Shire International GmbH

[redacted]

Date: 14 February 2014

Dr. Tomas Salmonson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Grouped variation EMEA/H/C/899/II/24/ G Firazyr (INN: Icatibant) 30 mg solution for injection in pre-filled syringe –Withdrawal of the clinical Type II variation for a new indication for the treatment of Angiotensin-converting Enzyme Inhibitors (ACE-I)-induced angioedema.

Dear Dr. Salmonson,

Shire Orphan Therapies GmbH submitted a grouped type II variation under the EMEA/H/C/899/II/24/ G application. I would like to inform you that Shire Orphan Therapies GmbH has taken the decision to withdraw one of these variations to narrow the scope of this application. We will withdraw the variation to extend Firazyr® (Icatibant) indication for the treatment of Angiotensin-converting Enzyme Inhibitors (ACE-I)-induced angioedema.

The decision to withdraw and narrow the scope of the application was taken since additional data are required to address questions raised during the assessment process of this variation. Additional data from an ongoing large pivotal study are required in order to address the Committee for Medicinal Products for Human Use (CHMP) questions relating to the assessment of icatibant in patients with ACE-I induced angioedema. These data will not be available within the timeframe allowed for this procedure.

Patients will continue to enrol in the ongoing phase III study in ACEI-induced angioedema in order to support a potential future re-submission to the Agency.

This withdrawal should allow the second submitted variation to update section 5.1 of the SmPC to progress.

This decision has no consequences on the use of Firazyr in its approved hereditary angioedema indication as the benefit-risk ratio remains positive in this indication.

I agree for this letter to be published on the European Medicines Agency website.

[redacted]