

Latest data from the FLAIR and CAPTIVATE trials, presented at EHA 2025

Phase III FLAIR trial:

Ibrutinib + venetoclax with MRD-guided duration of treatment vs ibrutinib vs FCR in patients with CLL¹

Population:
N = 786

Adaptive trial design:

FCR was first compared with ibrutinib + rituximab; the trial design was later adapted to include the I and I+V arms

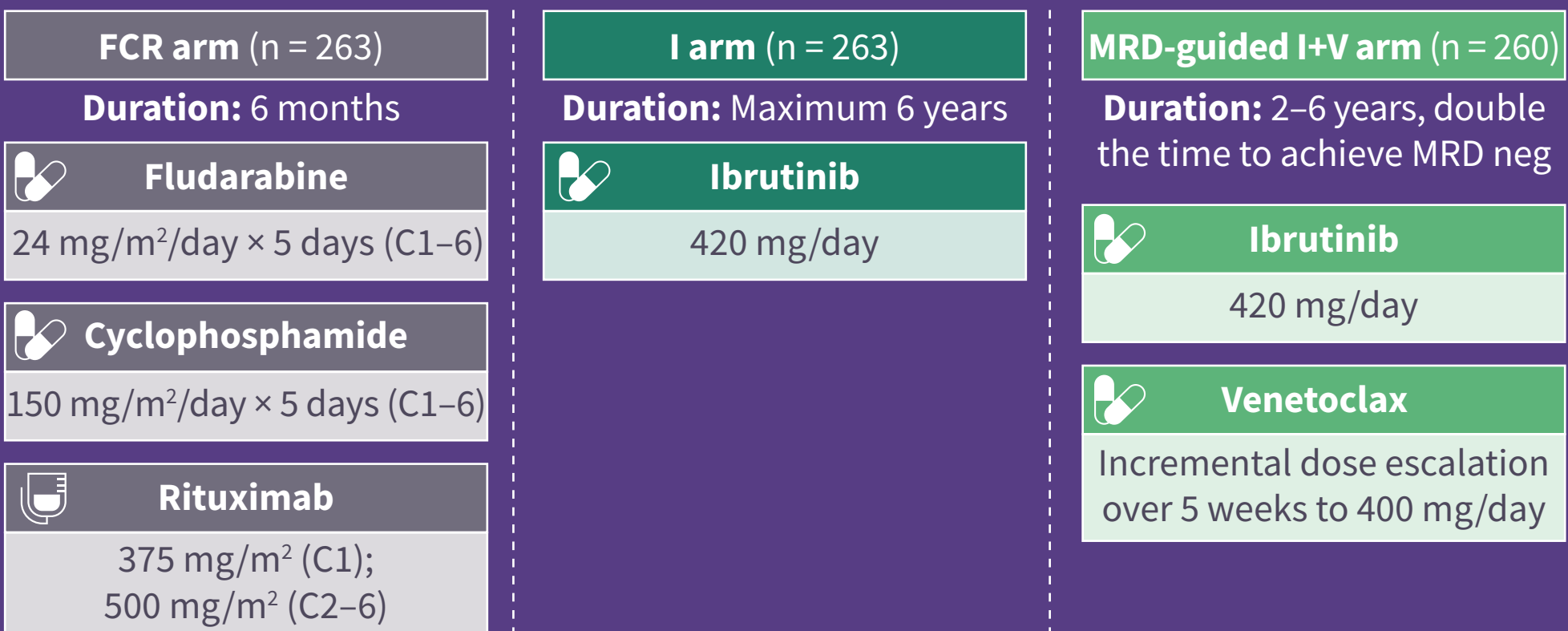
I+V vs FCR primary endpoint: PFS

I+V vs I primary endpoint: MRD negativity

