Minimal Cross-Intolerance Between Nilotinib and Imatinib in Patients With Imatinib-Intolerant Chronic Myeloid Leukemia in Chronic Phase (CML-CP) or Accelerated Phase (CML-AP)

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INTRODUCTION

• Nilotinib (Tasigna®) is now approved for the treatment of patients with CML-CP and CML-AP resistant to or intolerant of prior therapy, including imatinib

• Nilotinib has demonstrated impressive efficacy in the treatment of CML in both CML-CP and CML-AP, as well as significant activity in blast crisis (CML-BC)

• Nilotinib is a rationally designed, highly selective, and potent inhibitor of the BCR-ABL kinase and binds to ABL with a higher affinity and improved tolerability profile when compared with imatinib

• While nilotinib and imatinib have structural similarities, they are distinct molecules and have different safety profiles

• This post hoc analysis was conducted in order to determine the occurrence, if any, of cross-intolerance between nilotinib and imatinib in CML-CP and CML-AP patients. Importantly, patients with imatinib intolerance who were in major cytogenetic response (MCyR) were excluded from the trial

METHODS

Study Design

• Post hoc analysis of pivotal phase 2 registration study, open label, multicenter

Nilotinib Treatment

• 400 mg twice daily (bid) administered orally

Definition of Intolerance

• Patients without nilotinib intolerance were included under grade 3/4 AE.

Definition of Cross-intolerance

• The occurrence of any grade 3/4 AEs or persistent grade 2 AEs during nilotinib therapy that was previously reported in the same patient while on imatinib

RESULTS

• To evaluate the incidence of cross-intolerance between nilotinib and imatinib in patients with imatinib-intolerant CML in both CML-CP and CML-AP

• To evaluate the safety of nilotinib in patients who were previously intolerant to imatinib

• Study Design

RESULTS

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CONCLUSIONS

• The results confirm that there is minimal cross-intolerance with nilotinib therapy in imatinib-intolerant CML-CP and CML-AP patients

• Thrombocytopenia was the only imatinib-related AE that led to nilotinib intolerance and discontinuation in some patients

• These results indicate that nilotinib is an excellent therapeutic option for patients with prior intolerance to imatinib

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REFERENCES

DISCLOSURES

Jabbour: Novartis Pharmaceuticals Corporation, BMS, AstraZeneca, Gilead, Janssen, Amgen
Kantarjian: Novartis Pharmaceuticals Corporation, BMS, AstraZeneca, Gilead, Janssen, Amgen, Merck
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• Objective(s)

• Methods

• Results

• Conclusions

• Acknowledgments

• References

• Disclosure(s)