Indication: VENCLEXTA is indicated in combination with azacitidine, or decitabine, or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

THE POWER TO EXTEND SURVIVAL

IN A PHASE 3 TRIAL VENCLEXTA + AZACITIDINE WAS PROVEN TO HELP NEWLY DIAGNOSED AML PATIENTS LIVE LONGER

Median Overall Survival[1]

95% CI: (11.9, 18.7) 95% CI: (7.4, 12.7)

OS: HR=0.66; 95% CI: (0.52, 0.85); *P*<0.001

VIALE-A: A randomized (2:1), double-blind, placebo-controlled, multicenter, phase 3 study that evaluated the efficacy and safety of VENCLEXTA in combination with azacitidine (VEN+AZA; N=286) vs placebo with azacitidine (PBO+AZA; N=145) in adults with newly diagnosed AML who were ≥75 years of age, or with comorbidities that precluded the use of intensive induction chemotherapy. The primary endpoint was overall survival.[1]

NCCN RECOMMENDED

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommends venetoclax (VENCLEXTA®) combination regimens for AML patients[2]*

For patients ≥18 years of age who are not candidates for intensive induction chemotherapy in first-line AML **with or without actionable mutations†:**

VEN+AZA	VEN+DEC	VEN+LDAC
Category 1 preferred	Category 2A preferred	Category 2A other recommended

- Recommended **initiation, assessment, and management strategies** for select venetoclax regimens are consistent with the **Principles of Venetoclax Use with HMA or LDAC** included in the NCCN Guidelines® for AML

*See NCCN Guidelines for AML, Version 3.2023, for complete recommendations and principles. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
†Actionable mutations include *IDH1/2* and *FLT3*.

VEN+AZA=VENCLEXTA + azacitidine; CI=confidence interval; OS=overall survival; HR=hazard ratio; PBO=placebo; DEC=decitabine; LDAC=low-dose cytarabine; HMA=hypomethylating agent; *IDH*=isocitrate dehydrogenase; *FLT*=fms-like tyrosine kinase.

Important Safety Information

Tumor Lysis Syndrome

- Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA.
- VENCLEXTA can cause rapid reduction in tumor and thus poses a risk for TLS at initiation and during the ramp-up phase in all patients. Changes in blood chemistries consistent with TLS that require prompt management can occur as early as 6 to 8 hours following the first dose of VENCLEXTA and at each dose increase.
- In patients with AML who followed the current 3-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 1.1% in patients who received VENCLEXTA in combination with azacitidine. In patients with AML who followed a 4-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 5.6% and included deaths and renal failure in patients who received VENCLEXTA in combination with low-dose cytarabine.
- The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy.
- Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase, and requires VENCLEXTA dose reduction.

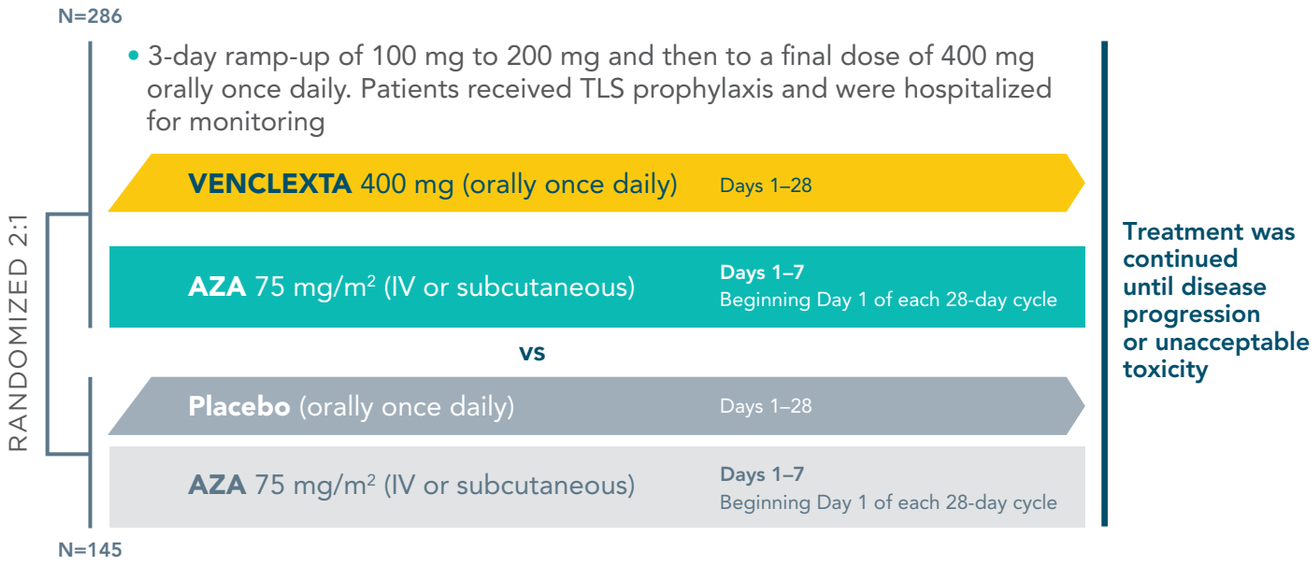
Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

VENCLEXTA®
venetoclax tablets 10mg, 50mg, 100mg

VIALE-A studied newly diagnosed AML patients ≥75 years of age or with comorbidities that made them ineligible for intensive induction chemotherapy[1]

