Dear SMA community,

Roche, together with our collaboration partners PTC Therapeutics and the SMA Foundation would like to provide you with a further update on the clinical development of our investigational medicine RG7916 (RO7034067) for spinal muscular atrophy (SMA).

We are pleased to let you know that two studies, SUNFISH and FIREFISH, assessing the safety and efficacy of our SMN2 splicing modifier RG7916 in people with SMA are expected to begin enrolling in October and November 2016, respectively.

SUNFISH (BP39055) will evaluate RG7916 in children and young adults (aged 2-25 years) with type 2 and 3 SMA and will be a placebo-controlled study. FIREFISH (BP39056) will evaluate RG7916 in infants (aged 1-7 months) with type 1 SMA. All infants will receive RG7916 in the FIREFISH study as there is no placebo group.

Both studies will have two parts: Part 1 will select the dose of RG7916 and will be conducted at a limited number of clinical trial sites, Part 2 will assess safety and efficacy of RG7916 at the selected dose and will be conducted in additional clinical trial sites and countries.

Please visit www.clinicaltrials.gov if you would like to read more about these clinical studies. Sites listed on www.clinicaltrials.gov will take part in Part 1 or Part 2, or both Parts of the studies, pending Health Authority and Ethics Committee approval. The information will be updated to show sites that will recruit into Part 1. Additional countries and sites will be included into Part 2 as the studies progress and information on www.clinicaltrials.gov will be updated to show this.

Patients who participated in the MOONFISH study with RG7800 soon may be eligible to enrol into a third study, JEWELFISH (BP39054) an open-label study with RG7916, provided they meet the inclusion criteria. More details will be shared as the study plans develop.
We are committed to addressing the urgent needs of people living with SMA and their families and are looking forward to partnering with you as our studies of the safety and efficacy RG7916 advance.

If you have any questions, or would like to discuss anything further, please contact me at sangeeta.jethwa@roche.com.

Best regards,

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