Gmail

James Love <jamespackardlove@gmail.com>

Risdiplam license request

Winkler, Thomas <thomas.winkler.tw3@roche.com> Fri, Aug 5, 2022 at 3:37 AM
To: James Love <jamespackardlove@gmail.com>

Dear Jamie,

Thank you for your letter and for your proposed solution to enable access to Evrysdi for patients in lower income countries. We appreciate and share your concerns for these patients and are committed to working with local healthcare systems in ensuring all patients with SMA who may benefit from Evrysdi have sustainable access to treatment.

Our first goal has been to get Evrysdi approved by health authorities in all markets where this is possible, as quickly as possible. We are proud to have achieved broad approvals in over 85 countries extraordinarily rapidly, within 2 years of the first regulatory approval. We are actively working to bring this number up to well over 100 countries in the near future. We see this as the first critical step in enabling access for patients.

Once approval is obtained, our local teams in each respective country/region are actively engaging with governments, payers and the SMA community to obtain broad and sustainable access for patients as soon as possible. We appreciate that at times this is challenging or not feasible, particularly in lower income countries. We are committed to finding appropriate solutions tailored to the local environment and are actively working with our local teams in these countries on various options.

At this time, we are not exploring voluntary licensing for Evrysdi for the following reasons:

1. The manufacturing and distribution process for Evrysdi is complex. We want to ensure that, as the license owner, we are overseeing the process designed to ensure we are, among other things, (a) delivering high quality medicines while maintaining the integrity of this therapy, which requires a complex supply chain, and (b) carefully educating stakeholders to support this very vulnerable patient population.
2. Since Evrysdi is a lifetime treatment, we want to ensure that access to treatment is sustainable. Disruption to treatment can cause disease progression, which can be rapid in certain cases.
3. For SMA, treatment is only part of the holistic care required for a given patient. It is critical patients not only have access to treatment but also appropriate standard of care is in place in a given country so that individualized sustainable care needed beyond drug is provided to every patient (ie., access to treating and knowledgeable physicians, physiotherapy, mobility equipment, etc)[1,2]

Thank you again for sharing our commitment to serving the SMA community.

Sincerely,
Thomas

1. E. Mercuri et al. Diagnosis and management of spinal muscular atrophy: Part 1: Recommendations for diagnosis, rehabilitation, orthopedic and nutritional care. Neuromuscular Disorders 28 (2018) 103–115.

2. R.S. Finkel et al. Diagnosis and management of spinal muscular atrophy: Part 2: Pulmonary and acute care; medications, supplements and immunizations; other organ systems; and ethics. Neuromuscular Disorders 28 (2018) 197–207

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On Fri, Jul 8, 2022 at 3:55 PM James Love <jamespackardlove@gmail.com> wrote:
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