VENCLEXTA + azacitidine (VEN+AZA) was evaluated in a pivotal phase 3 trial[1,3]

- Randomized (2:1), double-blind, placebo-controlled, multicenter, phase 3 study[1,3]



Comorbidities based on at least one of the following criteria[1]:

- Baseline ECOG performance status of 2–3
- Severe cardiac or pulmonary comorbidity
- Moderate hepatic impairment
- CrCl <45 mL/min
- Other comorbidities

Select clinical endpoints[1,3]

- **Primary endpoint:** overall survival
- **Select secondary endpoints:** CR, CR+CRh, CR+CRh by initiation of Cycle 2

Efficacy was based on overall survival (OS), measured from the date of randomization to death from any cause[1]

CR was defined as absolute neutrophil count (ANC) >1,000/microliter, platelets >100,000/microliter, RBC transfusion independence, and bone marrow with <5% blasts. Absence of circulating blasts and blasts with Auer rods; absence of extramedullary disease.
CRh was defined as <5% of blasts in the bone marrow, no evidence of disease, and partial recovery of peripheral blood counts (platelets >50,000/microliter and ANC >500/microliter).

TLS=tumor lysis syndrome; IV=intravenous; ECOG=Eastern Cooperative Oncology Group; CrCl=creatinine clearance; CR=complete remission; CRh=complete remission with partial hematologic recovery; RBC=red blood cell.

Important Safety Information (cont'd)

Neutropenia

- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Monitor complete blood counts. Interrupt dosing for severe neutropenia. Resume at same dose then reduce duration based on remission status and first or subsequent occurrence of neutropenia. Consider supportive measures including antimicrobials and growth factors (e.g., G-CSF).

Infections

- Fatal and serious infections such as pneumonia and sepsis have occurred in patients treated with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution and resume at same dose.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

VIALE-A included patients with various comorbidities and different mutational and cytogenetic profiles[1,3]

Select baseline characteristics for patients treated in the VIALE-A trial[1,3]

76
MEDIAN AGE[1]

~45%
ECOG 2–3[3]

100%
INTERMEDIATE OR POOR CYTOGENETIC RISK[1]

Additional baseline characteristics[1]

Characteristic	VEN+AZA (N=286)	AZA (N=145)
Age (years); median (range)	76 (49, 91)	76 (60, 90)
Race (%)		
White	76	75
Black or African American	1	1.4
Asian	23	23
Male (%)	60	60
ECOG performance status (%)		
0–1	55	56
2	40	41
3	5.6	3.4
Bone marrow blast (%)		
<30%	30	28
≥30% to <50%	21	23
≥50%	49	49

Additional baseline characteristics[1]

Characteristic	VEN+AZA (N=286)	AZA (N=145)
Disease history (%)		
De novo AML	75	76
Secondary AML	25	24
Cytogenetic risk detected* (%)		
Intermediate	64	61
Poor	36	39
Mutation analyses detected; n/N† (%)		
IDH1 or *IDH2*	61/245 (25)	28/127 (22)
IDH1	23/245 (9.4)	11/127 (8.7)
IDH2	40/245 (16)	18/127 (14)
FLT3	29/206 (14)	22/108 (20)
NPM1	27/163 (17)	17/86 (20)
TP53	38/163 (23)	14/86 (16)

*Cytogenetic risk grading from VIALE-A trial per the 2016 NCCN Guidelines.
†Number of evaluable bone marrow aspirate (BMA) specimens received at baseline.

IDH=isocitrate dehydrogenase; *FLT*=fms-like tyrosine kinase; *NPM*=nucleophosmin; *TP53*=tumor protein p53.

Important Safety Information (cont'd)

Immunization

- Do not administer live attenuated vaccines prior to, during, or after treatment with VENCLEXTA until B-cell recovery occurs. Advise patients that vaccinations may be less effective.

Embryo-Fetal Toxicity

- VENCLEXTA may cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.

Increased Mortality in Patients with Multiple Myeloma when VENCLEXTA is Added to Bortezomib and Dexamethasone

