To:
Head of Paediatric Medicines
European Medicines Agency
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Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): Recombinant Bet v1 folding variant (rBet v1-FV)
Invented name:

Latest Decision number(s): 1) P/244/2010 2) 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000742-PIP01-09 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:
Allergy caused by birch pollen or crossreactive allergens

☒ has been discontinued
☐ has been suspended/put on long-term hold (with possible re-start at a later time)

for the following reason(s): *(tick all that apply)*

☐ (possible) lack of efficacy in adults
☐ (possible) lack of efficacy in children
☐ (possible) unsatisfactory safety profile in adults
☐ (possible) unsatisfactory safety profile in children
☒ commercial reasons (please specify:)
☐ manufacturing / quality problems
☐ other regulatory action (please specify:) *(e.g. suspension, revocation of M.A.)*
☐ other reason (please specify:)

Please add a brief description (max 2000 characters) of the reason(s) for the discontinuation / suspension:
Regulatory requirements are much higher for recombinant products than for natural allergen extracts. No homologeous group principle is accepted. Additional studies for reimbursement are necessary. Budget for PIP studies > 30 mio €. Minimal chance to be able to fulfill PIP study requirements with perennial SCIT treatment, but the budget has still to be spend. Birch is only third important allergen....

Name and signature of the PIP contact point: i.A. Verena Gehrt

Date: 10.06.2013

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