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Re: Prospective Grant of Exclusive Patent License: Development and Commercialization of Regulatory T-Cell Therapies for the Treatment of Multiple Sclerosis (MS), Teralmmune, Inc. located in Gaithersburg, Maryland, USA.

Teralmmune

Teralmmune is a company run by former NIH employees that has received Small Business Innovation Research (SBIR) grants, Production Assistance for the Cellular Therapies (PACT) grants, and exclusive licenses from the NIH and Universities funded by the NIH. Yong Chan Kim, PhD is the CEO. He has worked at Chungnam National University, South Korea, the NIAID, and the DoD Uniformed Services University (USU). Jay Park, PhD, the COO, also worked at Chungnam National University and the NIH. The company web page lists the NIH employee Ethan M. Shevach, MD, as a CRADA PI.

Intellectual Property

The Intellectual Property to be licensed includes:

- U.S. Patent 9,481,866, entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells” [HHS Reference No. E-279-2011/0-US-02]
- U.S. Patent 11,060,059, entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells” [HHS Reference No. E-279-2011/0-US-03]
- U.S. Divisional Application No. 17/371,589—filed July 9, 2021, entitled “Methods of Producing T Cell Populations Enriched for Stable Regulatory T-Cells” [HHS Reference No. E-279-2011/0-US-04]

According to the Federal Register Notice, “The prospective exclusive license territory may be worldwide, and the field of use may be limited to: “Use of the Licensed Patent Rights to develop and commercialize Treg cell therapies for the treatment of multiple sclerosis (MS).”

Cystic Fibrosis

Cystic Fibrosis is a terrible disease. The incidence is thought to be higher in persons of European caucasion descent. The global incident varies, and is also somewhat uncertain due to less frequent screening in many countries. Due to better treatments available in countries that can afford them, outcomes have improved, and patients live longer.

Current treatments for Cystic Fibrosis are quite high, and probably provided the motivation for similar prices for expensive treatments for SMA. Trikafta is around \$300,000 per year. T-Cell Therapies for the Treatment of Multiple Sclerosis, if they provide durable benefits, may priced aggressively if the company is unconstrained in it's pricing decisions.

Public Interest provisions

No price discrmination against US residents

One safeguard that should be included in the license is a commitment to not charge more in the United States than the median price charged in other high income countries, including in particular Australia, Belgium, Canada, Denmark, France, Germany, Ireland, the Netherlands, Sweden, and the UK, as well as Korea and Japan.

Curbs on Excessive pricing

The NIH should retain the right to require progressive decreases in prices if the cumulative global revenues from a therapy using the licensed inventions exceed \$2 billion in sales.

Technology transfer

The United States should require the licensee to provide transfer of the manufacturing know-how to companies not infringing on the patents, and to ensure that monopolies for cell therapies do not extend forever.

Transparency

The NIH should implement the recommendations on transparency in the WHO's resolution WHA72.8, Improving the transparency of markets for medicines, vaccines, and other health products.

In particular, the company should be required to publish the costs of each clinical trial used to support registration of the treatment, the prices charged in each country, and the Units sold in each country. Also, the full unredacted text of the license agreement should be public.