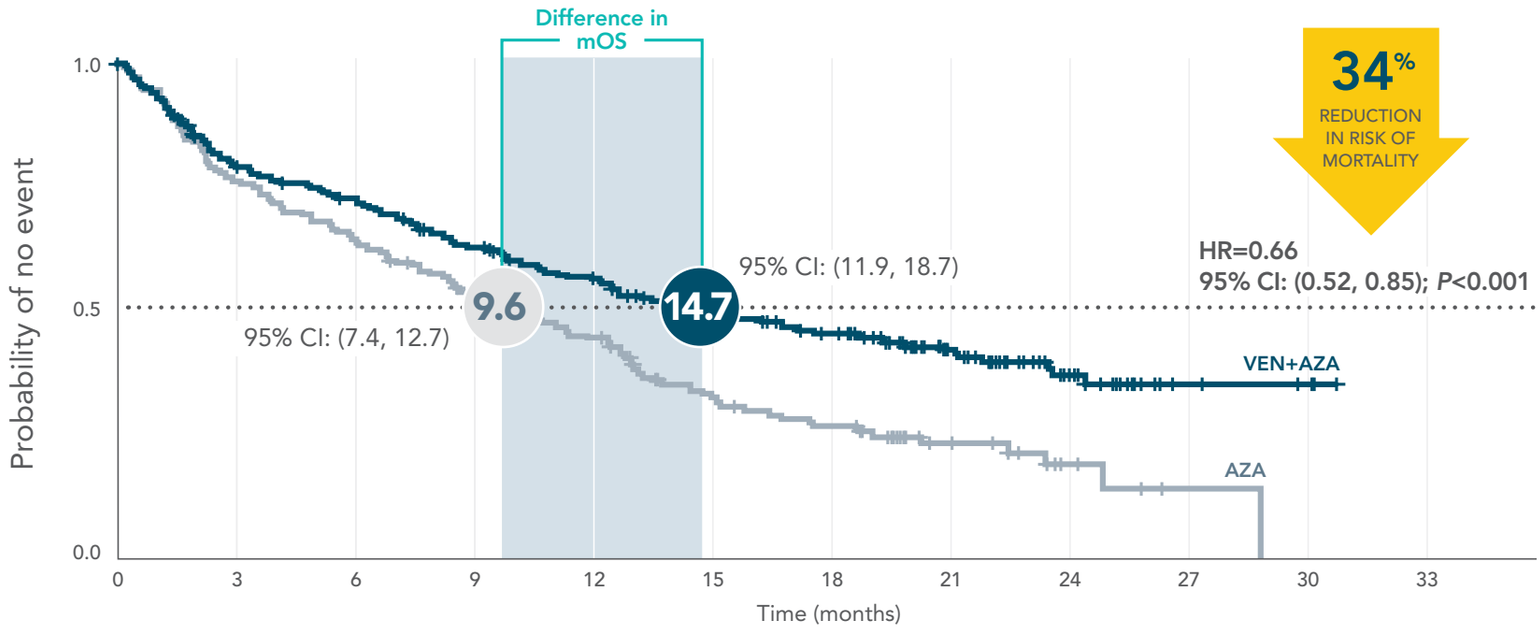
- In a randomized trial (BELLINI; NCT02755597) in patients with relapsed or refractory multiple myeloma, the addition of VENCLEXTA to bortezomib plus dexamethasone, a use for which VENCLEXTA is not indicated, resulted in increased mortality. Treatment of patients with multiple myeloma with VENCLEXTA in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

VEN+AZA demonstrated superior overall survival vs AZA[1]

PRIMARY ENDPOINT: OVERALL SURVIVAL

Median OS was extended by 5.1 months in patients treated with VEN+AZA vs AZA



Number of patients at risk

VEN+AZA	286	219	198	168	143	117	101	54	23	5	3	–
AZA	145	109	92	74	59	38	30	14	5	1	–	–

- Median follow-up for OS was approximately 20.5 months (range: <0.1–30.7 months)[3]
  - Median follow-up was estimated using reverse Kaplan-Meier methodology

mOS=median overall survival.

Important Safety Information (cont'd)

