XOSPATA™

gilteritinib 40 mg film-coated tablets

# Case Simulation-
# Prior TKI Exposure

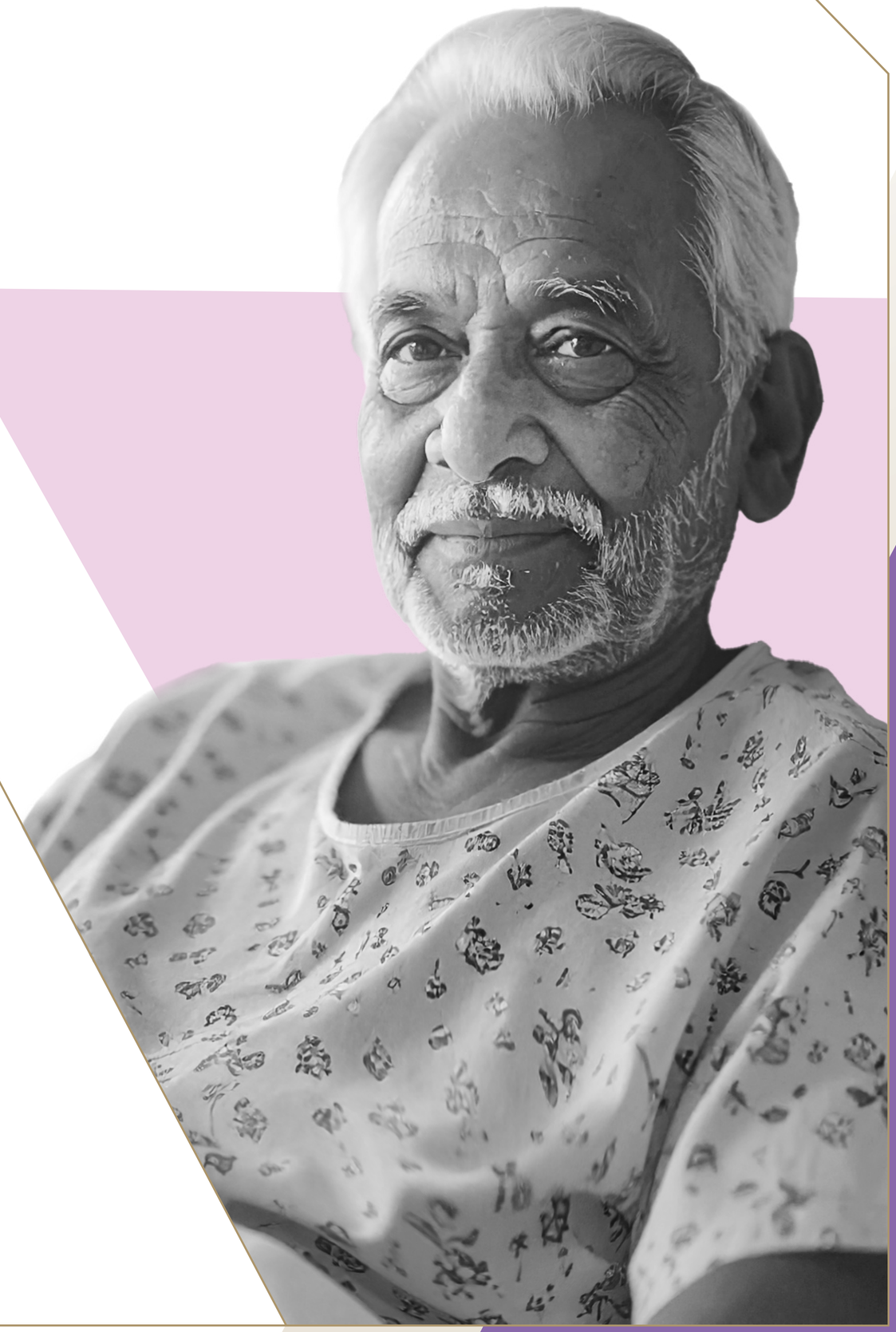
MAT-IN-XOS-2025-00063

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only, Additional Information Available on request.