Eligibility: Previously untreated CLL

Median age: 62 years

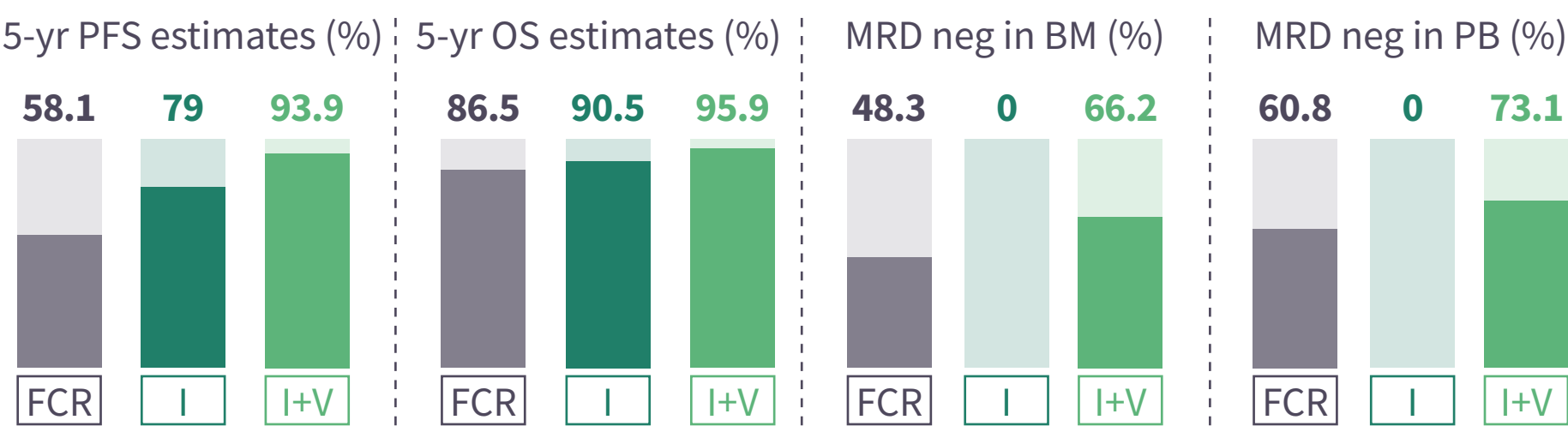
STUDY DESIGN (ISRCTN01844152)



EFFICACY

Median follow-up: 62.2 months

Median PFS



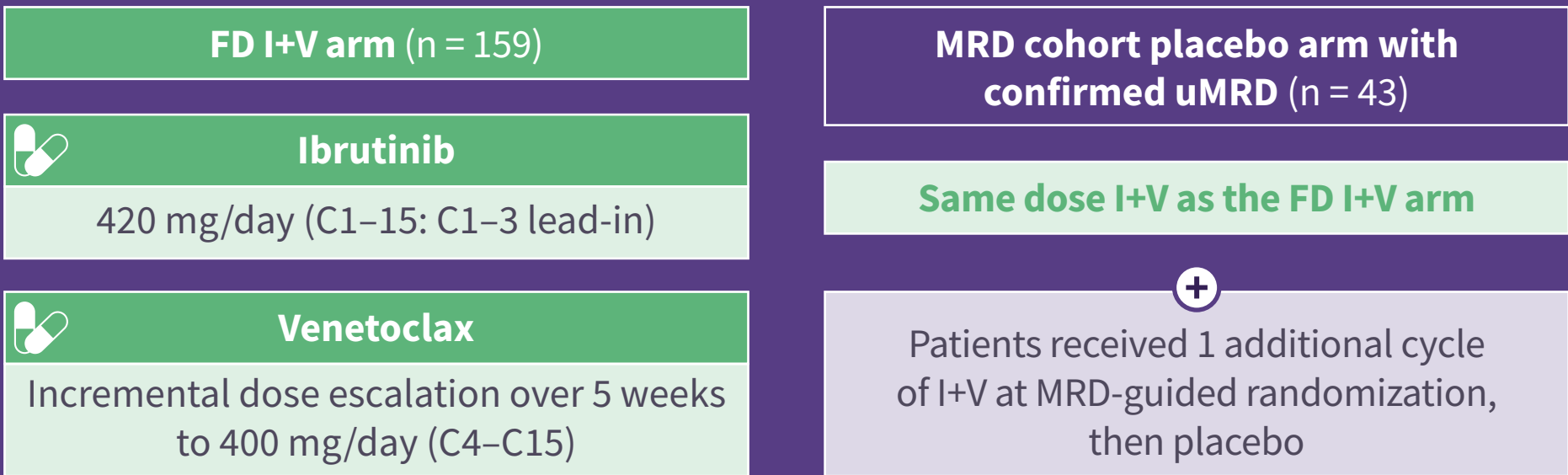
Phase II CAPTIVATE trial:

Final analysis of fixed-duration ibrutinib + venetoclax in patients with CLL/SLL²

Population:
N = 202

Eligibility: Previously untreated CLL/SLL; aged ≤70 years. **Median age:** 60 years