Adverse Reactions

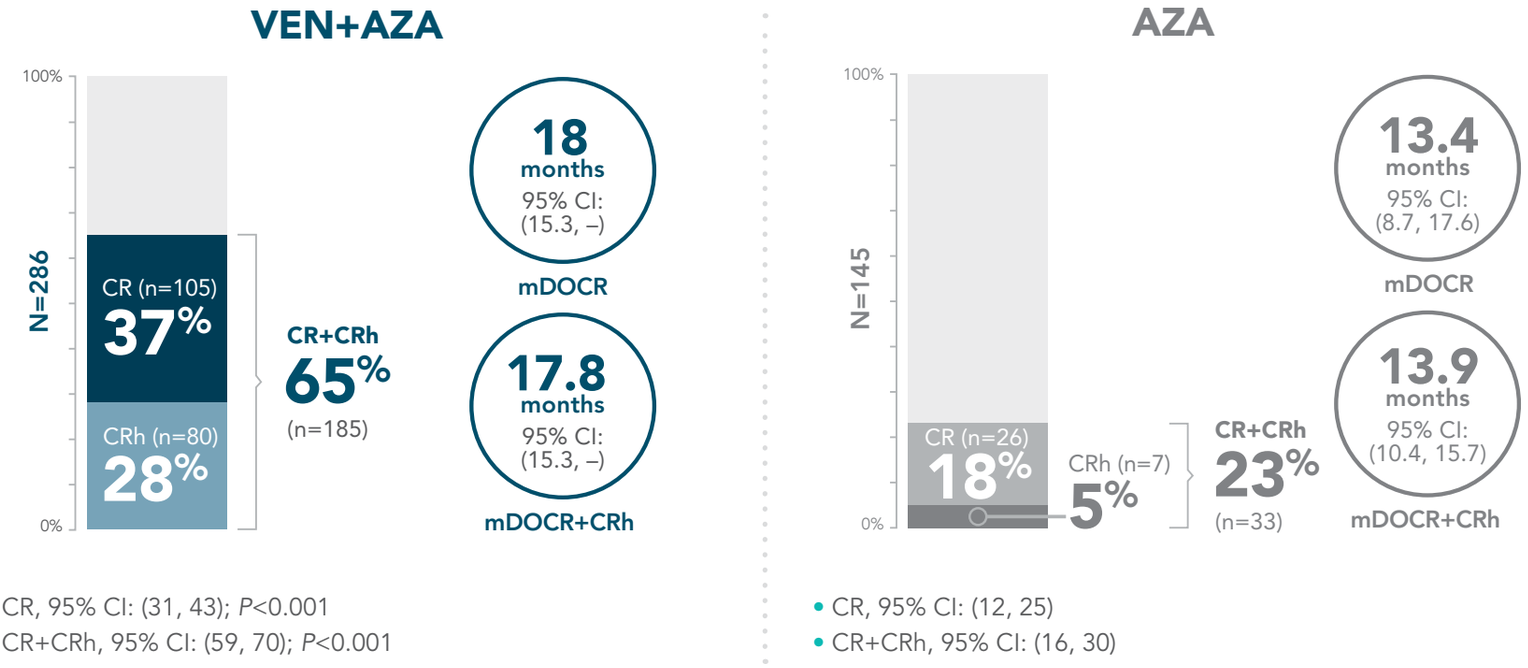
- **In patients with AML receiving combination therapy with azacitidine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia (30%), pneumonia (22%), sepsis (excluding fungal; 19%), and hemorrhage (6%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (98%), platelets decreased (94%), lymphocytes decreased (91%), hemoglobin decreased (61%), nausea (44%), diarrhea (43%), febrile neutropenia (42%), musculoskeletal pain (36%), pneumonia (33%), fatigue (31%), and vomiting (30%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with azacitidine, with the most frequent (≥2%) being pneumonia (4%), sepsis (excluding fungal; 3%), and hemorrhage (2%).
- **In patients with AML receiving combination therapy with decitabine,** the most frequent serious adverse reactions (≥10%) were sepsis (excluding fungal; 46%), febrile neutropenia (38%), and pneumonia (31%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (100%), lymphocytes decreased (100%), white blood cells decreased (100%), platelets decreased (92%), hemoglobin decreased (69%), febrile neutropenia (69%), fatigue (62%), constipation (62%), musculoskeletal pain (54%), dizziness (54%), nausea (54%), abdominal pain (46%), diarrhea (46%), pneumonia (46%), sepsis (excluding fungal; 46%), cough (38%), pyrexia (31%), hypotension (31%), oropharyngeal pain (31%), edema (31%), and vomiting (31%). One (8%) fatal adverse reaction of bacteremia occurred within 30 days of starting treatment.
- **In patients with AML receiving combination therapy with low-dose cytarabine,** the most frequent serious adverse reactions (≥10%) were pneumonia (17%), febrile neutropenia (16%), and sepsis (excluding fungal; 12%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were platelets decreased (97%), neutrophils decreased (95%), lymphocytes decreased (92%), hemoglobin decreased (63%), nausea (42%), and febrile neutropenia (32%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with LDAC, with the most frequent (≥5%) being pneumonia (6%) and sepsis (excluding fungal; 7%).

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Almost 3x more remissions,* longer mDOR observed with VEN+AZA vs AZA[1]

SECONDARY ENDPOINTS: CR, CR+CRh[1]
PRESPECIFIED EXPLORATORY ENDPOINTS: mDOCR,† mDOCR+CRh†

Powerful, durable remissions[1]



- CR, 95% CI: (31, 43); *P*<0.001
- CR+CRh, 95% CI: (59, 70); *P*<0.001

- CR, 95% CI: (12, 25)
- CR+CRh, 95% CI: (16, 30)

*Remission refers to CR+CRh.
†Endpoints were not powered or tested to demonstrate a statistically significant difference between the treatment arms.

DOCR (duration of CR) is defined as the number of days from the date of first response of CR to the date of earliest evidence of confirmed morphologic relapse, confirmed progressive disease, or death due to disease progression.

DOCR+CRh (duration of CR+CRh) is defined as the number of days from the date of first response of CR+CRh (the first of either CR or CRh) to the date of earliest evidence of confirmed morphologic relapse, confirmed progressive disease, or death due to disease progression.

mDOR=median duration of response; mDOCR=median duration of complete remission; mDOCR+CRh=median duration of complete remission and complete remission with partial hematologic recovery.

Important Safety Information (cont'd)

Drug Interactions

- Concomitant use with a P-gp inhibitor or a strong or moderate CYP3A inhibitor increases VENCLEXTA exposure, which may increase VENCLEXTA toxicities, including the risk of TLS. Consider alternative medications or adjust VENCLEXTA dosage and monitor more frequently for adverse reactions. Resume the VENCLEXTA dosage that was used prior to concomitant use of a P-gp inhibitor or a strong or moderate CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor.
- Patients should avoid grapefruit products, Seville oranges, and starfruit during treatment as they contain inhibitors of CYP3A.
- Avoid concomitant use of strong or moderate CYP3A inducers.
- Monitor international normalized ratio (INR) more frequently in patients receiving warfarin.
- Avoid concomitant use of VENCLEXTA with a P-gp substrate. If concomitant use is unavoidable, separate dosing of the P-gp substrate at least 6 hours before VENCLEXTA.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Greater transfusion independence observed with VEN+AZA vs AZA[1]

TRANSFUSION INDEPENDENCE CONVERSION, TRANSFUSION INDEPENDENCE MAINTENANCE[1]*

Greater transfusion independence conversion and/or maintenance rates with VEN+AZA

Transfusion independence conversion (conversion from dependent to independent)

VEN+AZA	AZA
49%	**27%**
(76/155)	(22/81)

RBC and PLATELET

Patients were dependent on RBC and/or platelet transfusions at baseline

Transfusion independence maintenance (independent from baseline to post-baseline period)

VEN+AZA	AZA
69%	**42%**
(90/131)	(27/64)

RBC and PLATELET

Patients were independent of both RBC and platelet transfusions at baseline

Transfusion independence was defined as no RBC and no platelet transfusion during any consecutive ≥56-day post-baseline period.[1] Transfusion dependence was defined as requiring RBC or platelet transfusion at baseline (within 8 weeks prior to the first dose of study drug or randomization).[3]

*Endpoints were not powered or tested to demonstrate a statistically significant difference between the treatment arms.