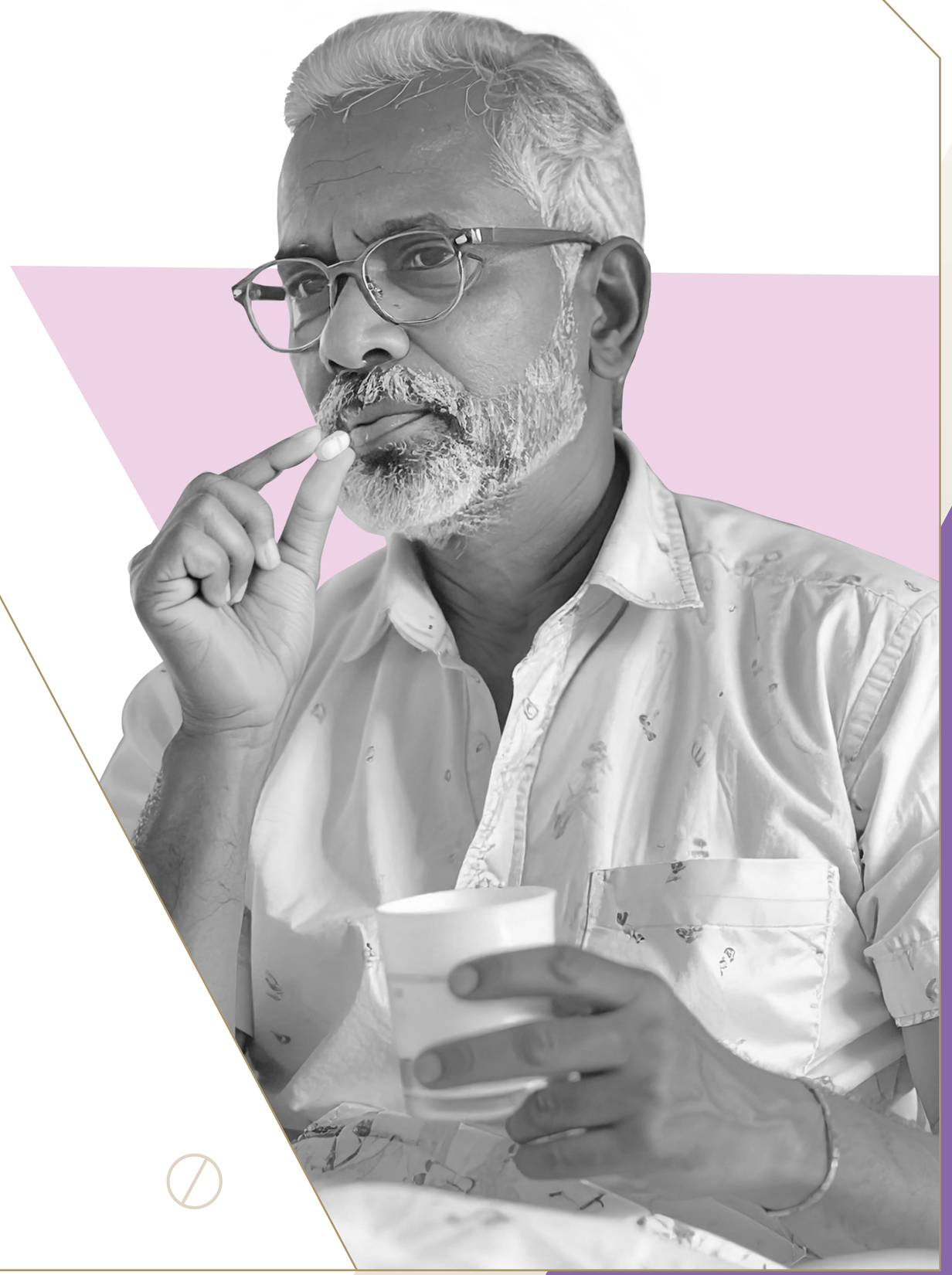
Scan for Prescibing Information

- A patient diagnosed with AML
- FLT3+
- Started on Midostaurin + Chemo

- Blast counts keep increasing
- Patient refractory to Midostaurin + chemo



# Patient started on Xospata



# PRIOR USE OF FLT3 TKI

## RESULTS

### Baseline and prior treatment characteristics of patients with R/R AML in the CHRYSALIS and ADMIRAL trials[1]

| Characteristic | CHRYSALIS 120-/200-mg Gilteritinib | | ADMIRAL 120-mg Gilteritinib vs Salvage Chemotherapy | | | |
|---|---|---|---|---|---|---|
| | | | Gilteritinib | | Salvage Chemotherapy | |
| | Prior TKI (n=33) | No Prior TKI (n=112) | Prior TKI (n=31) | No Prior TKI (n=216) | Prior TKI (n=14) | No Prior TKI (n=110) |
| Median age, years (range) | 56 (24-84) | 61 (22-87) | 55 (20-82) | 62 (22-84) | 64.5 (34-78) | 61 (19-85) |
| Female, n (%) | 18 (55) | 59 (53) | 12 (39) | 119 (55) | 8 (57) | 62 (56) |
| ECOG performance status, n (%) | | | | | | |
| 0-1 | 22 (67) | 87 (78) | 23 (74) | 183 (85) | 13 (93) | 92 (84) |
| ≥2 | 11 (33) | 25 (22) | 8 (26) | 33 (15) | 1(7) | 18 (16) |
| *FLT3* mutation type, n (%) | | | | | | |
| *FLT3*-ITD only | 29 (88) | 94 (84) | 22 (71) | 193 (89) | 13 (93) | 100 (91) |
| *FLT3*-TKD only | 0 | 9 (8) | 5 (16) | 16 (7) | 16 (7) | 9 (8) |
