UGA Biopharma

[redacted]

[redacted]

Prof. Harald Enzmann <CHMP Chairman>
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Hennigsdorf, 06.05.2022

Withdrawal of HemAryo, (INN), powder and solvent for solution for injection, 1,2 mg (60 KIU) - EMEA/H/C/005547

Dear Prof. Harald Enzmann,

For the withdrawal of initial marketing authorisation application

I would like to inform you that, at this point of time, UGA Biopharma has taken the decision to withdraw the application for Marketing Authorisation of HemAryo, (INN B02BD08), powder and solvent for solution for injection, 1,2 mg (60 KIU), which was intended to be used for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups:

- in patients with congenital haemophilia with inhibitors to coagulation factors VIII or IX > 5 Bethesda Units (BU)
- in patients with congenital haemophilia who are expected to have a high anamnestic response to factor VIII or factor IX administration
- in patients with acquired haemophilia
- in patients with congenital FVII deficiency
- in patients with Glanzmann's thrombasthenia with past or present refractoriness to platelet transfusions, or where platelets are not readily available.

This withdrawal is based on the following reasons:

- Identification of major manufacturing issues.

Please note that:

- We have planned to address all objections from the EMA on the initial Marketing Authorization Application. This requires a longer time than what is allowed for responding to the Day 120 List of Questions.
- All clinical trials of HemAryo have been completed.

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UGA Biopharma

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We reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

I agree for this letter to be published on the EMEA website.

Yours sincerely,

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