From

[redacted]

20 April 2026

[redacted]
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Subject: Withdrawal of ORBLID, (Bevacizumab), 25 mg/ml, concentration for solution for infusion - EMEA/H/C/006392/0000

Dear [redacted],

I would like to inform you that, at this point of time, Laboratoires DELBERT has taken the decision to withdraw the application for Marketing Authorisation of ORBLID, (Bevacizumab), 25 mg/ml, concentration for solution for infusion, which was intended to be used for :
Adult patients with confirmed hereditary hemorrhagic telangiectasia (HHT) presenting
(i) severe liver damage with cardiac repercussions such as hyper output associated with persistent dyspnea despite well-conducted cardiological medical treatment and/or
(ii) a severe hemorrhagic form (epistaxis and/or digestive bleeding) of the disease with dependence on transfusions and/or intravenous iron.

This withdrawal is based on the following reasons:
identification of major clinical issues

Addressing the major objections would require the conduct of a new clinical study. Furthermore, we understand that real-world data does not appear to be sufficiently considered, even though the product is recommended by various international guidelines and is frequently used off-label within reference centers across different countries, which makes the conduct of new clinical trials even more challenging. Therefore, we are unable to address the major objections within the allocated timelines.

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

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

[redacted]