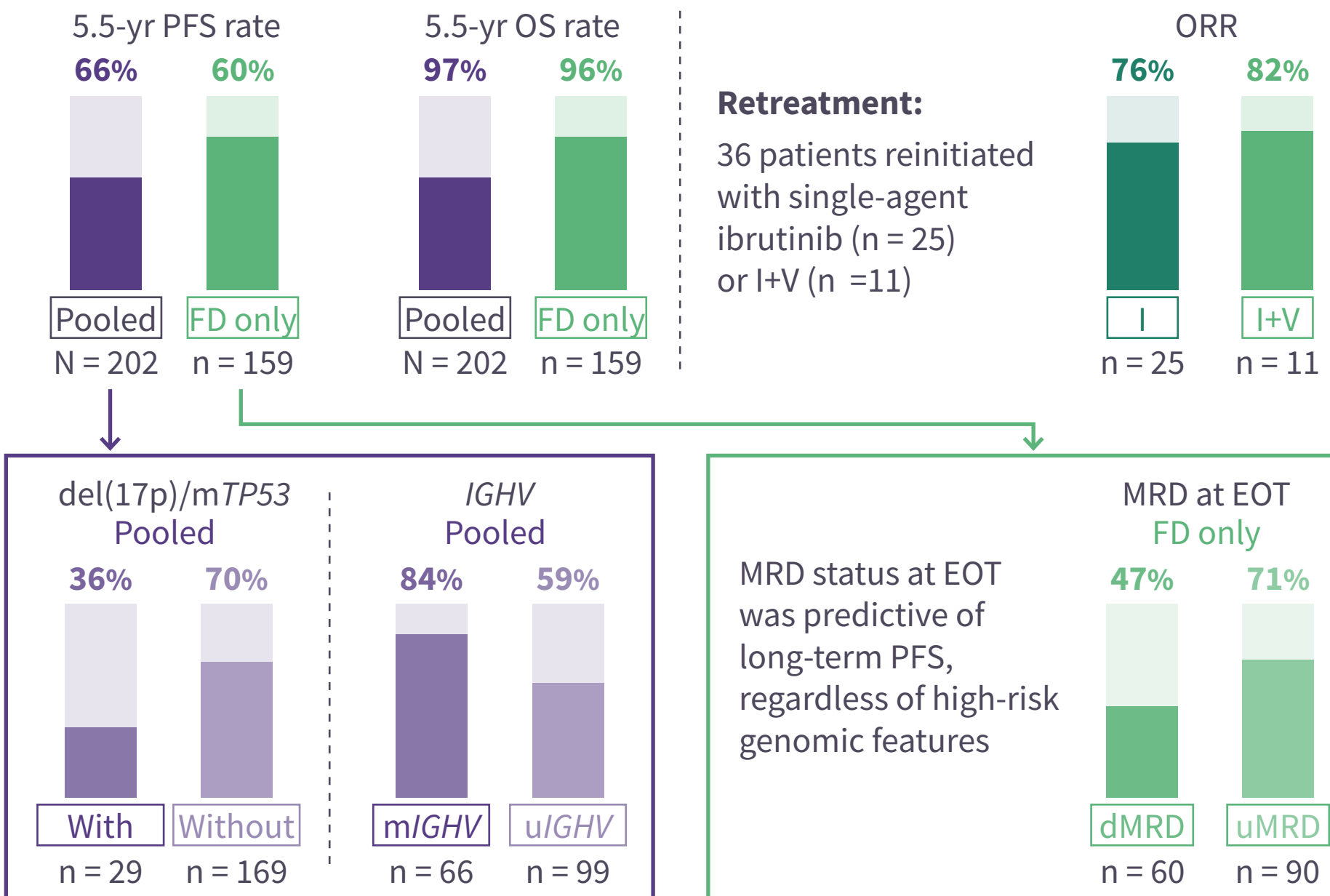
STUDY DESIGN (NCT02910583)



EFFICACY

Median follow-up: 68.9 months

Median PFS and median OS not reached



Together, the updated results from these trials, with longer follow-up, demonstrate the benefit of the all-oral, once-daily, chemotherapy-free I+V regimen in patients with previously untreated CLL.^{1,2} MRD-guided duration of therapy may further optimize outcomes.¹

BM, bone marrow; C, cycles; CLL, chronic lymphocytic leukemia; del, deletion; dMRD, detectable measurable residual disease; EHA, European Hematology Association; EOT, end of treatment; FCR, fludarabine + cyclophosphamide + rituximab; FD, fixed-duration; I, ibrutinib; I+V, ibrutinib + venetoclax; mIGHV, mutated IGHV; MRD, measurable residual disease; mTP53, mutated TP53; neg, negativity; NR, not reached; ORR, overall response rate; OS, overall survival; PB, peripheral blood; PFS, progression-free survival; SLL, small lymphocytic lymphoma; uIGHV, unmutated IGHV; uMRD, undetectable measurable residual disease.

References: **1.** Munir T. Oral Abstract #S155. EHA 2025 Congress; Jun 12–15, 2025; Milan, IT; **2.** Ghia P. Oral Abstract #S156. EHA 2025 Congress; Jun 12–15, 2025; Milan, IT.