David A. Lambertson, Ph.D.,
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NCI Technology Transfer Center
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Date: June 22, 2018

RE: Prospective Grant of an Exclusive Patent License: The Development of an Anti-BCMA Immunotoxin for the Treatment of Human Cancer

Dear David A. Lambertson:

The following groups are concerned about drug pricing and access to patented medicines, jointly offering comments on the grant of an exclusive license, between the National Institutes of Health (NIH) and BEORO Therapeutics, GmbH. ("Beoro"), located in Seefeld, Germany, for patents noticed in the Federal Register (83 FR 26487) the Development of an Anti-BCMA Immunotoxin for the Treatment of Human Cancer.[1]

- Health GAP
- Knowledge Ecology International (KEI)
- People of Faith for Access to Medicines (PFAM)
- Social Security Works (SSW)
- Union for Affordable Cancer Treatment (UACT)
- Universities Allied for Essential Medicines (UAEM)

The above entities oppose the issuing of an exclusive license unless:

A. The NIH has determined that an exclusive license is "a reasonable and necessary incentive" to induce investments for the development and practical application of the invention, as is required by 35 USC § 209, and shares its analysis with the public; and

B. The NIH limits the scope of rights for the exclusivity to only those rights reasonably necessary to induce investments for the development and practical application of the invention, and in particular, that the field of use is sufficiently narrow, that the term of the exclusivity is sufficiently limited, and that the license contains sufficient safeguards to ensure that the invention is "available to the public on reasonable terms," as is required by 35 USC § 209 and 35 USC § 201(f).

[1] https://www.gpo.gov/fdsys/pkg/FR-2018-06-07/pdf/2018-12179.pdf

Our comments address three areas of concern, (1) pricing, affordability and access issues, (2) freedom for researchers to use the inventions, and (3) requirements for transparency of the development and commercialization of the medicine.

We propose the following safeguards regarding the pricing of and access to products that use the inventions:

1. Products are priced no higher in the United States than the median price charged in the seven largest economies as measured by nominal GNI that have a nominal GNI per capita of at least 50 percent of the United States. To fully appreciate our concerns about the discriminatory pricing that makes US residents pay more than everyone else, please review the cross country price comparisons here: http://drugdatabase.info/drug-prices/

2. Prices for products in the United States do not exceed the estimated value of the treatment, to be determined by independent health technology assessments selected by Department of Health and Human Services (HHS).

3. Patient co-payments under third party Medicare and private reimbursement programs are affordable.

4. The geographic area for the exclusivity should exclude countries with a per capita income less than 30 percent that of the United States. If there is no such exclusion, the company would be required to report annually on the reasonable and feasible measures that will be taken to ensure access to patients living in such countries. Here, please note the data from the drug price database referenced above, which shows that in many developing countries, prices are frequently higher than the prices for high income countries in Europe, despite the much lower per capita income in developing countries (including the prices for taxpayer-funded cancer drugs), illustrating the need for a policy to be included in NIH licenses. We also note that the Medicines Patent Pool (MPP) has recently announced it will expand the scope of diseases for its licenses. The NIH should retain the flexibility to provide licenses to the MPP in the future, perhaps as an option clause in the license.

5. The initial period of exclusivity is set at seven years, subject to extensions if the company can demonstrate it has not recovered sufficient profits given the risk-adjusted value of the clinical trials used to register similar drugs for the lead indication, or, alternative, the exclusivity of the product be reduced when cumulative global revenues for the product exceed $1 billion, by one year for every $0.5 billion in cumulative sales that exceed $1 billion in cumulative sales.

The NIH might consider a different set of benchmarks than $1 billion and $0.5 billion. In considering any benchmarks for global sales, note that the licensing of inventions to the company significantly reduces the company's costs of preclinical research, which various

studies have estimated to be 40 to 55 percent of drug development costs on a risk- and capital cost-adjusted basis.[2]

To address research by third parties on the patented invention, we propose the NIH explicitly permit researchers worldwide to use the inventions for research purposes, regardless of whether or not the research has a grant or contract from a US government agency, and for both for profit or non-profit organizations.

To address transparency, we propose that the company be required to provide an annual report for the public, which would provide disclosures of the following items:

1. The amount of money spent on R&D to obtain FDA and foreign government approvals of the inventions, including in particular, the amount of money spent each year on each trial, and the relevant tax credits, grants and other subsidies received from any government or charity relating to those R&D outlays,

2. The prices and revenue for the products, by country,

3. The number of units sold, in each country,

4. The product-relevant patents obtained in each country, and

5. The regulatory approval obtained in each country.

Sincerely,

James Love
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And, the following organizations and individuals:

Health GAP
Knowledge Ecology International (KEI)
People of Faith for Access to Medicines (PFAM)
Social Security Works (SSW)
Union for Affordable Cancer Treatment (UACT)
Universities Allied for Essential Medicines (UAEM)

Dean Baker

[2] http://drugdatabase.info/estimates-of-drug-development-costs/