SANOFI

Product and Application Business Support (PA-BUS)
European Medicines Agency

[redacted]

To the attention of:

[redacted]

Chilly-Mazarin, 05 July 2012

1	Applicant/MAH Name	sanofi-aventis groupe
2	Customer Account Number	[redacted]
3	Customer Reference / Purchase Order Number	Not applicable
4	Product Name	Mulsevo
5	Product Number or Procedure Number	EMEA/H/C/002516
6	INN / Active substance	semuloparin sodium
7	Application Type	Initial Marketing Authorisation Single ☐ Grouping ☐
8	Description of Submission	Withdrawal
9	Submission in accordance to Art. 8 of Paediatric Regulation (EC) No 1901/2006 of 12/12/2006	Is your product is protected by a Supplementary Protection Certificate (SPC) or a patent that qualifies for a SPC? ☐ Yes ☒ No
10	eCTD sequence	[redacted] Related sequence [redacted]
11	Contact Persons' details (include email address)	A) Regarding the content of the submission: [redacted] B) Regarding eCTD technical questions: [redacted] C) Regarding financial queries: [redacted]

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Subject: Withdrawal of MULSEVO (semuloparin sodium), 20 mg, solution for injection - **EMEA/H/C/002516**

Dear [redacted],

I would like to inform you that, at this point of time, Sanofi-aventis has taken the decision to withdraw the application for Marketing Authorisation of MULSEVO (semuloparin sodium) 20 mg, solution for injection, which was intended to be used for the primary prophylaxis of venous thromboembolism (VTE) in cancer patients receiving chemotherapy for locally-advanced or metastatic solid tumors.

This withdrawal is based on the outcome of the FDA Oncologic Drugs Advisory Committee (ODAC) meeting and on comments made by certain regulatory agencies, following which the decision was made not to pursue the registration in the US, in the EU or any other country in which the application is pending.

As a consequence of the withdrawal decision, the only ongoing clinical trial with semuloparin (a PK/PD/tolerability trial initiated as per the Paediatric Investigation Plan agreed with the PDCO) was terminated early and the relevant national competent authorities and ethics committees are being informed accordingly.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMA website.

This submission is compliant with eCTD specifications ICH v3.2 and will be provided to you on a CD/DVD as sequence number 0003, with copies provided to the Rapporteur, Co-Rapporteur and all CHMP Members. Virus scan information and the MD5 checksum are indicated on the CD/DVD. The details of the previously submitted sequences (0000, 0001 and 0002) are summarized in the appended table in Annex 1.

Yours sincerely,

[redacted]

[redacted]

Sanofi-aventis Recherche & Développement

[redacted]

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