April 17, 2020

Dear members of SMA Europe,

Over the last few weeks, Roche, alongside our partners, has been monitoring the COVID-19 global pandemic to better understand the impact on the SMA community. We are living through an unprecedented time in our societal history and we recognize that people living with or caring for those with SMA might be facing a higher level of uncertainty and anxiety.

As part of our ongoing partnership and following your request to receive important and timely updates on such matters, we want to provide you with a summary of the COVID-19 response measures we are currently taking to ensure the continued safety of those involved in our SMA clinical trial programmes and to support the wider community during this time.

Maintaining risdiplam supply

We are continually assessing the potential implications of COVID-19 to our manufacturing and supply chain operations and we are monitoring the demand for all our therapies to mitigate potential stock out risks. Currently, we are not facing any supply or logistics interruptions due to COVID-19. However, we are taking proactive measures in collaboration with our logistics service providers to ensure the delivery of products to/from affected countries and regions remains as stable as possible.

Ongoing risdiplam clinical trials and support services

The risdiplam clinical studies are currently ongoing and our primary focus is ensuring patient safety, access to treatment and data integrity. We are actively working with clinical trial teams, as well as trial sites and partners, to mitigate risks where possible and are regularly reviewing the situation.

Many countries have invoked travel and resident restrictions as well as distancing requirements, and we appreciate that trial participants may be concerned about leaving their homes or may not be able to leave their homes. In these situations where patients in our trials can no longer visit the clinic or hospital for a study appointment, the investigators and their teams will remain in regular contact with the patient/the patient's caregiver over telephone to monitor the general health of the participant, discuss any potential adverse events and any other issues the patients and families may have during this time.

Finally, we have introduced optional services to safely and comfortably enable the continued participation of individuals in our studies. A home drug delivery service is now available in all clinical trial countries, which uses a contactless pickup and delivery process to mitigate the spread of COVID-19 between patients and drivers. Additionally, we are offering home nursing services in countries where it is feasible and allowed.

If trial participants are facing challenges, or have concerns about topics related to our studies, we encourage them to discuss these openly with their healthcare team (study physician and site team members), who are dedicated to supporting families. It is also important that all trial participants and families abide by any guidance issued by local government bodies.

Update to Pre-Approval Access / Compassionate Use (PAA/CU) Programme for risdiplam

Following your request to receive more information about our PAA/CU Programme plans, Roche announced earlier this year the initiation of a global PAA/CU Programme for risdiplam in countries where applicable laws and regulations allow such Programmes and which fulfil the criteria based on applicable company policy. Since that time, Roche has been offering patients with Type 1 SMA and no other

treatment options the opportunity to access risdiplam through the PAA/CU Programme. We also previously announced that the Programme will be expanded, in countries where applicable, to patients with Type 2 SMA at the moment of filing of the regulatory application for risdiplam in that respective country.

In response to requests received as well as to the unique pressures that the COVID-19 pandemic is exerting on health systems, Roche has decided to amend the eligibility criteria for the risdiplam PAA/CU Programme to also include patients whose current treatment have been interrupted as a direct consequence of the COVID-19 pandemic. This change to the risdiplam PAA/CU Programme applies to patients with Type 1 SMA or Type 2 SMA who will not be able to continue receiving their therapies due to the COVID-19 outbreak and who could subsequently face the risk of their condition worsening due to treatment interruption. Further eligibility criteria still need to be met and any decision to apply for the Programme must be made by the treating physician.

We would like to note that variations in the implementation of these changes will occur across different countries and in some cases these changes to the PAA/CU Programme will need to be agreed with local authorities. Roche will work collaboratively with the local authorities to make the changes effective as soon as possible.

It is important to highlight that all efforts must first be made by the treating physician to investigate all options for patients to stay on their current therapy.

Also, for patients with Type 2 SMA not currently on a treatment or whose treatment has not been affected by the pandemic, the amended risdiplam PAA/CU Programme eligibility does not apply. For these patients, the Programme will become available as originally planned, i.e. at the moment of filing of the regulatory application for risdiplam in that respective country.

During these challenging times, we remain as committed as ever to supporting the global SMA community. We are continuing to monitor the global spread of the COVID-19 outbreak and we will keep you updated should new developments occur.

If you have any questions about this update, please do not hesitate to contact me.

Sincerely,

Fani Petridis

Fani Petridis, on behalf of the Roche Global SMA Team
Senior Global Patient Partnership Director, Rare Diseases