



Thomas Winkler, PhD  
Roche  
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Dear Dr. Winkler,

It was a pleasure to meet you at the Harvard Law School meeting on voluntary licensing. I would like to follow-up on the specific issues I raised during that meeting.

KEI has been contacted by families of children living in developing countries that do not have access to any of the three treatments for Spinal Muscular Atrophy (SMA) - the drugs nusinersen (TN: Spinraza) and risdiplam (TN: Evrysdi) and the gene therapy onasemnogene abeparvovec (TN: Zolgensma).

KEI is interested in manufacturing and distributing the drug risdiplam for use by patients living in lower income countries.

We request a non-exclusive voluntary license to the patents and the rights in regulatory test data in order to:

1. manufacture risdiplam, and
2. distribute risdiplam to patients living in countries with per capita incomes less than 1/4 of the United States.

We suggest a royalty of 7 percent on net sales.

I recognize that Roche, if willing at all to license this product for use in developing countries, may prefer a more nuanced or restrictive geographic area, as well as other terms and conditions. KEI is open to negotiations on any terms or conditions.

Our goal is to find a way to expand affordable access to risdiplam. I personally have been contacted by families that have been unable to obtain access to any of the three leading SMA treatments, and I have been frustrated by our inability to engage the three companies holding the rights (Biogen, Novartis and Roche) to connect the families with feasible treatment options.

The current list price of approximately \$900 per day is clearly not affordable for families. Many families clearly do not have access to government or private insurance reimbursements for this drug.

KEI has entered into discussions with companies that we believe can manufacture risdiplam, at prices that would be affordable for many families living in developing countries. A voluntary license would remove one of the barriers to such manufacturing, which is a concern by some potential manufacturers that manufacturing would expose a company to lawsuits for infringement of patents. In this regard, we note the recent voluntary licenses issued by Merck and Pfizer for two COVID 19 therapeutics, which allow manufacturing to take place anywhere, while sales and distribution to patients are restricted by geography and patent landscapes.

As you know, each of the three most important treatments for SMA were originally developed with funding from the NIH or from SMA charities, including in the case of risdiplam, the SMA Foundation. I will also be reaching out to the SMA Foundation about this request, and will forward that correspondence to you.

I would very much like to discuss this further with the appropriate persons at Roche.

Sincerely,



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