ASH 2025 DATA REVIEW
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LEUKEMIA

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PARADIGM: Frontline Azacitidine with venetoclax demonstrated deep and more frequent response than induction chemotherapy (ORR: 88% vs 62%) in newly diagnosed intermediate or adverse-risk FLT3-wild type acute myeloid leukemia – FDA approved November 2018

ASC2ESCALATE: In chronic myeloid leukemia previously treated with one TKI, asciminib achieved major molecular response of 59.4% at week 48, supporting its potential as a standard of care in the second line setting – FDA granted accelerated approved October 2024

KOMET-007: Ziftomenib with venetoclax in the first-line setting provided complete response with an overall response rate of 89% in newly diagnosed NPM1-mutated acute myeloid leukemia – not yet approved in this curative setting

VICEROY: In the frontline treatment setting for newly diagnosed FLT3-mutated acute myeloid leukemia ineligible for intensive induction chemotherapy, venetoclax and azacitidine plus gilteritinib produced high response rates with manageable toxicity – not yet FDA approved

SAVE: Frontline revumenib with decitabine/cedazuridine and venetoclax all-oral combination demonstrated early efficacy and high overall response (86%) in a small cohort for newly diagnosed acute myeloid leukemia – not yet FDA approved

FASCINATION: In newly diagnosed chronic myeloid leukemia first-line setting, asciminib-based combination therapies improved long-term tolerability while maintaining deep molecular responses – FDA approved October 2024

VERONA: For first-line treatment-naïve intermediate- and higher-risk myelodysplastic syndrome, venetoclax plus azacitidine improved response rates but did not achieve an overall survival benefit versus azacitidine alone – not yet FDA approved

GIMEMA ALL2820: In newly diagnosed Ph+ acute lymphoblastic leukemia front-line setting, ponatinib plus blinatumomab improved event-free survival (90% vs 74%) and overall survival (94% vs 77%) compared with imatinib plus chemotherapy – not yet FDA approved

MYELOMA

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MajesTEC-3: Teclistamab plus daratumumab after 1-3 prior lines of therapy demonstrated strong progression free survival (HR:0.17) and overall survival (HR:0.46) for relapse-refractory multiple myeloma compared to investigators choice treatment – Not yet FDA approved

COBRA: In newly diagnosed multiple myeloma first-line setting, carfilzomib, lenalidomide and dexamethasone at 12 months demonstrated a higher MRD-negative CR rate at the 10-5 threshold among those treated with KRd than with VRd (31% vs. 18%, respectively), and PFS benefit of KRd was observed regardless of cytogenetic risk – Not yet FDA approved

AQUILA: Daratumumab monotherapy in patients with high-risk smoldering multiple myeloma reduced the risk of progression to active multiple myeloma or death by 51% compared to active monitoring for high-risk smoldering multiple myeloma (HR-SMM) – FDA approved November 2025

JCOG1911/B-DASH: In patients with transplant-ineligible newly diagnosed multiple myeloma, adding bortezomib to daratumumab maintenance therapy did not improve progression-free survival compared to daratumumab alone, primarily due to higher rates of adverse events with the combination – Not yet FDA approved

CEPHEUS: Daratumumab with bortezomib, lenalidomide, and dexamethasone (D-VRd) in the first-line setting provided higher complete response rates compared to VRd alone (81.2% vs. 61.6%) and improved progression-free survival (69.0% vs 48.0% at 54 months) for patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant (ASCT) – FDA approved January 2026monitoring / management and careful patient selection – FDA approved May 2019

LYMPHOMA

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CLL17: Front-line fixed-duration venetoclax-obinutuzumab and venetoclax-ibrutinib achieved non-inferiority in progression-free survival vs continuous ibrutinib (3-yr PFS rate: Ven + Ibr 79.4%; Ven + Obin 81.1%; Ibr 81.0%) in patients with previously untreated chronic lymphocytic leukemia – Not yet FDA approved

BRUIN CLL-314: In treatment-naive and BTKi-naive CLL/SLL, first-line pirtobrutinib demonstrated noninferior ORR vs ibrutinib in the ITT (87.0% vs 78.5%) and R/R (84.0% vs 74.8%) populations compared to ibrutinib – Not yet FDA approved

BRUIN CLL-313: Pirtobrutinib in the first-line setting reduced risk of progressive disease or death by 80% compared to bendamustine plus rituximab for patients with treatment-naive CLL/SLL – Not yet FDA approved

EPCORE-FL-1: Epcoritamab plus rituximab and lenalidomide in second line or later showed a 79% reduction in the risk of progression or death (HR 0.21) and demonstrated significantly higher ORR (95% vs 79%) and CRR (83% vs 50%) compared to R2 respectively for patients with relapsed/refractory follicular lymphoma – FDA approved November 2025

TRANSCEND FL: Follicular lymphoma in third-line or later, single infusion of lisocabtagene maraleucel demonstrated deep and durable responses (36-month DOR, 70%) with sustained survival (36-month OS, 86%) – FDA approved May 2024

SEQUOIA: In treatment naïve CLL/SLL, first-line zanubrutinib reduces the risk of progression or death 72% compared to bendamustine + rituximab – FDA approved January 2023

BGD-11417-201: Sonrotoxlax monotherapy showed to provide clinically beneficial outcomes of 52.4% overall response rate (ORR) and median duration of response (DoR) of 15.8 months in heavily pretreated patients with advanced mantle cell lymphoma – Not yet FDA approved

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