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): expanded autologous bone marrow-derived osteoblastic cells

Invented name: PREOB

Latest Decision number(s): 1) P/0164/2014 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-EMEA-001329-PIP02-13 2) EMEA- 3) EMEA- 4) EMEA-

Please note that development of the medicinal product above in the [condition(s)/indication(s)]:

☒ 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:

As allowed by the study protocol, Bone Therapeutics S.A. has decided to follow the recommendations of the DSMB and to stop the trial in the osteonecrosis indication (PREOB-ON3) for futility reason. The conclusion of the DSMB is: "The DSMB do not believe that including more patients has a chance to conclude this trial with statistical and clinical relevant outcomes for the primary endpoint". Following the early termination of PREOB-ON3, the company has decided to discontinue the clinical development of PREOB in all the indications.

Name and signature of the PIP contact point: signature on file
Date: 18 February 2019

Contact for inquiries from interested parties:

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