

May 29, 2018

Submission Request  
National Comprehensive Cancer Network<sup>®</sup> (NCCN<sup>®</sup>)

**RE: Real-World Evidence in Support of Votrient<sup>®</sup> (pazopanib) in Patients with Advanced Renal Cell Carcinoma**

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Date of request: May 29, 2018  
NCCN Guidelines Panel: Kidney Cancer

To Whom It May Concern:

As the Panel reviews the NCCN Clinical Practice Guidelines in Oncology<sup>®</sup> (NCCN Guidelines<sup>®</sup>) with Evidence Blocks<sup>™</sup> for Kidney Cancer and v.4.2018, we have enclosed data related to treatment with Votrient<sup>®</sup> (pazopanib) for your consideration:

- Real-world evidence (RWE) in support of the first-line use of pazopanib in patients with advanced renal cell carcinoma (RCC).

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**Pazopanib for first-line treatment of advanced RCC in elderly patients**

This request is for the Panel to consider the submitted RWE when assessing the efficacy, safety and affordability scores of first-line pazopanib in advanced RCC in the Kidney Cancer Guidelines with Evidence Blocks<sup>™</sup>.

A retrospective Medicare claims database review of 1711 patients at least 65 years of age with advanced RCC who started first-line pazopanib (n = 526) or sunitinib (n = 1185) between January 1, 2006 and December 31, 2014 assessed real-world overall survival (OS), healthcare resource utilization (HRU) and healthcare costs. Patients were stratified 1:1 by treatment and matched according to baseline-propensity scores; outcomes were assessed among propensity-matched cohorts. Median OS was 18.2 months for pazopanib versus 14.6 months for sunitinib (log-rank  $P = 0.015$ ). Overall, HRU and healthcare costs were lower for the pazopanib arm.<sup>1</sup>

**Specific changes recommended for the Guidelines with Evidence Blocks**

Based on the provided RWE, please consider increasing the scores for efficacy, safety and affordability of pazopanib as a first-line systemic therapy for clear cell carcinoma (KID-3A) and as a first-line systemic therapy for non-clear cell carcinoma (KID-5A).

**FDA status**

Pazopanib is indicated for the treatment of patients with advanced RCC and advanced soft tissue sarcoma who have received prior chemotherapy.<sup>2</sup>

Limitations of use: the efficacy of pazopanib for the treatment of patients with adipocytic soft tissue sarcoma or gastrointestinal stromal tumors has not been demonstrated.<sup>2</sup>

**Rationale for recommended change**

Real-world data from the retrospective claims database review have demonstrated improved real-world outcomes for elderly patients with advanced RCC receiving first-line pazopanib as compared with sunitinib.

**Literature support**

1. Vogelzang N, Pal S, Ghatge S, et al. Clinical and economic outcomes in elderly advanced renal cell carcinoma patients starting pazopanib or sunitinib treatment: a retrospective Medicare claims analysis. *Adv Ther.* 2017. 34:2452-2465.
2. Votrient [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; 2017.

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We appreciate the opportunity to provide this additional information for consideration by the NCCN Kidney Cancer Panel. If you have any questions or require additional information, please do not hesitate to contact me at 1-862-778-5494 or via e-mail at [Neilda.baron@novartis.com](mailto:Neilda.baron@novartis.com).

Thank you for your time and consideration.

Sincerely,

Neilda Baron, MD  
Executive Director, Medical Information Oncology  
Novartis Pharmaceuticals Corporation

Enclosures: Copy of Prescribing Information and publication; author disclosures included within reference