TI=transfusion independence.

Important Safety Information (cont'd)

Lactation

- Advise nursing women not to breastfeed during treatment with VENCLEXTA and for 1 week after the last dose.

Females and Males of Reproductive Potential

- Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.
- Based on findings in animals, VENCLEXTA may impair male fertility.

Hepatic Impairment

- Reduce the dose of VENCLEXTA for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more frequently for signs of adverse reactions. No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

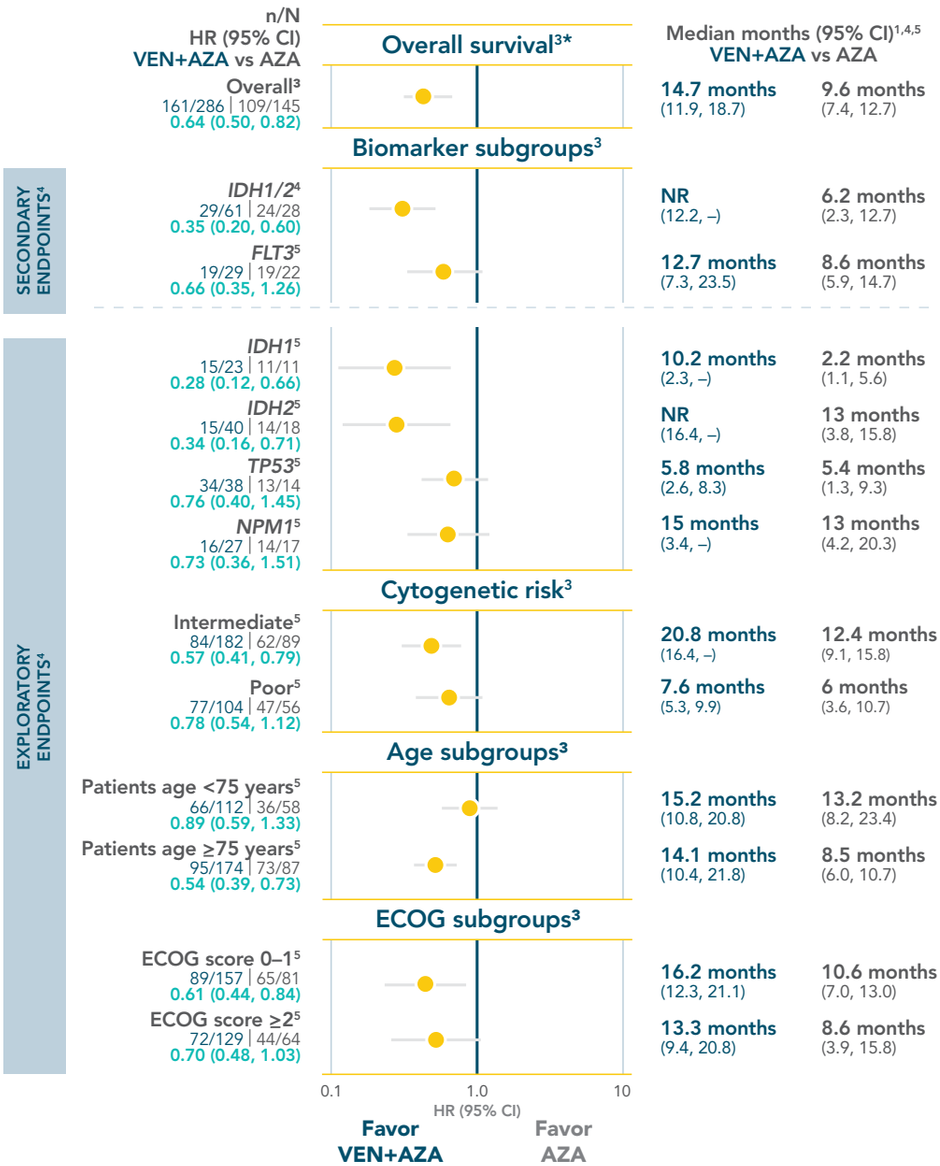
Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Overall survival outcomes in different subgroups[3]

Descriptive analysis of OS secondary and exploratory endpoints[3]

- OS in the *IDH1/2* and *FLT3* subgroups was a prespecified secondary endpoint. Other select biomarker subgroups (*IDH1*, *IDH2*, *TP53* and *NPM1*), cytogenetic risk, age, and ECOG score were exploratory endpoints[4]

*The HR of overall survival was estimated using the unstratified log-rank test and the Cox proportional hazards model for OS.[3]



Subgroup analyses were not powered to demonstrate a statistically significant difference in OS. Small patient numbers and lack of multiplicity adjustments for some subgroups can be a limitation of these analyses. No conclusions of efficacy or safety can be drawn from these data.

n/N=total number of events per total number of patients; NR=not reached.