| *FLT3*-ITD and -TKD | 4 (12) | 7 (6) | 4 (13) | 3 (1) | 3 (1) | 0 |
| Other/unknown/missing | 0 | 2 (2) | 0 | 4 (2) | 4 (2) | 1 (0.9) |
| Cytogenetic risk status, n (%) | | | | | | |
| Favorable | 0 | 4 (4) | 0 | 4 (2) | 0 | 1 (0.9) |
| Intermediate | 23 (70) | 78 (70) | 28 (90) | 154 (71) | 13 (93) | 76 (69) |
| Unfavorable | 4 (12) | 14 (13) | 3 (10) | 23 (11) | 1(7) | 10 (9) |
| Other/unknown/missing | 6 (18) | 16 (14) | 0 | 35 (16) | 0 | 23 (21) |
| Response to first-line therapy, n (%) | | | | | | |
| Relapsed | 22 (67) | 74 (66) | 19 (61) | 130 (60) | 11 (79) | 65 (59) |
| Primary refractory | 11 (33) | 38 (34) | 12 (39) | 86 (40) | 3 (21) | 45 (41) |
| Prior lines of therapy, n (%) | | | | | | |
| 1 | 3 (9) | 42 (38) | 31 (100) | 216 (100) | 14 (100) | 110 (100) |
| 2 | 6 (18) | 46 (41) | 0 | 0 | 0 | 0 |
| ≥3 | 24 (73) | 34 (30) | 0 | 0 | 0 | 0 |
| Prior HSCT, n (%) | | | | | | |
| Yes | 14 (42) | 34 (30) | 10 (32) | 38 (18) | 4 (29) | 22 (20) |
| No | 19 (58) | 78 (70) | 21 (68) | 178 (82) | 10 (71) | 88 (80) |

AML, acute myeloid leukemia; ECOG, Eastern Cooperative Oncology Group; *FLT3*, FMS-like tyrosine kinase; HSCT, hematopoietic stem cell transplantation; ITD, internal tandem duplication; R/R, relapsed or refractory; TKD, tyrosine kinase domain; TKI, tyrosine kinase inhibitor.

