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P627 LONG-TERM OUTCOMES WITH CONTINUOUS IBRUTINIB IN PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA: ANALYSIS OF TIME TO PROGRESSION

Topic: 6. Chronic lymphocytic leukemia and related disorders - Clinical

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Background:

Over the past decade, the introduction of targeted agents like ibrutinib has resulted in advances in treatment and improved outcomes for patients with CLL. Ibrutinib is the only once-daily Bruton's tyrosine kinase inhibitor (BTKi) therapy to demonstrate significant progression-free survival (PFS) and overall survival (OS) benefit in multiple phase 3 studies in patients with CLL. Compared with newer BTKis, ibrutinib has a comprehensive body of clinical and real-world data, providing a unique opportunity to assess long-term outcomes. Median PFS in the first-line (1L) RESONATE-2 study has not been reached after median 8 years of follow-up; a recent data analysis has also shown that patients treated with ibrutinib have similar OS estimates over an 8-year follow-up period as those from an age-matched general population (Ghia et al, ASH 2022).

Aims:

Since PFS is a combination of progression and survival events, we assessed the time to disease progression (PD) in previously untreated patients with CLL who were treated with ibrutinib, excluding patients who died prior to PD.

Methods:

Time to progression (TTP) was analyzed in a pooled data set comprising three 1L CLL clinical trials (RESONATE-2, ECOG1912, and iLLUMINATE) and included patients treated with continuous single-agent ibrutinib or an ibrutinib + anti-CD20 combination. Patients with a survival event prior to PD were censored per TTP definition. TTP was also assessed for patients who remained on treatment by censoring those who discontinued treatment for reasons other than PD. OS and safety were also evaluated.

Results:

A total of 603 patients received continuous ibrutinib treatment (single agent, n=136; anti-CD20 combination, n=467). Median (range) age was 63 years (31–89 years), and 65% of patients were male. Among patients with available genetic data, 10% (56/538) had del(17p)/TP53 mutation and 55% (334/603) had unmutated IGHV. Overall median follow-up for this analysis was 42 months, with respective median follow-up of 89, 46, and 38 months for RESONATE-2, iLLUMINATE, and ECOG1912. Of 603 patients treated with an ibrutinib-based regimen, 79 (13%) patients had PD at any time and 42 (7%) had PD while on ibrutinib treatment. Overall, the probability of remaining progression free at 8 years was 71% (95% CI, 62–78); in patients on active ibrutinib treatment until progression, the probability of remaining progression free at 8 years was 78% (95% CI, 69–85) (Figure). The 72-month OS probability (95% CI) was 76% (60–86) for patients who experienced PD at any time

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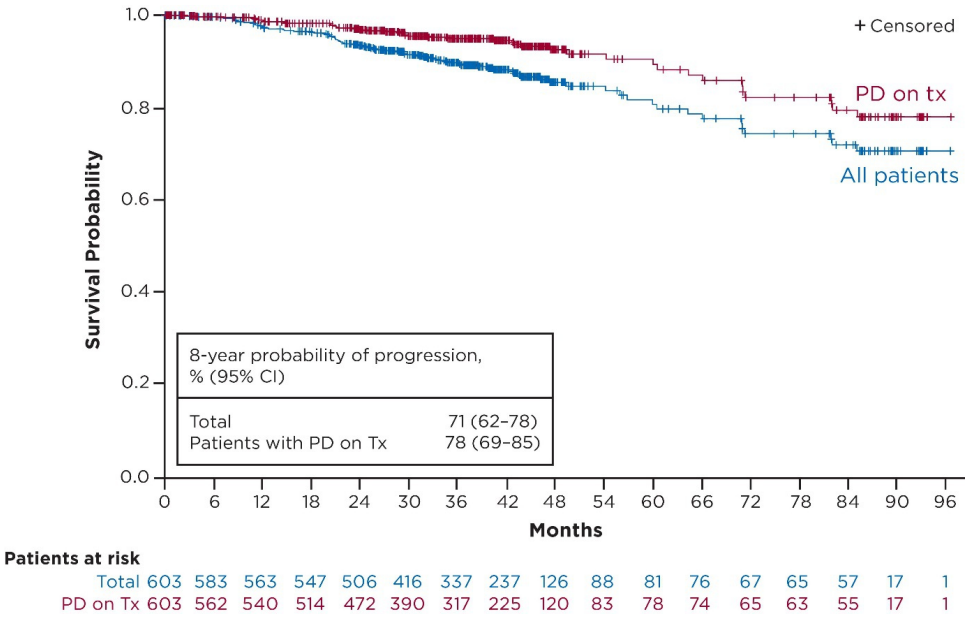
and 75% (54–87) for patients who experienced PD on treatment. Of the 600 patients included in the safety analysis, 171 (29%) had a grade ≥3 adverse event (AE). The 3 most frequent grade ≥3 AEs in each of the respective studies were previously published and included pneumonia, neutropenia, and anemia (RESONATE-2); neutropenia, thrombocytopenia, and pneumonia (iLLUMINATE); and neutropenia, increased lymphocyte count, and hypertension (ECOG1912).

Summary/Conclusion:

Overall, 13% of previously untreated patients with CLL had PD with ibrutinib-based standard-of-care treatment at a median 42 months of follow-up. Only 7% of patients who remained on active ibrutinib treatment experienced PD, and the likelihood of remaining progression free at 8 years was 78%. No new safety signals were identified in published results of the respective studies. These data demonstrate that PD is a rare event for patients who remain on active ibrutinib treatment, and together with OS benefit established in multiple trials, contribute to the evidence of long-term outcomes with ibrutinib treatment.



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