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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

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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 (interguartile 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 \geq 1 year and 84% (n=85/101) \geq 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

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showed that 72% (n=42/58) of patients had received \geq 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.

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