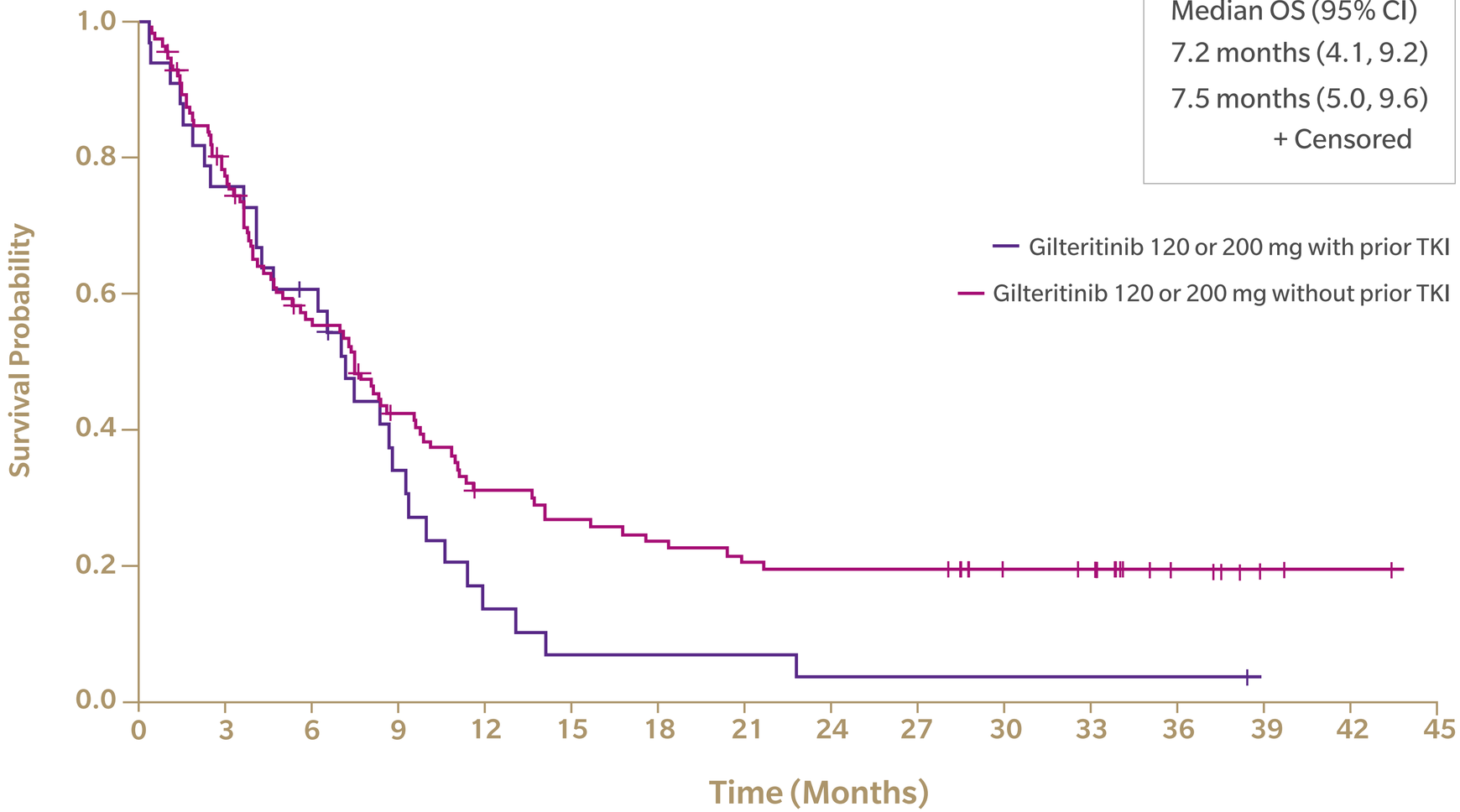
1. Perl AE, Martinelli G, Cortes JE, et al. *N Engl J Med*. 2019;381:1728–1740

