Questions regarding the proposed license to OcQuila Therapeutics, 84 FR 65169

Shmilovich, Michael (NIH/NHLBI) [E] <michael.shmilovich@nih.gov> Tue, Jan 7, 2020 at 8:56 AM

To: Kathryn Ardizzone <kathryn.ardizzone@keionline.org>, Luis Gil Abinader <luis.gil.abinader@keionline.org>, Jamie Love <james.love@keionline.org>, "Rohrbaugh, Mark (NIH/OD) [E]" <rohrbaum@od.nih.gov>, "Goldstein, Bruce (NIH/NHLBI) [E]" <goldsteb@mail.nih.gov>

Dear Ms. Ardizzone:

Regarding your email. Our responses are shown below in blue:

Dear Mr. Shmilovich:

Thank you for answering my colleague Luis Abinader's questions regarding the proposed license to OcQuila. I have a few questions about the licensed inventions.

1. The clinical trial NCT02317887, Study of RS1 Ocular Gene Transfer for X-linked Retinoschisis, investigated the first invention listed in the notice. **Will the second invention, Newly Improved Method and Composition for Treating Genetically Linked Diseases of the Eye, be investigated in any clinical trials, including NCT02317887?** So far, it appears that it has only been studied in mice, yet the development stage for the invention is listed as "clinical" in this licensing opportunity notice.

That is not known at this time and will be up to the licensee and NEI.

2. Can you provide us a copy of the unpublished patent applications associated with the second invention? This is not confidential business material and will help us to evaluate the license.

The PCT application has not yet published yet. Under our policy, until a PCT application is published, it is only available under a Confidential Disclosure Agreement.

3. You told Mr. Abinader that NIH is not required to perform an economic analysis to determine that an exclusive license is appropriate. **What analysis, if any, did you undergo before deciding to propose**

an exclusive license? If you determined that exclusivity was necessary, on what basis did you so conclude?

XLRS is a rare disease and information about its incidence is readily available.

4. Dr. Mark Rohrbaugh, Special Advisor for Technology Transfer to the NIH Deputy Director for Intramural Research, has publicly stated that **"[t]he closer a technology is to the marketplace, the lower the risk and cost to the licensee, and the more valuable the technology from a royalty standpoint."** Mark L. Rohrbaugh, NIH: Moving Research from the Bench to the Bedside, Testimony before the House Committee on Energy and Commerce, Subcommittee on Health, July 10, 2003, https://www.govinfo.gov/content/pkg/CHRG-108hhrg88429/html/CHRG-108hhrg88429.htm. **How is the NIH negotiating this license in a way that reflects that commercial potential of these inventions? Are all inventions treated equally per NIH's licensing practices regardless of development stage, risk, and cost?**

The value of patent commercialization licenses are not uniform and depend on many factors including the state of development. The present invention is early stage. Negotiation of a license, including royalties, does not occur until a final decision is made based on any competing applications and comments submitted during the notice period. The question has also been previously answered in Dr. Rohrbaugh's November 26, 2019 letter (enclosed), and the answer in that letter applies to the current case as well.

Regards,

Michael A. Shmilovich, Esq., CLP

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