

June 19, 2017

NCCN Guidelines Panel: Kidney Cancer

AMENDMENT TO PFIZER'S JANUARY 12, 2017 SUTENT® (sunitinib) for ADJUVANT USE SUBMISSION

Dear Ms. McClure:

Reference is made to our January 12, 2017 filing to NCCN and request to review for inclusion in the Kidney Cancer Guidelines the Sunitinib Treatment of Renal Adjuvant Cancer (S-TRAC) study in order to consider Sutent® (sunitinib), as a treatment option, for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy.

Reference is also made to your correspondence of May 19, 2017 in response to our telephone query and email of the same day advising us that the NCCN Kidney Cancer Panel is scheduled to meet via web conference on June 21, 2017 and that if we have additional information, we can append our submission of January 12th and submit it to submissions@nccn.org.

Since our original filing, significant new information that could contribute to your assessment has become available. This includes the following information:

1. Pfizer has performed a series of additional analyses on the ASSURE dataset and the results provide substantial insight into the influence of differences in patient population and dosing employed for sunitinib in this trial relative to the S-TRAC study on DFS outcome. This dataset was made available to us through the collaborative research agreement between Pfizer and ECOG that served as a basis for these analyses. These additional analyses are also part of our briefing materials for the Oncologic Drugs Advisory Committee (ODAC) tentatively scheduled for September 19, 2017 at which a labeling update for Sutent® (sunitinib), as a treatment option, will be discussed for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy. Unfortunately, per the contract with ECOG, we are unable to share with NCCN additional information on ASSURE until after the ODAC September 19th meeting when the briefing document and presentation slides will be made public, as per the FDA regulations.
2. While the randomized phase III trial of adjuvant pazopanib versus placebo after nephrectomy in patients with locally advanced renal cell carcinoma (RCC) (PROTECT) concluded that pazopanib at the reduced dose of 600 mg daily as adjuvant therapy did not prolong DFS, the secondary analyses of DFS at the full dose 800 mg did. This information further supports the importance of keeping patients at full dose to maximize the treatment benefits of TKIs in the adjuvant setting.
3. Assessments across subgroups from the S-TRAC study are ongoing in order to determine the relationship between baseline factors and DFS, patterns of recurrence and updated, although still not mature, overall survival data. These data, presently incorporated into a manuscript we have submitted to a peer-reviewed journal, are considered confidential under journal embargo and will be presented at the ODAC meeting on September 19th.

In summary, the information on Sutent® (sunitinib) for adjuvant use following nephrectomy in patients with RCC continues to evolve.

The subgroup analyses from ASSURE provide new information on the influence of patient selection and dosing of sunitinib while subgroup analyses and updated overall survival data from S-TRAC support the positive outcomes in the overall S-TRAC population. Furthermore, data from PROTECT provide support of the importance of maintaining full dose/exposure in the adjuvant setting.

Pfizer is committed to sharing the information described herein with NCCN at the earliest possible opportunity. Should NCCN defer a formal category of evidence and consensus for Sutent® (sunitinib) as an adjuvant treatment option for adult patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy until after the September 19th ODAC meeting where additional information will be addressed and debated, greater insights and understandings will undoubtedly be achieved.

Given that the proposed adjuvant indication for Sutent® (sunitinib) is also currently under regulatory review, we appreciate the NCCN panel treating all information contained in this communication, including reference to the tentatively scheduled ODAC which is not yet public information, as confidential.

Thank you for your kind consideration for deferral.

Sincerely,

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