Important Safety Information

Tumor Lysis Syndrome

- Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA.
- VENCLEXTA can cause rapid reduction in tumor and thus poses a risk for TLS at initiation and during the ramp-up phase in all patients. Changes in blood chemistries consistent with TLS that require prompt management can occur as early as 6 to 8 hours following the first dose of VENCLEXTA and at each dose increase.
- In patients with AML who followed the current 3-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 1.1% in patients who received VENCLEXTA in combination with azacitidine. In patients with AML who followed a 4-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 5.6% and included deaths and renal failure in patients who received VENCLEXTA in combination with low-dose cytarabine.

Please see additional Important Safety Information on pages 22 and 23.
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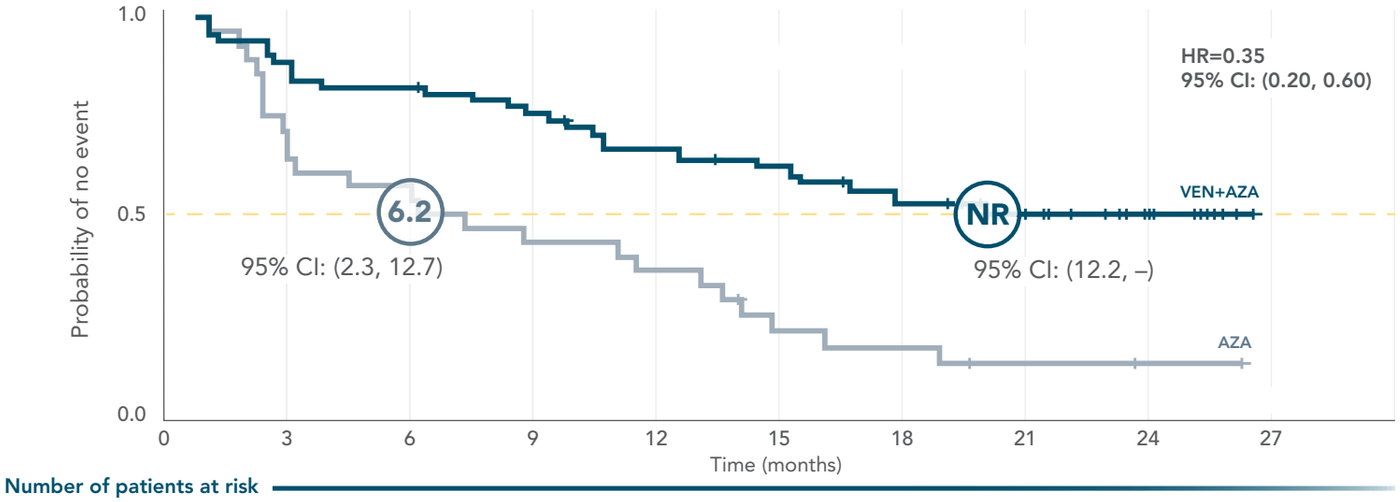
Overall survival data in the consolidated *IDH1/2* group[4]

- OS in *IDH1/IDH2* was a prespecified secondary endpoint[3]

Subgroup analyses were not powered to demonstrate a statistically significant difference in OS. Small patient numbers in this subgroup can be a limitation of this analysis. No conclusions of efficacy or safety can be drawn from these data.



Number of patients at risk

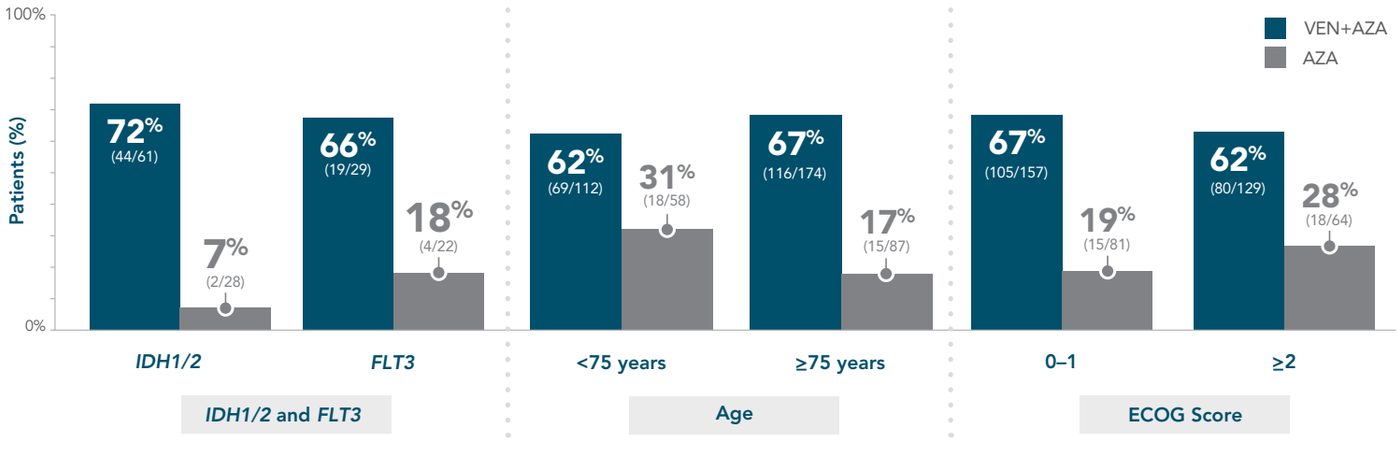
VEN+AZA	61	51	48	44	39	34	29	18	9	0
AZA	28	17	14	12	10	5	4	2	1	0

Results are based on Kaplan-Meier estimates.
NR=not reached.

