

## **Response to open letter**

June 17, 2013

Dear parents,

Thank you for your letter of June 10 regarding the discontinuation of our collaboration with Seaside Therapeutics on the compound arbaclofen for autism and fragile X. While Roche neither owns nor develops arbaclofen, the questions raised in your letter are very important to us.

Please let me assure you that I take your concerns for your children very seriously. As a parent, we never want to see our children suffer and will do whatever is needed to ensure their safety, health and well-being. So, I really do understand your concerns regarding Seaside Therapeutics' decision to stop developing arbaclofen.

Roche had hoped for a much different outcome, one that would show a clear benefit for those patients affected with these disorders and their families. In the case of the Seaside Therapeutics trials, we regret that the clinical data collected in autism and fragile X did not show the benefit we had hoped for. While it may appear that some patients had a favourable response to this experimental compound, this did not unfortunately appear to be the case when looking at the clinical trial results in their entirety.<sup>1</sup>

I am sure you realize that it is important for Roche as well as regulatory authorities to have a set of convincing clinical data that support the continued use of a drug in patients.

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<sup>1</sup> For detailed questions on the study results, please contact the sponsor and owner of the results Seaside Therapeutics directly (<http://www.seasidetherapeutics.com/contact-us>).

While we are not continuing our support for Seaside's development of arbaclofen, it is important to note that Roche currently is one of only a few companies committed to finding innovative treatment options for individuals with neurodevelopmental conditions such as autism, fragile X and Down syndrome. Indeed, we continue to investigate three compounds in clinical trials, V1A (RG7314) for autism, MGluR5 (RG7090) for fragile X and GABA-A  $\alpha 5$  (RG1662) for Down syndrome. More information on these trials can be accessed via [www.roche-trials.com](http://www.roche-trials.com) and [www.clinicaltrials.gov](http://www.clinicaltrials.gov).<sup>2</sup>

Again, let me assure you that I as well as my colleagues in neuroscience research understand your urgent need for effective treatment options, and that we are working tirelessly to discover and develop such treatment options.

A handwritten signature in black ink, appearing to read "Severin Schwan".

Severin Schwan

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<sup>2</sup> Autism trial: <http://www.roche-trials.com/trialDetailsGet.action?studyNumber=BP28420>

Fragile X trials: <http://www.roche-trials.com/trialDetailsGet.action?studyNumber=NP27936> and <http://www.roche-trials.com/trialDetailsGet.action?studyNumber=NP28571>