[redacted]

14 December 2021

Dr Harald Enzmann
CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of TOOKAD (padeliporfin), 183 mg and 366 mg, Powder for Solution for Injection
Type II variation procedure: EMEA/H/C/004182/II/0013

Dear Dr Enzmann

I would like to inform you that, at this point of time, Steba biotech S.A., has taken the decision to withdraw the Type II variation application EMEA/H/C/004182/II/0013 for an extension of the indication of the marketing authorisation for TOOKAD 183 mg and 366 mg, in the treatment of adenocarcinoma of the prostate.

This withdrawal is based on the following reasons: Company's strategy.

The withdrawal of this application does not impact any ongoing clinical trials and any future development of the product.

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 EMA website.

Yours sincerely,

[redacted]