Sandwich Laboratories
Pfizer Limited

Dr. Tomas Salmonson
European Medicines Agency
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Subject: **Withdrawal of Type II variation EMEA/H/C/00687/II/0065 for Sutent (sunitinib malate)**

Extension of Indication to include "adjuvant treatment of patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy"

Dear Dr. Salmonson,

I would like to inform you that Pfizer Limited has taken the decision to withdraw the application for a new indication for Sutent (sunitinib malate), for the adjuvant treatment of patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy.

On March 16, 2017, the MAH submitted a Type II variation based on a randomized double-blind Phase 3 study of adjuvant sunitinib vs. placebo in subjects at high risk of recurrent RCC. The study met its primary endpoint of improving disease-free survival (DFS) as determined by blinded independent central review in patients with RCC who are at high risk for recurrence after surgery. The safety profile was consistent with the well-characterized and generally manageable safety profile of sunitinib.

This withdrawal is based on the CHMP opinion that the data provided in support of the new indication do not allow the committee to conclude on a positive benefit risk balance for this indication.

This withdrawal does not have any impact on ongoing clinical trials with sunitinib.

There are no consequences on the use of Sutent in its approved indications as the benefit-risk ratio remains positive in these indications.

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

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

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