cti
BIOPHARMA

20 February 2017

Dr. Tomas Salmonson
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of ENPAXIQ, pacritinib, 100mg hard capsule, EMEA/H/C004193/0000

Dear Dr. Salmonson,

I would like to inform you that, at this point of time CTI BioPharma has taken the decision to withdraw the application for Marketing Authorisation of ENPAXIQ, pacritinib, 100mg hard capsule, which was intended to be used in the treatment of splenomegaly or the symptoms in adult patients with primary myelofibrosis (PMF), post-polycythemia vera myelofibrosis (PPV-MF), and post-essential thrombocythaemia myelofibrosis (PET-MF).

The withdrawal is based on the following reasons:

To address the concerns of the review team provided in the original Day 120 LoQs CTI BioPharma will need to integrate into the dossier the data from the second pivotal phase III study, PERSIST-2. There is insufficient time to complete this within the required CHMP timeframe for this procedure. We also acknowledge that presentation of a new pivotal study as part of the D120 LoQ response would create a challenge for the review team to provide a thorough assessment by Days 150 / 180.

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

Yours sincerely,

[redacted]