July 22, 2017

Surekha Vathyam, Ph.D.,
Senior Technology Transfer Manager,
NCI Technology Transfer Center,
9609 Medical Center Drive,
RM 1E530 MSC 9702,
Bethesda, MD 20892-9702 (for business mail),
Rockville, MD 20850-9702
Telephone: (240) 276-5530
Facsimile: (240) 276-5504

Via Email: vathyams@mail.nih.gov

Re: Request for Information and Comments on Prospective Grant of Exclusive Patent License: Composition and Methods for Delivering Inhibitory Oligonucleotides for the Treatment of Pancreatic Cancer, to VeriLuce Therapeutics ("VLT") located in Toronto, ON, Canada.

Dear Dr. Vathyam,

I am writing to request information and to provide comments regarding the proposed exclusive patent license noticed in the Federal Register on July 10, 2017, document citation: 82 FR 31783, regarding the treatment of pancreatic cancer, to VeriLuce Therapeutics, located in Toronto, Ontario, Canada.

VeriLuce does not seem like a big company. It's web page is just a single page which provides almost no information about the company leadership or its experience in product development. The entire contents of the web page are as follows:

> *VeriLuce Therapeutics - A DRUG DEVELOPMENT COMPANY*
>
> *VeriLuce Therapeutics in-licenses compounds in pre-clinical stage of development and progresses them to early clinical for divestment or further development through collaboration with other Companies*
>
> *About Us*

We are a team of dedicated and experienced individuals who are passionate about drug development and about improving the lives of patients; Our experience spans from scientific research and medical to regulatory and business development; We are currently focusing our efforts in seeking, in-licensing and developing compounds that treat rare oncology diseases.

Licensing and Collaborations

We are seeking licensing and collaboration opportunities in the area of oncology. Please contact us to discuss potential current and future opportunities.

Contact Us: elena.frigerio@verilucetherapeutics.com 647-965-1

According to Linkedin, the company was founded in 2015, and has 1-10 employees.

It is not clear how a company located in Canada with almost no track record and very few employees was selected to obtain an exclusive license to a portfolio of United States owned patents relating to pancreatic cancer.

My requests for information are as follows:

1. Who are the principals in Veriluce Therapeutics?
2. Why did the NIH select Veriluce Therapeutics for an exclusive license?
3. Is the NIH giving Veriluce Therapeutics the opportunity to obtain exclusive rights in order to market the patents to a bigger more capable firm?
4. Are any of the personnel in Veriluce former NIH employees or relatives or business partners of NIH employees?
5. Are the patent applications public, and if not, can you share them?
6. How many companies have expressed interest in licensing the patents?
7. What is the term of the proposed license?
8. What is the royalty obligation?
9. How much money did the federal government spend on the development of this technology?
10. How much money has VeriLuce invested in the technology?
11. What has VeriLuce promised to do as regards investments in the development of products based upon the patented inventions?
12. Did the NIH propose any provisions in the license that would protect US residents from paying high prices on products, or ensure access in developing countries, and if so, can you share the proposals and the response by the VeriLuce?
13. Please provide a copy of all CRADA agreements, if any, between the NIH and VeriLuce.

KEI proposes the NIH include the following measures in the license to address the pricing and availability of products based upon the patented invention:

1. The lessee agrees to make products based upon the invention available to the public in the United States at prices [that are reasonable, and in any case] no higher than the median price charged in the seven countries with the largest GDP, that have per capita incomes of at least half that of the United States.

2. The lessee is expected to either (a) register and make available the products based upon the invention in developing countries at an affordable price and with sufficient quantities, or (b) offer sufficient technology transfer and rights in intellectual property for third parties to provide the products on a competitive basis.

KEI proposes the NIH undertake the following measures to address transparency.

1. Provide some information on who runs and owns the company and why the company was selected.

2. Require the lessee to provide a report annually that will be made available to the public without redaction that provides the following information.
    a. Expenditures on specific clinical trials,
    b. Average prices and revenues in every national market,
    c. All government subsidies for the development of the product,
    d. All outlays on marketing the product, by national market.

3. Make public an unredacted copy of the license agreement and any associated CRADA. This was the practice earlier at the NIH, and which is the current practice of some companies when they provide disclosures to shareholders through the SEC. These patents were funded by the U.S. taxpayers, and the public has the right to see the terms of the exclusive license to this unknown Canadian firm.

Thank you.

James Love
Knowledge Ecology International
1621 Connecticut Avenue, Suite 500
Washington, DC 20009
http://www.keionline.org | mailto:james.love@keionline.org