8 September, 2014

Dear Fragile X community members,

It is with regret that we inform you of our difficult decision to discontinue the Fragile X development programme for RG7090 (RO4917523), based on our negative phase II clinical study results. We deeply appreciate the collaboration with the Fragile X community, including the FRAXA Research Foundation, the National Fragile X Foundation, and, especially, the patients and families who have participated in our studies.

We evaluated RG7090, an investigational metabotropic glutamate receptor subtype 5 (mGluR5) negative allosteric modulator, in two phase II studies in people with Fragile X syndrome:

- Fragxis, evaluated the safety and efficacy of RG7090 in 183 adults and adolescents, with a primary endpoint of improvement in the Anxiety Depression and Mood Scale (ADAMS) total score
- FoXtail, evaluated the safety of RG7090 in 47 children aged 5 – 13 years

Unfortunately, Fragxis did not demonstrate the hoped for efficacy based on the primary and secondary endpoints employed. As the FoXtail study was designed to evaluate the tolerability and safety of RG7090, conclusions about efficacy could not be reached. We will present data at upcoming medical meetings.

We are disappointed that the results of Fragxis and FoXtail in their entirety do not provide the hoped for clinical improvement in the studied population, which has led us to discontinue the development of this compound in Fragile X. The programme was not discontinued for safety reasons.

To provide further detail on both Fragile X studies, we are inviting you to a webcast on 18 September, 2014. The webcast will be led by our principal scientists in neuroscience who will present information on the studies and participate in a Q&A session. We hope this will provide insight for the community and for other researchers. Please find the dial-in details below.

We remain committed to the development of novel treatments for patients with neurodevelopmental disorders and thank the scientific and patient community for their continuous support in our endeavours.

Regards,

Luca Santarelli
Head Neuroscience, Ophthalmology and Rare Diseases
Roche Pharma Research and Early Development

Webcast on Thursday, 18 September from 6:30 pm – 7:30 pm CEST

To pre-register and download this event to your calendar, please go to:

http://services2.choruscall.ch/diamondpass/registration?confirmationNumber=7527049

To access the live webcast, please go to:

http://services.choruscall.com/dataconf/productusers/roche/mediaframe/9487/indexr.html

To listen to the webcast call, please dial in 10-15 minutes prior to the scheduled start, using the following numbers:

+41 (0)58 310 50 00 (Europe)

+44 (0)203 059 58 62 (UK)

+1 (1)631 570 5613 (USA)