Recall -- Firm Press Release

LEO Pharma Inc. voluntarily recalls innohep® (tinzaparin sodium injection) multidose vials

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FOR IMMEDIATE RELEASE – February 10, 2011 – LEO Pharma Inc. is conducting a voluntary recall of innohep® (tinzaparin sodium injection) multidose vials.

The following lots of innohep® 20,000 IU/ml, 2ml are being recalled at both the wholesaler and retailer levels:

10 x 2ml vials, lot number	Expiry date
DC3957	02-2011
DC5102	02-2011
DC6685	03-2011
DC7549	04-2011
DC7118	04-2011
DC8258	05-2011
DC7550	05-2011
DC9390	07-2011
DC9391	07-2011
DC9651	07-2011
DD0713	09-2011
DE4704	01-2013
DE4708	02-2013
DE4957	03-2013
1 x 2 ml vial, lot number	**Expiry date**
DC3381	02-2011
DC6985	04-2011
DC8228	05-2011
DC9158	07-2011
DC9874	07-2011
DC9873	08-2011
DE4705	01-2013
DE6288	03-2013

LEO Pharma Inc. is recalling these lots from the US market as a voluntary measure after a dialogue with the FDA following an inspection at the production facility in Ballerup, Denmark. The dialogue concerned the production process and more specifically, the theoretical risk of presence of particulate matter in the released vials.

The recall is not linked to any incidents of adverse events or customer complaints

Based on the limited quantity delivered to the US market, LEO Pharma Inc. has decided to discontinue marketing innohep® 20,000 IU/ml multidose vials in the US effective February 10, 2011.

Patients and healthcare providers can learn more about the recall by contacting LEO Pharma Inc. at:
Phone: 973-637-1690
Website: http://www.leo-pharma.us/Home/Contact/Contact-Global-Patient-Safety.aspx

See full product information:
http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=31375

Adverse events that may be related to the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program either online, by regular mail or by fax:

Online: www.fda.gov/medwatch/report.htm
Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm.
Mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787 Fax: 1-800-FDA-0178

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