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Additional inquiry regarding 84 FR 28063 Doc 2019-12708, "Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors"

Luis Gil Abinader <luis.gil.abinader@keionline.org> Thu, Jun 27, 2019 at 9:40 AM
To: Jamie Love <james.love@keionline.org>, "claire.cassedy" <claire.cassedy@keionline.org>
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From: **Shmilovich, Michael (NIH/NHLBI) [E]** <michael.shmilovich@nih.gov>
Date: Thu, Jun 27, 2019 at 9:32 AM
Subject: RE: Additional inquiry regarding 84 FR 28063 Doc 2019-12708, "Prospective Grant of Exclusive Patent License: Lutetium-177 Radiotherapeutics Against Somatostatin-Receptor Expressing Neuroendocrine Tumors"
To: Luis Gil Abinader <luis.gil.abinader@keionline.org>

Dear Mr. Abinader— With regards to your questions:

Dear Mr. Abinader – thank you for your email. The answers to your questions are as follows:

1. Does the license includes the Singapore patent application 11201809982R, which entered the national phase via the PCT procedure PCT/US2017/031696?

Yes, the Singapore application filing number wasn't reported to us in time for the FR notice but that application will be included.

2. Is http://www.mtarget.com/SFNT.html the website of the prospective licensee?

Yes

3. The Federal Register notice 84 FR 28063 states that the NIH is contemplating amending "an existing license". Is the "existing license" the prospective exclusive license described in the Federal Register notice 83 FR 35663, published on July 27, 2018?

Yes, this will be an amendment to that now executed license.

4. Was the license proposed in the Federal Register notice 83 FR 35663 executed?

Yes

5. How will the exclusive license proposed in the Federal Register notice 84 FR 28063 amend the previous license described in the Federal Register notice 83 FR 35663?

The amendment adds the IP rights listed in this FR notice but narrows the field of use of the license to 177Lu radiotherapeutics. If you look through the claims of the published PCT there is a list of other potential radionuclides that can be used therapeutically.

6. What is the rationale for granting additional exclusive rights to a company that presumably has outstanding obligations under a previous license?

The company has no outstanding obligations. The company and NIH discussed that the instant patent rights should be included to complete the patent portfolio licensed by the company so long as it is constrained by field of use.

7. A clinicaltrials.gov search for the term “DOTA-EB-TATE” returns two phase I clinical trials, NCT03308682 and NCT03478358, both related to neuroendocrine tumors. These trials were co-sponsored by the Peking Union Medical College Hospital and the National Institute of Biomedical Imaging and Bioengineering (NIBIB), according to clinicaltrials.gov. Are these trials related to the proposed exclusive license?

Not related.

8. Based on our own research, our understanding is that the invention covered in the proposed license, 177Lu-DOTA-EBTATE, has more favorable pharmacokinetics compared to 177Lu-DOTATATE, a therapy for neuroendocrine tumors recently approved by the FDA and marketed under the brand name Lutathera. Is this correct?

We hope so as does the company; however, this remains to be determined through controlled clinical trials.

Regards,

Michael A. Shmilovich, Esq., CLP

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"*Always be yourself….unless you can be a pyrate… then; obviously, be a pyrate"*

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