Remission rates in different subgroups[5]

- CR+CRh rates for *IDH1/2* and *FLT3* were prespecified secondary endpoints[4]
- CR+CRh rates for Age and ECOG subgroups were exploratory endpoints

Subgroup data do not support conclusions of efficacy or safety in any of the examined groups presented. The percentages are not adjusted for stratification.



Important Safety Information (cont'd)

Tumor Lysis Syndrome (cont'd)

- The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy.
- Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase, and requires VENCLEXTA dose reduction.

Please see additional Important Safety Information on pages 22 and 23.
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A tolerable, manageable, and predictable safety profile[1]

No additional warnings or precautions for VENCLEXTA were observed in the AML trials.

The safety profile of VEN+AZA was consistent with the known side effect profile of both agents.

Adverse reactions (≥10%) in patients with AML who received VEN+AZA with a difference between arms of ≥5% for all grades or ≥2% for Grade 3 or 4 reactions compared with PBO+AZA*

Adverse reaction by body system					
		VEN+AZA (N=283)		PBO+AZA (N=144)	
Body system	**Adverse reaction**	**All Grades (%)**	**Grade 3 or 4 (%)**	**All Grades (%)**	**Grade 3 or 4 (%)**
Gastrointestinal disorders	Nausea	44	2	35	<1
	Diarrhea†	43	5	33	3
	Vomiting†	30	2	23	<1
	Stomatitis†	18	1	13	0
	Abdominal pain†	18	<1	13	0
Blood and lymphatic system disorders	Febrile neutropenia	42	42	19	19
Musculoskeletal and connective tissue disorders	Musculoskeletal pain†	36	2	28	1
General disorders and administration site conditions	Fatigue†	31	6	23	2
	Edema†	27	<1	19	0
Vascular disorders	Hemorrhage†	27	7	24	3
	Hypotension†	12	5	8	3
Metabolism and nutrition disorders	Decreased appetite†	25	4	17	<1
Skin and subcutaneous tissue disorders	Rash†	25	1	15	0
Infections and infestations	Sepsis† (excluding fungal)	22	22	16	14
	Urinary tract infection†	16	6	9	6
Respiratory, thoracic, and mediastinal disorders	Dyspnea†	18	4	10	2
Nervous system disorders	Dizziness†	17	<1	8	<1

*Patients who received at least one dose of either treatment.[3]
†Includes multiple adverse reaction terms.

Hematologic laboratory abnormalities

New or worsening Grade 3 or 4 hematologic laboratory abnormalities (≥10%) in VIALE-A with a difference between arms of ≥2% for VEN+AZA vs PBO+AZA, respectively: neutrophils decreased 98% vs 81%, platelets decreased 88% vs 80%, lymphocytes decreased 71% vs 39%, hemoglobin decreased 57% vs 52%.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Patients maintained treatment with VENCLEXTA in the VEN+AZA arm for a median of 7.6 months[1]

Median duration of exposure to VEN or PBO

VEN+AZA[1]	PBO+AZA[6]
7.6 months (range: <0.1-30.7)	**4.3** months (range: 0.1–24.0)

Median number of treatment cycles

VEN+AZA[3]	PBO+AZA[3]
7.0 cycles (range: 1.0–30.0)	**4.5** cycles (range: 1.0–26.0)

Rate of serious adverse reactions

	VEN+AZA (N=283)[1]		PBO+AZA (N=144)[3,6]	
	(%) occurrence	Most frequent adverse reaction(s)	(%) occurrence	Most frequent adverse reaction(s)
Serious ARs	83	**≥5%**: febrile neutropenia (30%), pneumonia (22%), sepsis (excluding fungal; 19%), hemorrhage (6%)	73	**≥5%**: pneumonia (22%), febrile neutropenia (10%), sepsis (8%)
Fatal ARs	23	**≥2%**: pneumonia (4%), sepsis (excluding fungal; 3%), hemorrhage (2%)	20	**≥2%**: sepsis (4%), pneumonia (2%)

Discontinuation, reduction, and interruption rates of VEN or PBO

	VEN	VEN+AZA (N=283)	PBO	PBO+AZA (N=144)
ARs leading to permanent drug discontinuation	24	**≥2%**: sepsis (excluding fungal; 3%), pneumonia (2%)	20	**≥2%**: sepsis (4%), pneumonia (3%), thrombocytopenia (2%), malignant neoplasm progression (2%)
Most frequent AR leading to dose reductions	3[6]	pneumonia (0.7%)	4	pneumonia (1%)
ARs leading to dose interruptions	72	**≥5%**: febrile neutropenia (20%), neutropenia (20%), pneumonia (14%), sepsis (excluding fungal; 11%), thrombocytopenia (10%)	57	**≥5%**: pneumonia (13%), neutropenia (10%)

