abbvie

03 August 2016

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

Subject: Withdrawal of Cokiera (dasabuvir/ombitasvir/paritaprevir/ritonavir), 200 mg / 8.33 mg / 50 mg / 33.33 mg, Modified Release Tablets - EMEA/H/0004235

Dear Dr. Salmonson,

We would like to inform you that AbbVie Ltd. has taken the decision to withdraw the application for Marketing Authorisation of Cokiera, (dasabuvir/ombitasvir/paritaprevir/ritonavir), 200 mg / 8.33 mg / 50 mg / 33.33 mg, modified release tablets, which was intended to be used for the treatment of chronic hepatitis C (CHC) in adults. The withdrawal is based on strategic business reasons for this specific product.

This decision has no impact on currently available treatments. There are no ongoing clinical trials or compassionate use programmes for this specific product.

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

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

Yours sincerely,

[redacted]

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