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): abatacept

Invented name: ORENCIA

Latest Decision number(s): 1) P/P/0005/2017 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-000118-PIP03-15 2) EMEA- 3) EMEA- 4) EMEA-

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

Condition: Treatment of systemic lupus erythematosus / Indication: Treatment of chilhood-onset lupus nephritis caused by systemic lupus erythematosus (SLE) with abatacept in combination with mycophenolate mofetil (MMF) or cyclophosphamide (CF), and corticosteroids (CS) in paediatric patients 5 years of age and older who are newly diagnosed or who had an insufficient response to MMF or CF, and CS.

☒ 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:

Study IM101291 "A Phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of BMS-188667 (abatacept) or placebo on a background of mycophenolate mofetil (MMF) and corticosteroids in the treatment of subjects with active class III or IV lupus nephritis" in adults subjects did not meet its primary endpoint and was prematurely terminated. As a result, BMS has decided to stop the lupus nephritis development program and to not pursue an Adult and Paediatric indication in Lupus Nephritis.

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

Date: 4 February 2019

Contact for inquiries from interested parties: Bristol-Myers Squibb International Corporation

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