## PRIOR USE OF FLT3 TKI

RESULTS

### Overall survival by prior TKI status[1]

**A.** CHRYSALIS trial




| Patients at risk (n) | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Gilteritinib 120 or 200 mg with prior TKI | 33 | 25 | 19 | 10 | 4 | 2 | 2 | 2 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| Gilteritinib 120 or 200 mg without prior TKI | 112 | 82 | 57 | 41 | 29 | 25 | 22 | 19 | 18 | 18 | 14 | 13 | 6 | 2 | 1 | 0 |

CI, confidence interval; OS, overall survival; TKI, tyrosine kinase inhibitor.

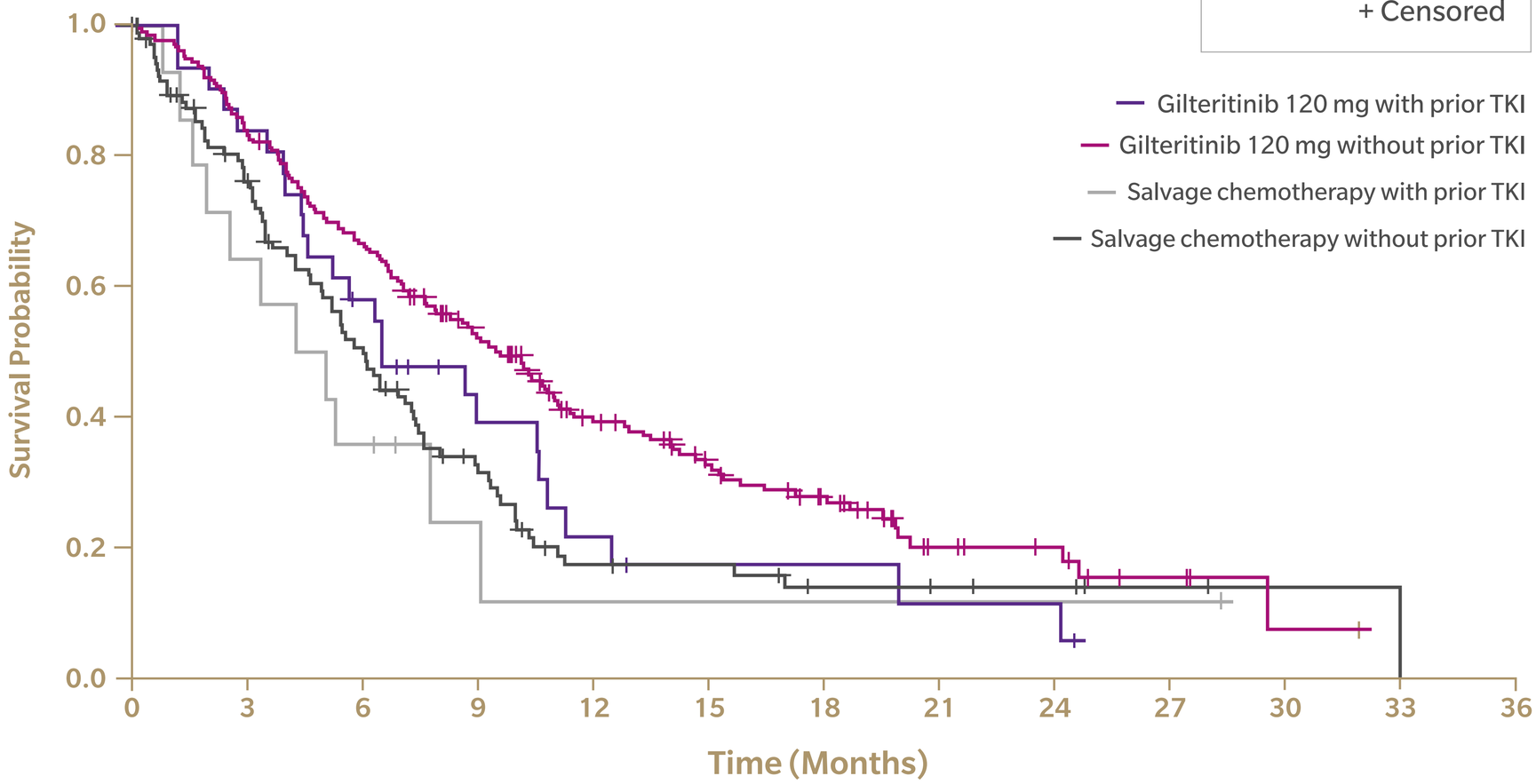
1. Perl AE, Martinelli G, Cortes JE, et al. *N Engl J Med*. 2019;381:1728–1740

