Avapritinib (BLU-285) is a potent and selective inhibitor of activated KIT and PDGFRA

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**An Open-label, Randomized, Phase 3 Study of Avapritinib vs Regorafenib in Patients With Locally Advanced Metastatic or Unresectable Gastrointestinal Stromal Tumors**

Sebastian Bauer,†1 Suzanne George,‡ Yoohn-Koo Kang,§ William D. Tap,¶ Teresa Zhou,¶ Natasha Picazio,* Maria Roche,‖ Anthony L. Boral,‡ Michael Heinrich,⇑

1West German Cancer Center, University of Duisburg-Essen, Germany; 2Baina-Farber Cancer Institute, Boston, MA, USA; 3Asian Medical Center, Seoul, South Korea; 4Memorial Sloan Kettering Cancer Center, New York; 5Knight Cancer Institute, Oregon Health and Science University, Portland, OR, USA.

**INTRODUCTION**

- Approximately 80% of GIST harbor mutations in KIT.
- Approximately 30% of GIST harbor mutations in PDGFRA.

**METHODS**

- **Key Eligibility Criteria**
  - 18 years of age
  - Eastern Cooperative Oncology Group performance status of 0-1
  - Histologically or cytologically confirmed metastatic or unresectable GIST
  - Prior treatment with imatinib and 1 or 2 prior regimens for metastatic GIST
  - No prior treatment with avapritinib or regorafenib
  - No prior treatment with a KIT or PDGFRA inhibitor
  - No prior treatment with a KIT or PDGFRA inhibitor
  - No prior treatment with any other anti-GIST therapy
  - No prior treatment with a KIT or PDGFRA inhibitor
  - No prior treatment with any other anti-GIST therapy

- **Objective**
  - To evaluate the efficacy and safety of avapritinib versus regorafenib in patients with metastatic or locally advanced unresectable GIST previously treated with imatinib and 1 or 2 other TKIs

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**Study Endpoints and Evaluations**

- **Primary**
  - PFS, based on central radiological assessment by modified Response Evaluation Criteria in Solid Tumors (mRECIST, v1.1)

- **Secondary**
  - TTP
  - OS
  - Safety
  - Efficacy

- **Correlative**
  - Correlation of baseline PDGFRA mutations and TKI resistance
  - Correlation of baseline PDGFRA mutations and TKI resistance

- **Conclusions**

  - Data from the ongoing NAVIGATOR study will support avapritinib New Drug Application submission for 3rd line GIST and PDGFRA-mutant GIST, and led to the evaluation of avapritinib in 4th line GIST and PDGFRA-mutant GIST.

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**References**