Pirtobrutinib vs ibrutinib in treatment-naïve and R/R CLL/SLL: Results from the first randomized phase III study comparing a non-covalent and covalent BTK inhibitor (BRUIN CLL-314)

Randomized phase III trial of pirtobrutinib versus bendamustine plus rituximab in untreated patients with CLL/SLL (BRUIN CLL-313)

Pirtobrutinib has not been approved in the first-line or BTKi-naive setting for CLL/SLL patients by the FDA & the safety and effectiveness of these unapproved uses have not been established.

This information is intended for U.S HCPs for medical, scientific and educational purposes. Not intended for product promotion.

Pirtobrutinib is approved for the treatment of adult patients with R/R CLL/SLL who have previously been treated with a covalent BTK inhibitor.

Click thumbnails or scan QR codes to see the full results published in THE JOURNAL OF CLINICAL ONCOLOGY

CLL-314





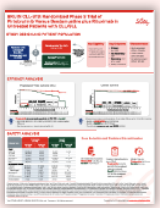
CLL-313

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CLL-314 **CLL-313**

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Limitations of this analysis of CLL-314:

- The median follow-up remains limited for progression-free survival, and further analyses are planned.
- This was an open-label study, and therefore, there is a risk of investigator-bias.
- This study was designed to test for ORR non-inferiority of pirtobrutinib versus ibrutinib. Conclusions about ORR superiority with pirtobrutinib cannot be drawn.

Limitations of this analysis of CLL-313:

- Patients with del(17p) were excluded, as these patients were not considered appropriate for the control arm. Thus, these data cannot be generalized to newly diagnosed patients with del(17p).
- OS was not yet mature at this analysis, further analyses with longer follow-up are planned.
- This was an open-label study, and therefore, there is a risk of investigator-bias.

Click here to access the full Prescribing Information for pirtobrutinib.

Highlights of Prescribing Information | Warnings and Precautions:

- Infections: Monitor for signs and symptoms of infection, evaluate promptly, and treat. (5.1)
- Hemorrhage: Monitor for bleeding and manage appropriately. (5.2)
- Cytopenias: Monitor complete blood counts during treatment. (5.3)
- Cardiac Arrythmias: Monitor for symptoms of arrhythmias and manage appropriately. (5.4)
- Second Primary Malignancies: Other malignancies have developed, including skin cancers and other carcinomas. Monitor and advise patients to use sun protection. (5.5)
- Hepatotoxicity, Including Drug-Induced Liver Injury: Monitor hepatic function throughout treatment. (5.6)
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential of potential risk to a fetus and to use effective contraception. (5.7, 8.1, 8.3)

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