Regulatory Notification Form

Regulatory Submissions and Outcomes

IMPORTANT REMINDER. If you are receiving this notification directly from a Regulatory Affairs representative, you are your functional area's nominated recipient of record. As such, you are responsible for further dissemination of this information on behalf of your functional area. If you are receiving this in error, please notify your functional area's management and inform the distribution list owner (in Outlook) regarding any changes to the distribution list. If you do not know who the distribution list owner is, please inform the notification sender instead.

Product Name Natpar (recombinant parathyroid hormone)

Procedure/Application/MA number Study PAR-C14-007 (Eudra CT: 2015-003108-22)

Type of Submission End of Trial Notification

Change control number (if applicable)

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Related to the Regions:

☒ **EU** (and select one from the right): ☐ **Centralised Product**
☒ **Other** (If checked, in the list below, mark all that apply. If applicable to all, mark ALL BELOW only)

☐ *All below*							
AT ☐	BE ☐	BG ☐	CY ☐	CZ ☐	DE ☐	DK ☐	EE ☐
EL ☐	ES ☐	FI ☐	FR ☐	HU ☐	IS ☐	IE ☐	IT ☐
LT ☐	LU ☐	LV ☐	MT ☐	NL ☐	NO ☐	PL ☐	PT ☐
RO ☐	SE ☐	SI ☐	SK ☐	UK ☒			

☐ **Other Countries** (If checked, in the list below, mark all that apply.)

Argentina ☐	Australia ☐	Brazil ☐	Canada ☐	China ☐	Hong Kong ☐
India ☐	Indonesia ☐	Israel ☐	Japan ☐	Korea ☐	Malaysia ☐
Mexico ☐	Philippines ☐	Russia ☐	Singapore ☐	Switzerland ☐	Taiwan ☐
Thailand ☐					
Other country(ies) ☐	Please list if Other is checked				

Reason for Notification (pick one only):
Submission ☒ Approval ☐ Other Outcome ☐

Date of Submission / Approval / Outcome: 05-July-2016

Details of Notification (description of the submission or of approved changes/outcome) and additional details (e.g., anticipated timelines of a procedure; conditions of approvals):

[redacted]

To date, no patients were enrolled into Study PAR-C14-007.

[redacted]

[redacted]

[redacted]

As no data has been collected in this trial, as part of the application the sponsor has confirmed that no Clinical Study Report will be submitted.

The study was terminated on the 20th June 2016. In line with the EU guidelines, any early termination of a trial will need to be notified to the relevant competent authority within 15 days of the date of termination.

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Additional details of note (if applicable):

Additionally some text has been updated in line with the updated QRD template.
N/A

For Approvals:

☐ Attachments for approved Labelling and Labelling Components, as applicable*

(EN only, nationals to follow after approval)

Implementation timeframe of approved labelling component changes (if applicable):

☐ **Next production run/next printing**

☐ **Date** (dd-mmm-yyyy): Per SOP

☐ **Update of compendia and compendia website (UK and IE only):**

eMC ☐ IPHA ☐ Not Applicable ☐

Details NA.

☐ **Impact to xEVMPD data (Europe only):**

xEVMPD Update: Select

If Other selected, provide details: _____

☐ **Approved Label Sent to Distributor / Partner (Europe and International only)**

[redacted]

Regulatory Affairs Contact in case of queries: [redacted]

*please detail if attached documents are the English/RMS version of the SmPC/PIL and national language versions will follow when approved

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