Press Release

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Shire Pharmaceuticals Initiates Voluntary Nationwide Recall Of One Batch, Packaged into Three Lots, of VPRIV® (velaglucerase alfa for injection)

Lexington, Mass. – March 14, 2014 – Shire Pharmaceuticals announced today the initiation of a voluntary recall in the United States of one batch, packaged into three lots, of VPRIV due to the presence of visible particulate matter, identified as stainless steel and barium sulfate. The particulate matter was found in a small number of vials in the three packaged lots of VPRIV. A Shire investigation identified the particulate matter root cause as the third party supplier fill finish process.

Shire believes the safety risk to patients is very low. If infused, there is a possibility of rare but serious adverse events associated with particulate containing barium sulfate. Shire believes this health risk was and continues to be mitigated by the package insert's required visual inspection of the reconstituted VPRIV product and by administration of VPRIV through an in-line low protein-binding filter. The product is being recalled and should not be used.

Importantly, there have been no reported adverse events or customer complaints associated with the use of these lots. To ensure that patients are not exposed to foreign particles during administration, Shire is reinforcing recommendations of the approved package insert in order to mitigate any risk: (1) visual inspection of the reconstituted VPRIV product should be done prior to administration and (2) VPRIV should be administered through an in-line low protein-binding filter. The safety profile of VPRIV remains unchanged.

VPRIV is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for pediatric and adult patients with type 1 Gaucher disease. VPRIV is supplied as a sterile, preservative-free, lyophilized powder in single-use vials, for intravenous use. This voluntary recall is limited to the following packaged lots: FEW13-001, FEW13-002, and FED13-006. These lots were distributed nationwide to hospitals, infusion clinics, patients, and home health agencies in the United States and all have the same NDC code (54092-701-04) and same expiration date of 10/15 (Oct 2015).

Shire has notified patients, hospitals, infusion clinics, and home health agencies via letter not to use product from the recalled lots. Customers should locate and remove all affected product from their facility and/or residence. Affected product should be returned by contacting Shire at 1-888-899- 9293 (Monday through Friday between the hours of 8:00am and 5:00pm Eastern Time). Shire has significant quantities of VPRIV to replace any affected product. Shire does not anticipate any disruption in supply as a result of this voluntary recall.

Unaffected lots of VPRIV can continue to be used according to the instructions for use.

Consumers or health care providers with questions regarding this recall can call Shire at 1-888-899-9293 (Monday through Friday between the hours of 8:00am and 5:00pm Eastern Time). Consumers should contact their physician or health care provider if they have experienced any problems that may be related to using this drug product.

Any adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular mail or fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

This voluntary recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

At Shire, patient safety is of the highest priority and corrective and preventative actions have been implemented to prevent reoccurrence.

Important Safety Information for VPRIV

- The most serious side effects seen in patients in clinical trials with VPRIV were hypersensitivity reactions, including one case of anaphylaxis. Hypersensitivity reactions in the clinical trials include any event considered related to and occurring within 24 hours of VPRIV infusion.
- The most common side effects seen in patients in clinical trials with VPRIV were hypersensitivity reactions. Patients were not routinely pre-medicated prior to infusion of VPRIV. The most commonly observed symptoms of hypersensitivity reactions include headache, dizziness, low blood pressure, high blood pressure, nausea, weakness/fatigue, and fever. Generally, the reactions were mild and, in newly treated patients, occurred mostly during the first 6 months of treatment and tended to occur less frequently with time.
- Management of hypersensitivity reactions should be based on severity of the reactions and may include slowing the infusion rate, treatment with medications such as antihistamines, fever-reducing agents and/or corticosteroids, and/or stopping and resuming treatment with increased infusion time. Side effects and any treatment concerns should be discussed with your physician.
- The most commonly reported side effects (occurring in ≥ 10% of patients) that were considered related to VPRIV included: hypersensitivity reactions, headache, dizziness, abdominal pain, nausea, back pain, joint pain, upper respiratory tract infection, aPTT prolonged (eg, blood clotting difficulty), fever and weakness/fatigue.
- All adult side effects of VPRIV are considered relevant to children (ages 4 to 17 years). Side effects more commonly seen in children compared with adult patients included: upper respiratory tract infection, rash, aPTT prolonged, and fever. The safety of VPRIV has not been established in patients younger than 4 years of age.
- As with all therapeutic proteins, there is a potential of developing antibodies. It is unknown if the presence of antibodies to VPRIV is associated with a higher risk of infusion reactions. Patients with an immune response to other enzyme replacement therapies who are switching to VPRIV should continue to be monitored for antibodies.
- Your doctor may prescribe VPRIV to you if you are pregnant, only if it is clearly necessary.

