Conclusions[1]

Most patients with R/R FLT3mut+ AML achieved CRc **within 6 cycles of XOSPATA monotherapy**

- **LRs were more likely than** ERs to achieve full-count recovery and were more frequently undergoing HSCT in CR
- **Fewer LRs experienced** treatment discontinuation due to disease relapse and progression, and they also had fewer drug-related TEAEs compared to ERs

Continuing XOSPATA, especially in those who tolerated the drug, **should be considered given the possibility of achieving late sustained remission**

FLT3: FMS-like tyrosine kinase 3, CRc: Composite complete remission, CRi: Complete remission with incomplete hematologic recovery, CRp: Complete Remission with partial haematologic recovery, HSCT: Haematopoietic stem cell transplant, AML: Acute Myeloid Leukaemia, LR: Late Responders, ER: Early Responders, OS: Overall Survival, E/PY: Events per Patient Year, TEAEs: Treatment Emergent Adverse Events CR: Complete Remission

References:

1. Alexander E. Perl, Mark J. Levis, Andrew Wei, Hee-je Kim, June-won Cheong, Yu Zhang, Jian Li, Hisayuki Yokoyama, Naoko Hosono, Nahla Hasabou, Dina Elsouda, Jamie Jung-Hee An, Jianxiang Wang; Timing of Response with Gilteritinib Monotherapy in Relapsed or Refractory FLT3-Mutated Acute Myeloid Leukemia. Blood 2024; 144 (Supplement 1): 2889

Additional information available on request

MAT-IN-XOS-2025-00015
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Scan for Xospata PI

XOSPATA gilteritinib

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XOSPATA™ ADVANTAGE

Timing of response with XOSPATA monotherapy in Relapsed or Refractory FLT3 mutated Acute Myeloid Leukemia[1]

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MAT-IN-XOS-2025-00015

Rationale for the study[1]

XOSPATA, is a type 1, second generation FLT3 inhibitor approved globally for the treatment of R/R FLT3mut+ AML[1]

Many patients treated with XOSPATA have marrow blast clearance after 1-2 months, but slower response is not uncommon and full count recovery can take up to 6 months[1]

Data are needed on the timing of response for XOSPATA which typically elicits a response within two cycles[1]

This study was conducted to investigate the timing of response (measured by CRc) for patients with R/R FLT3mut+ AML on XOSPATA[1]

Study Design[1]

- This was a post-hoc analysis of XOSPATA arms of the two phase 3, randomized controlled trials – ADMIRAL[1] and COMMODORE[2]
- All XOSPATA-treated patients who achieved CRc before on-study HSCT from full analysis sets and safety analysis sets from both trials were included
- Both studies had XOSPATA treatment cycles of 28 days
- CRc was defined as the sum of CR, CRi, and CRp

Patients Included

Early Responders who achieved CRc by the end of cycle 2[1]

Late Responders who achieved CRc after initiation of cycle 3[1]

Variables assessed (by responder status)[1]

- Achievement of CRc before on-study HSCT
- Type of remission
- Overall Survival
- Baseline characteristics
- TEAEs

This post-hoc analysis of the XOSPATA arms of the two phase 3, randomized controlled trials (ADMIRAL and COMMODORE) investigated the timing of response for patients with R/R FLT3 mutated AML on XOSPATA monotherapy, measured by CRc[1]

205
(pooled analysis) XOSPATA treated CRc responders from two phase 3 trials: ADMIRAL and COMMODORE

29.3%
Early responders (n=60)
achieved CRc by the end of cycle 2

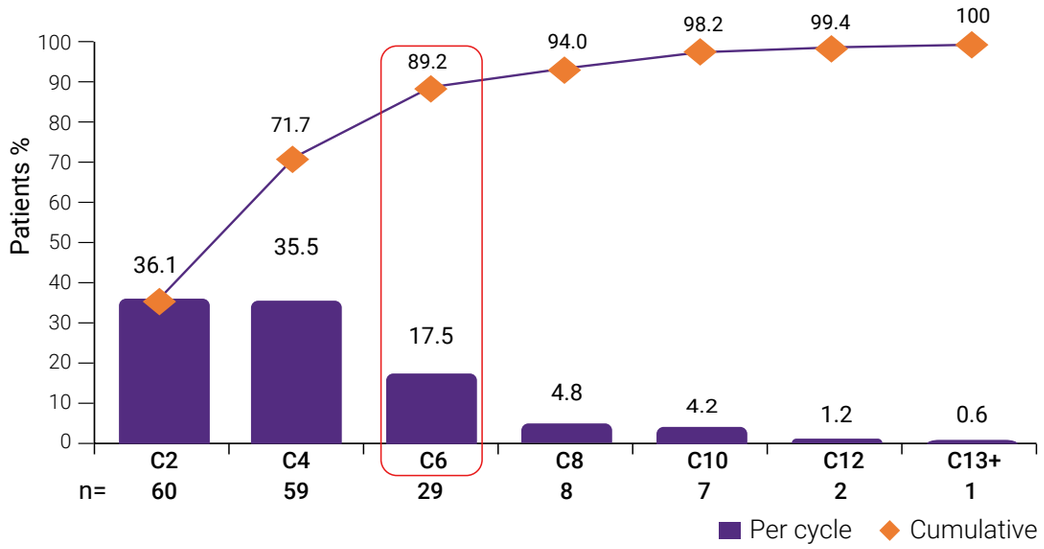
70.7%
Late responders (n=145)
achieved CRc after initiation of cycle 3

