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Cytokinetics

6 May 2024

For the attention of:
Dr Harald Enzmann
CHMP Chairman
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

RE: Withdrawal of KINHARTO (*omecamtiv mecarbil*) 25 mg, 37.5 mg and 50 mg prolonged-release tablets
Procedure no: EMEA/H/C/006112/0000

Dear Dr. Enzmann,

I would like to inform you that, at this point in time, Cytokinetics (Ireland) Limited ("Cytokinetics") has taken the decision to withdraw the application for Marketing Authorisation of KINHARTO (*omecamtiv mecarbil*) 25 mg, 37.5 mg and 50 mg prolonged-release tablets which was intended to be used for the treatment of adult patients with symptomatic chronic heart failure and reduced ejection fraction less than 30%.

This withdrawal is based on the following reason:

- feedback from the CHMP indicates that the Committee will not be able to conclude that the benefits outweigh the risks on the basis of the results from GALACTIC-HF alone.

There are no ongoing clinical trials with *omecamtiv mecarbil* that would be impacted by this withdrawal.

Cytokinetics is considering its next steps regarding the potential development of *omecamtiv mecarbil* for the treatment of symptomatic chronic heart failure.

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

Cytokinetics would like to sincerely thank the (Co-) Rapporteurs and EMA for the time dedicated to reviewing this application and the support provided during the procedure.

Cytokinetics agrees for this letter to be published on the EMA website.

On behalf of Cytokinetics,

Yours sincerely

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