- Tell your healthcare provider if you experience any side effects. For more information about VPRIV, ask your healthcare provider, read the Full Prescribing Information or call Shire at 1-866-888-0660.

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NOTES TO EDITORS

Shire enables people with life-altering conditions to lead better lives.

Our strategy is to focus on developing and marketing innovative specialty medicines to meet significant unmet patient needs.

We provide treatments in Neuroscience, Rare Diseases, Gastrointestinal, Internal Medicine and Regenerative Medicine and we are developing treatments for symptomatic conditions treated by specialist physicians in other targeted therapeutic areas.

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FORWARD - LOOKING STATEMENTS - "SAFE HARBOR" STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

Statements included in this announcement that are not historical facts are forward-looking statements. Forward-looking statements involve a number of risks and uncertainties and are subject to change at any time. In the event such risks or uncertainties materialize, Shire's results could be materially adversely affected. The risks and uncertainties include, but are not limited to, that:

- Shire's products may not be a commercial success;
- revenues from ADDERALL XR are subject to generic erosion and revenues from INTUNIV will become subject to generic competition starting in December 2014;
- the failure to obtain and maintain reimbursement, or an adequate level of reimbursement, by third-party payors in a timely manner for Shire's products may impact future revenues, financial condition and results of operations;
- Shire conducts its own manufacturing operations for certain of its Rare Diseases products and is reliant on third party contractors to manufacture other products and to provide goods and services. Some of Shire's products or ingredients are only available from a single approved source for manufacture. Any disruption to the supply chain for any of Shire's products may result in the Shire being unable to continue marketing or developing a product or may result in Shire being unable to do so on a commercially viable basis for some period of time.

- the development, approval and manufacturing of Shire's products is subject to extensive oversight by various regulatory agencies and regulatory approvals or interventions associated with changes to manufacturing sites, ingredients or manufacturing processes could lead to significant delays, increase in operating costs, lost product sales, an interruption of research activities or the delay of new product launches;
- the actions of certain customers could affect Shire's ability to sell or market products profitably. Fluctuations in buying or distribution patterns by such customers can adversely impact Shire's revenues, financial conditions or results of operations;
- investigations or enforcement action by regulatory authorities or law enforcement agencies relating to Shire's activities in the highly regulated markets in which it operates may result in the distraction of senior management, significant legal costs and the payment of substantial compensation or fines;
- adverse outcomes in legal matters and other disputes, including Shire's ability to enforce and defend patents and other intellectual property rights required for its business, could have a material adverse effect on Shire's revenues, financial condition or results of operations;
- Shire faces intense competition for highly qualified personnel from other companies, academic institutions, government entities and other organizations. Shire is undergoing a corporate reorganization and the consequent uncertainty could adversely impact Shire's ability to attract and/or retain the highly skilled personnel needed for Shire to meet its strategic objectives;
- failure to achieve Shire's strategic objectives with respect to the acquisition of ViroPharma Incorporated may adversely affect Shire's financial condition and results of operations;
- and other risks and uncertainties detailed from time to time in Shire's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K.