To:

Head of Paediatric Medicines
European Medicines Agency
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London E14 5EU
United Kingdom
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***Notification of discontinuation of a paediatric development which is covered by an agreed PIP Decision***

Actives substances(s): Anti proprotein convertase subtilisin kexin type 9 humanized monoclonal antibody (PF-04950615)

Invented name: CLERAMARC

Latest Decision number(s): 1) P/0080/2014 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001430-PIP01-13 2) EMEA- 3) EMEA- 4) EMEA-

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

Condition: Treatment of elevated cholesterol (Indication - Treatment of heterozygous or homozygous familial hypercholesterolaemia.

Condition: Treatment of mixed dyslipidaemia

Condition: Prevention of cardiovascular events in patients with cardiovascular disease or cardiovascular disease risk equivalent.

☒ 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: Pfizer has determined that the product profile for bococizumab is not likely to provide value for patients or physicians.)

☐ 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:

The purpose of this submission is to inform the Agency that Pfizer has decided to discontinue the global clinical development program for bococizumab. This decision was not based on a recommendation by the independent Data Monitoring Committee to stop the program. Rather, after careful consideration, in light of the emerging clinical profile of bococizumab and evolving treatment

landscape for lipid-lowering agents, Pfizer has determined that the product profile for bococizumab is not likely to provide value for patients or physicians.

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| Name and signature of the PIP contact point: | Signature on file |
| Date: | 16Nov2016 |


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| Contact for inquiries from interested parties: | PIP Enquiries |
| Telephone: | +44 (0)1304 646607 |
| Email: | pip_enquiries@pfizer.com |