Basel, Friday November 13th, 2015

Dear Board Members of SMA Europe,

We would like to thank you for being so forthcoming with your questions about our progress in development. Over the past few months, we have had the privilege to meet with many patient groups. We are inspired and humbled by the determination we have witnessed in the efforts you, families and caregivers put forward for loved ones with SMA. Your stories and experiences highlight the urgency needed in advancing new treatments such as olesoxime to address the many challenges of SMA. We would like to take this opportunity to address your most pressing question - when will olesoxime be available to people with SMA?

Since the acquisition of Trophos in March 2015, the Roche team has consistently focused on bringing olesoxime to the SMA community as quickly as possible. As quickly as possible is a firm commitment on our part. The efforts of the team over the past eight and a half months are now bearing the first tangible results, with two major milestones achieved.

First, we are pleased to confirm that all people previously enrolled in the Trophos SMA trials will be eligible to restart their therapy in the context of an open-label follow-up trial. From the start, we made a firm commitment to ensure that people with SMA who had previously been on olesoxime could re-enroll in therapy without further disruption. Before the end of this year, the first people previously enrolled in the Trophos SMA trials will be back on therapy, and over the next six months all remaining participants from the previous Trophos trials will be contacted by their doctor for re-enrolment as soon as the trial is approved by the trial site, regulatory and ethics authorities in their country.

This first achievement is the result of a concentrated effort by our technical experts in starting up a small-scale manufacturing round since at the time of acquisition, there was neither product in stock nor an immediately actionable manufacturing facility in place. In parallel our trial team has been working closely with trial sites and local authorities to minimize any delay between availability of study drug and getting previous Trophos trial participants back on treatment. The combination of these efforts will make it possible that within a timing of less than ten months from acquisition, people with SMA will be back on treatment.

Secondly, we have been moving swiftly to pull the information together that will be required for regulatory authorities to review olesoxime. In order to ensure access to new treatments for people with SMA, the approval from regulatory authorities is necessary. Interactions with regulatory authorities are ongoing and we will have clarity on the regulatory path moving forwards during the first half of 2016. Our current timeline is focused on submitting our regulatory files during the first half of 2017.

We are conscious that in practical terms this may seem like a long time away for people and families confronted with SMA. Why does it take so long? The large-scale production process that is currently being put in place and the output of this process, i.e. the product, both need to be validated

by regulatory authorities. There are numerous steps that need to be undertaken in the establishment of this process. To name some: engineering the design of the large-scale manufacturing process, validating the process to ensure consistent quality and stability, designating storage facilities, establishing fill and pack capabilities. These activities are highly complex and time-intensive. It is our responsibility as a company to ensure the product that will be made available meets the quality requirements as defined by health authority rules and guidelines. We understand that although these timelines present a challenge, we are moving as quickly as we can, and discussing with authorities, to bring olesoxime to people living with SMA.

We are very conscious of the emotional distress linked to the progressive nature of SMA and the need for immediate treatment options. Therefore, we continue to work on options to make olesoxime available to those who did not participate in the Trophos studies, through Pre-Approval Access (PAA) to Unauthorized Medicinal Product (UMP) for compassionate use (CU) of olesoxime. While we continue to advance swiftly and do everything we can with the objective of providing timely access to the SMA community, at this moment in time it is not possible for us to comment and commit on a possible starting timing for PAA. This is highly dependent upon a multitude of factors, of which many are external and not in our hands. Acknowledging the need to address this question as soon as possible, we commit to provide an update mid-2016, when we will have the needed and adequate information available. Roche's Position on Pre-Approval Access to Investigational Medicinal Products explains our approach in detail and can be found here: http://www.roche.com/position_on_pre_approval_access_on_investigational_medicinal_products.pdf

We do recognize the need for information on our developments in SMA, and we commit to inform you whenever we have important information to share. Please do not take intermediate times without communication as an equivalent to non-activity. We are working with the objective to bring olesoxime to patients as soon as possible. Pharmaceutical product development is a lengthy and highly complex process, where important milestones are sometimes met months apart. We understand that time is of the essence for families and people with SMA, and that regular communication addressing their key questions is the best way we can work together to progress on our common goal.

Finally, we are inspired by the hope and determination we continually witness in the efforts that families and caregivers make every day for their loved ones with SMA – and your stories continue to be our motivation. To these people and families, we would like to address our gratitude: thank you for your tireless efforts and persistence in finding hope for all those living with SMA.

Please do not hesitate to contact us should you have any questions.

Respectfully yours

The Roche Olesoxime-Team