21.7%
Early responders with CR (n=13)

48.3%
Late responders with CR (n=70)

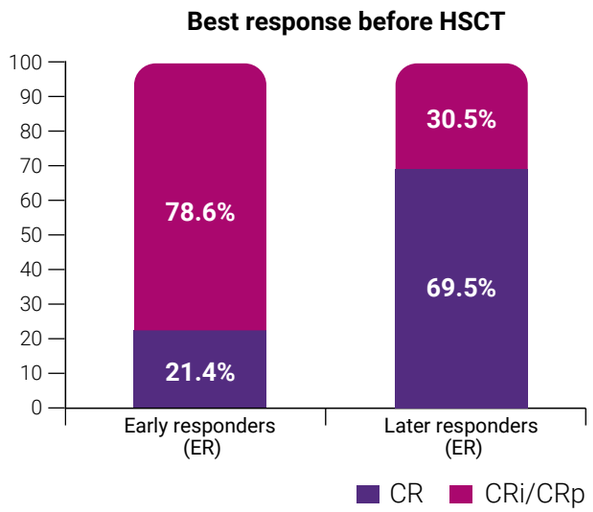
166/205
patients achieved CRc prior to on-study HSCT

Patients achieving CRc by treatment cycle[1]



- Almost 90% of CRc responders achieved remission within 6 cycles of XOSPATA treatment

Patients achieved CR with full count recovery prior to on-study HSCT were more in LR than ER[1]

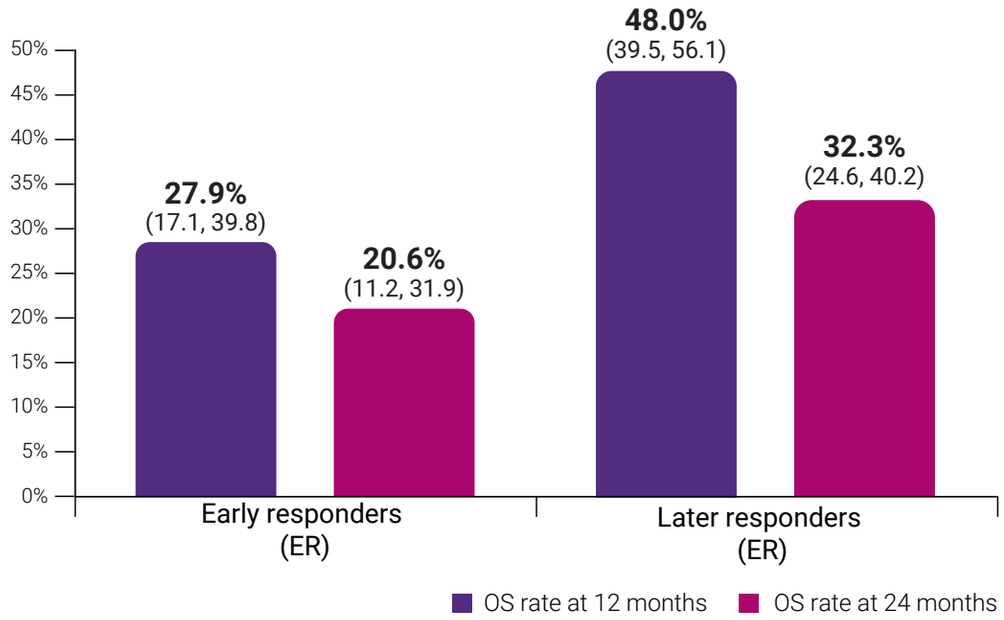


- More LRs [40.7% (59/145)] received on-study hematopoetic stem cell transplantation after XOSPATA treatment compared with ERs [23.3% (14/60)]
- More LRs (69.5% [41/59]) underwent HSCT in CR compared with ERs (21.4% [3/14]). More ERs (78.6% [11/14]) underwent on-study HSCT in CRi or CRp compared with LRs (30.5% [18/59]).

The survival outcomes in patients were slightly better in LRs as compared to ERs[1]

Survival outcomes

The median OS (95% CI), indexed from the CRc date, was 9 (7, 10) months for ERs and 11 (9, 16) months for LRs.



Safety Results[1]

- Grade 3 or higher treatment-emergent adverse events (TEAEs), adjusted by the total duration of exposure time, were 22.2 E/PY and 13.5 E/PY in ERs and LRs, respectively
- Drug-related grade 3 or higher TEAEs were 10.6 E/PY in ERs, and 6.5 E/PY in LRs
- Treatment discontinuation due to disease relapse (ERs, 41.7% [25/60]; LRs, 27.6% [40/145]) and progression (ERs, 25.0% [15/60]; LRs, 19.3% [28/145]) was higher in ERs than LRs.