

To:

Head of Paediatric Medicines
European Medicines Agency
30 Churchill Place
London E14 5EU
United Kingdom
paediatrics@ema.europa.eu

Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision

Actives substances(s): odanacatib

Invented name: not yet proposed

Latest Decision number(s): 1) P/0307/2015 2) P/0301/2013 3) P/ 4)
P/

Corresponding PIP number(s): 1) EMEA-001123-PIP01-11-M03 2) EMEA-001499-PIP01-13
3) EMEA- 4) EMEA-

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

Treatment of osteoporosis.

☒ 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:

Merck Sharp & Dohme is discontinuing the development of odanacatib, Merck's investigational cathepsin K inhibitor for osteoporosis, and will not seek regulatory approval for its use. Merck previously reported a numeric imbalance in adjudicated stroke events in the pivotal Phase III fracture outcomes study in postmenopausal women. The company has decided to discontinue development after an independent adjudication and analysis of major adverse cardiovascular events confirmed an increased risk of stroke. The data from the analysis will be presented at the American Society for Bone Mineral Research (ASBMR) in September. The agency was informed about this decision on 1-Sep-2016 and a press release was made public on 2-Sep-2016.

Name and signature of the PIP contact point: Signature on file

Date: 23-Sep-2016

Contact for inquiries from interested parties: Merck Sharp & Dohme (Europe), Inc.

Telephone: +33 180 464 738

Email: pip.information@merck.com