To:

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

Actives substances(s): Covalently closed DNA plasmids coding for cytomegalovirus phosphoprotein 65 and glycoprotein B genes (ASP0113)

Invented name: TRANSVAX

Latest Decision number(s): 1) P/0338/2014 2) P/ 3) P/ 4) P/

Corresponding PIP number(s): 1) EMEA-001612-PIP01-14 2) EMEA- 3) EMEA- 4) EMEA-

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

Prevention of cytomegalovirus disease in patients with impaired cell-mediated immunity.

☒ 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:

ASP0113, an investigational DNA vaccine, did not meet its co-primary endpoint of overall mortality and end-organ disease in the 0113-CL-1004 clinical trial. Several secondary endpoints also were not met.

0113-CL-1004 was a Phase 3 randomized, double-blind, placebo-controlled trial to evaluate the protective efficacy and safety of a therapeutic vaccine, ASP0113, in cytomegalovirus (CMV)-seropositive recipients undergoing allogeneic, hematopoietic cell transplant (HCT).

The primary objective of the study was not met. For the primary endpoint, which was defined as the composite endpoint of all-cause mortality and adjudicated CMV EOD, statistical significance was not achieved. Both of the key secondary endpoints which were analyzed using a time to event approach were similar between the treatment groups.

Name and signature of the PIP contact point:	Signature on file
Date:	25th October 2018

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