## PRIOR USE OF FLT3 TKI

RESULTS

Overall survival by prior TKI status[1]

**B.** ADMIRAL trial




| Median OS (95% CI) |
|---|
| 6.5 months (4.5, 10.6) |
| 9.6 months (7.9, 11.0) |
| 4.7 months (1.6, 9.1) |
| 6.0 months (5.0, 7.4) |
| + Censored |

— Gilteritinib 120 mg with prior TKI
— Gilteritinib 120 mg without prior TKI
— Salvage chemotherapy with prior TKI
— Salvage chemotherapy without prior TKI

| Patients at risk (n) | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Gilteritinib 120 mg with prior TKI | 31 | 26 | 17 | 9 | 5 | 3 | 3 | 2 | 2 | 0 | 0 | 0 | 0 |
| Gilteritinib 120 mg without prior TKI | 216 | 180 | 140 | 97 | 59 | 41 | 28 | 12 | 9 | 4 | 1 | 0 | 0 |
| Salvage chemotherapy with prior TKI | 14 | 9 | 5 | 2 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 |
| Salvage chemotherapy without prior TKI | 110 | 75 | 47 | 27 | 12 | 11 | 7 | 6 | 4 | 2 | 1 | 0 | 0 |

CI, confidence interval; OS, overall survival; TKI, tyrosine kinase inhibitor.

1. Perl AE, Martinelli G, Cortes JE, et al. *N Engl J Med*. 2019;381:1728–1740

# PRIOR USE OF FLT3 TKI : CONCLUSIONS[1]

**Patients with *FLT3*-mutated R/R AML who received prior midostaurin or sorafenib achieved high remission rates with gilteritinib**

- **High response rates** with 120- or 200-mg gilteritinib **after prior TKI therapy** were observed in heavily pretreated patients in the CHRYSALIS trial
- **Higher response rates with gilteritinib than with SC** were observed in prior TKI-treated patients in the ADMIRAL trial
- **Remission after prior TKI** therapy was **achieved in patients with *FLT3*-ITD, *FLT3*-TKD, or both *FLT3*-ITD and -TKD mutations**

Among patients who received prior midostaurin or sorafenib in the ADMIRAL trial, **survival was longer in patients treated with gilteritinib than in those treated with SC**

AML, acute myeloid leukemia; CI, confidence interval; *FLT3*, FMS-like tyrosine kinase; ITD, internal tandem duplication; R/R, relapsed or refractory; SC, salvage chemotherapy; TKD, tyrosine kinase domain; TKI, tyrosine kinase inhibitor.

1. Perl AE, Martinelli G, Cortes JE, et al. *N Engl J Med*. 2019;381:1728–1740

Report any adverse events to Astellas Pharma India Pvt. Ltd. at pv@in.astellas.com.
Astellas Pharma India Pvt. Ltd. 301, 3rd Floor, C & B Square, 127 Andheri Kurla Road, Chakala, Andheri East, Mumbai 400 069, India