/10/16/2014-24502/prospective-grant-of-exclusive-license-development-of-t-cell-receptors-for-adoptive-transfer-in

Prospective Grant of Exclusive License: The Development of an Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancers
https://www.federalregister.gov/documents/2015/06/26/2015-15657/prospective-grant-of-exclusive-license-the-development-of-an-anti-cd19-chimeric-antigen-receptor-car

Prospective Grant of Exclusive Patent License: Development of T Cell Receptors (TCRs) Targeting the KRAS G12D Mutation for the Treatment of Cancer
https://www.federalregister.gov/documents/2016/08/17/2016-19549/prospective-grant-of-exclusive-patent-license-development-of-t-cell-receptors-tcrs-targeting-the

Prospective Grant of Exclusive Patent License: Development of Anti-CD70 Chimeric Antigen Receptors for

the Treatment of CD70 Expressing Cancers
https://www.federalregister.gov/documents/2016/10/05/2016-24030/prospective-grant-of-exclusive-patent-license-development-of-anti-cd70-chimeric-antigen-receptors

Prospective Grant of an Exclusive Patent License: The Development of an Anti-CD30 Chimeric Antigen Receptor (CAR) for the Treatment of Human Cancer
https://www.federalregister.gov/documents/2017/12/20/2017-27416/prospective-grant-of-an-exclusive-patent-license-the-development-of-an-anti-cd30-chimeric-antigen

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