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7 February 2019

Dr. Harald Enzmann
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Subject: Marketing Authorisation Application Withdrawal of EPJEVY, pacritinib, 100 mg hard capsule, Procedure no. EMEA/H/C/004793

Dear Dr. Enzmann

I would like to inform you that, at this point of time, the MAA Applicant CTI Life Sciences Limited has taken the decision to withdraw the application for Marketing Authorisation of EPJEVY, pacritinib, 100 mg hard capsule, which was intended to be used for the treatment of disease related splenomegaly and control of symptoms in adult patients with primary myelofibrosis (PMF), post polycythemia vera myelofibrosis (PPV MF), or post essential thrombocythemia myelofibrosis (PET MF) who have significant thrombocytopenia (platelet counts < 100,000 /µL).

The withdrawal is based on the following reasons:
Additional data are required to resolve some of the points raised in the assessment report. The data cannot be generated within the procedural timeline.

CTI BioPharma confirms that there is no impact for patients in on-going clinical trials or in the compassionate use program.

CTI BioPharma intends to finish integration of the new data into a new dossier and approach the EMA again to discuss a new procedure.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

CTI agrees to this letter being published on the EMA website.

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