ELSEVIER

Blood 142 (2023) 6530–6531

The 65th ASH Annual Meeting Abstracts

ONLINE PUBLICATION ONLY

642.CHRONIC LYMPHOCYTIC LEUKEMIA: CLINICAL AND EPIDEMIOLOGICAL

Epic: A Second Interim Analysis of the Non-Interventional, Observational Multi-Centre Cohort Study of Patients with Chronic Lymphocytic Leukaemia Treated with First-Line Acalabrutinib through the UK Early Access Programme

Renata Walewska[1], *Nicolas Martinez-Calle*[2], *Joe Hickey*[3], *Hannah Harding*[4], *Sukhjit Hunjan*[4], *Betina T. Blak*[4], *Toby A. Eyre, MBChB, DipMedEd, MRCP, FRCPath, MD*[5]

[1]Department of Haematology, University Hospitals Dorset NHS Foundation Trust, Bournemouth, United Kingdom
[2]Clinical Haematology, Nottingham University Hospitals NHS Trust, Nottingham, United Kingdom
[3]Real-World Evidence, OPEN Health, Marlow, United Kingdom
[4]AstraZeneca, London, United Kingdom
[5]Department of Haematology, Cancer and Haematology Centre, Oxford University Hospitals NHS Trust, Oxford, United Kingdom

Background:
Acalabrutinib, a second-generation Bruton Tyrosine Kinase inhibitor (BTKi), has shown an acceptable safety profile and high response rates in clinical trials of treatment naïve patients with chronic lymphocytic leukaemia (CLL). However, real-world data detailing the safety and effectiveness of first-line acalabrutinib treatment for CLL is limited. Here we present a second interim analysis (IA) of patients with CLL who were initiated on first-line acalabrutinib within the UK Early Access Programme (EAP).

Methods:
This is an ongoing observational multi-centre cohort study involving retrospective data collection from medical records (ClinicalTrials.gov: NCT05557695). Treatment-naïve patients with CLL from 9 UK clinical centres who initiated acalabrutinib as part of the UK EAP between 1 st April 2020 - 1 st April 2021 were eligible to participate. Patients will be followed for up to 60 months from the date of acalabrutinib initiation (index). Collected data for this IA (data cut-off 31 st May 2023) includes baseline demographics, clinical characteristics, and treatment patterns.

Results:
101 patients were included in this IA. Median (interquartile range (IQR)) age at index was 73.8 (66.1-78.4) years; 56% (n=57/101) of patients were male; 89% (n=83/93) of patients were White British, 6% (n=6/93) were White other, 3% (n=3/93) were Asian and 1% (n=1/93) were of Mixed ethnicity (missing data n=8). Median (IQR) duration of follow-up was 32.4 (29.2-35.4) months; 89% (n=90/101) of patients had a follow-up duration of ≥1 year and 84% (n=85/101) ≥2 years. 88% (n=52/59) of patients had an Eastern Cooperative Oncology Group performance status (PS) of 0-1, 10% (n=6/59) had a PS of 2 and 2% (n=1/59) had a PS of 3 (missing n=42). 50% (n=40/80) of patients had a creatinine clearance <60 mL/min at index. 5% (n=5/101) of patients had a confirmed ATM mutation and no patients had a confirmed 17p13.1 deletion. 5% (n=5/101) had a confirmed TP53 mutation and of 10 patients with confirmed IgHV mutational status, 20% (2/10) had mutated IgHV (91 unknown). Median (IQR) time between CLL diagnosis and index was 2.8 (1.2-5.4) years. At index, 100 patients received 100 mg of acalabrutinib twice a day, 1 patient received 100 mg daily. The continuation rate (n=100) at 12 and 24 months was 81.0% (95% confidence interval [CI], 73.7%-89.1%) and 74.0% (95% CI, 65.9%-83.1%), respectively (1 patient not recorded). 68% (n=69/101) of patients remained on treatment at the time of data cut. Of those patients reporting reasons for treatment discontinuation, 48% (n=15/31) were due to adverse events (AEs; of the 14/15 patients reporting type of AEs resulting in discontinuation, 14% (2/14) was reported for each of the following AEs; cardiovascular, haematoma, headache and urinary tract infection), 6% (n=2/31) due to disease progression, 3% (n=1/31) due to patients' decision and 42% (n=13/31) other reasons (1 unknown). Of 39 patients with treatment interruptions, 72% (n=28/39) patients had interruptions due to AEs, 15% (n=6/39) due to a minor operation and/or procedure and 21% (n=8/39) other reasons. Of the 22/28 patients reporting type of AE resulting in treatment interruption, the most common AEs were upper respiratory tract infection (23%, n=5/22) and thrombocytopenia (18%, n=4/22). Of those with relevant medical records, 62% (n=40/65) had a recorded COVID-19 diagnosis; of these, 93% (n=37/40) diagnoses were confirmed via test. Sotrovimab was the most common treatment received for COVID-19 (20% of patients, n=8/40). COVID-19 vaccination and biannual boosters is offered to all patients with CLL as per UK guidelines, available data from 58 patients

showed that 72% (n=42/58) of patients had received ≥4 COVID-19 vaccination doses and 28% (n=16/58) had received <4 doses at the time of datacut (missing n=43).

Conclusion:

This IA reports 12 and 24-month real-world acalabrutinib continuation rates of 81.0% (95% CI, 73.7%-89.1%, n=100) and 74.0% (95% CI, 65.9%-83.1%, n=100), respectively, in treatment naïve patients with CLL in UK. These findings provide clinical decision makers with valuable insights into acalabrutinib use in the real-world as well as highlighting the importance of BTKi AE management in a real-world clinical setting. Further IAs are planned.

Disclosures Walewska: *AbbVie:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Meeting Attendance, Speakers Bureau; *AstraZeneca:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Meeting Attendance, Speakers Bureau; *Janssen:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: Meeting Attendance, Speakers Bureau; *Beigene:* Membership on an entity's Board of Directors or advisory committees, Other: Meeting Attendance, Speakers Bureau; *Secura Bio:* Honoraria, Speakers Bureau. **Martinez-Calle:** *Janssen:* Honoraria; *AbbVie:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Other: travel support; *AstraZeneca:* Honoraria, Other: travel support; *Takeda:* Honoraria, Membership on an entity's Board of Directors or advisory committees. **Hickey:** *OPEN Health:* Current Employment, Other: Contracted by AstraZeneca to conduct this study. **Harding:** *AstraZeneca:* Current Employment. **Hunjan:** *AstraZeneca:* Current Employment. **Blak:** *AstraZeneca:* Current Employment, Other: Company shares. **Eyre:** *Incyte:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *Abbvie:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *Beigene:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding, Speakers Bureau; *PeerView:* Speakers Bureau; *Loxo Lilly:* Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *Autolus:* Consultancy; *KITE:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *Gilead:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *Janssen:* Consultancy, Honoraria, Speakers Bureau; *Loxo Oncology:* Consultancy, Honoraria, Other, Speakers Bureau; *Eli Lilly and Company:* Consultancy, Honoraria, Speakers Bureau; *Medscape:* Speakers Bureau; *AstraZeneca:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding, Speakers Bureau; *Roche:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Speakers Bureau; *Secura Bio:* Membership on an entity's Board of Directors or advisory committees.

https://doi.org/10.1182/blood-2023-181641