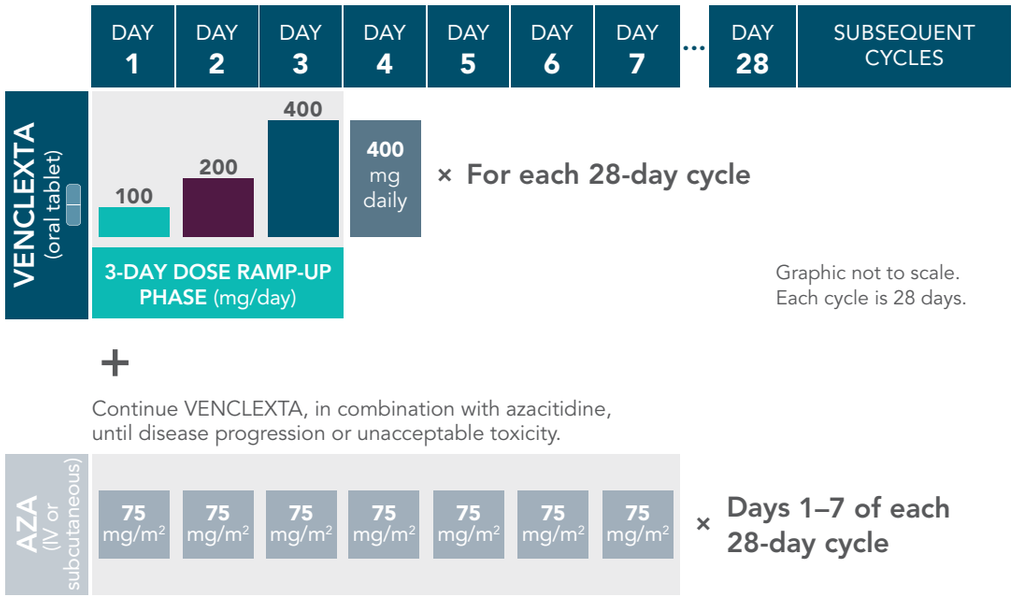
- In the VEN+AZA arm, among patients who achieved bone marrow clearance of leukemia, 53% (114/216)* underwent dose interruptions for ANC <500/microliter[1,7]
- Once bone marrow assessment confirmed a remission, defined as less than 5% leukemia blasts with cytopenia, VENCLEXTA or placebo was interrupted up to 14 days or until ANC ≥500/microliter and platelet count ≥50 × 10^3/microliter[1]
- Azacitidine was resumed on the same day as VENCLEXTA or placebo following interruption[1]
- Azacitidine dose reduction was implemented in the clinical trial for management of hematologic toxicity[1]

*Of patients who achieved a morphologic leukemia-free state of response or better.[7]
AR=adverse reaction.

Dose ramp-up is designed to allow patients to safely attain the recommended daily dose[1]

- Assess patient-specific factors for level of risk of tumor lysis syndrome (TLS) and provide prophylactic hydration and anti-hyperuricemics to patients prior to first dose of VENCLEXTA to reduce risk of TLS
- Instruct patients to take VENCLEXTA tablets with a meal and water at approximately the same time each day. VENCLEXTA tablets should be swallowed whole and not chewed, crushed, or broken prior to swallowing

VENCLEXTA is taken orally in combination with AZA, DEC, or LDAC[1]



Please see Section 2.3 of the full Prescribing Information for VEN+DEC or VEN+LDAC dosing.

- If using VENCLEXTA in combination with **decitabine**, follow the 3-day dose ramp-up schedule, up to 400 mg of VENCLEXTA, and administer decitabine at 20 mg/m^2 intravenously once daily on Days 1-5 of each 28-day cycle beginning on Cycle 1, Day 1
- If using VENCLEXTA in combination with **low-dose cytarabine**, follow the 4-day dose ramp-up schedule, up to 600 mg of VENCLEXTA, and administer cytarabine at 20 mg/m^2 subcutaneously once daily on Days 1–10 of each 28-day cycle beginning on Cycle 1, Day 1

TLS in clinical trials[1,7]

- With implementation of dosing ramp-up plus standard TLS prophylaxis and monitoring:
  - **In VIALE-A, the rate of TLS was 1.1% (3/283) in patients who received VENCLEXTA in combination with azacitidine. All events were laboratory TLS**
  - In VIALE-C, the rate of TLS was 5.6% (8/142) in patients who received VENCLEXTA in combination with low-dose cytarabine. There were 4 events of laboratory TLS and 4 events of clinical TLS, which included 2 deaths and cases of renal failure

Pretreatment TLS risk assessment and prophylaxis[1]

- All patients should have white blood cell count less than 25 × 10^9/L prior to initiation of VENCLEXTA. Cytoreduction prior to treatment may be required
- Prior to first VENCLEXTA dose, provide all patients with prophylactic measures including adequate hydration and anti-hyperuricemic agents and continue during ramp-up phase
- Assess blood chemistry and correct pre-existing abnormalities prior to initiation of VENCLEXTA treatment
- Monitor blood chemistries for TLS at pre-dose, 6 to 8 hours after each new dose during ramp-up, and 24 hours after reaching final dose
- For patients with risk factors for TLS, consider additional measures, including increased laboratory monitoring and reducing VENCLEXTA starting dose

Important Safety Information (cont'd)

Neutropenia

- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Monitor complete blood counts. Interrupt dosing for severe neutropenia. Resume at same dose then reduce duration based on remission status and first or subsequent occurrence of neutropenia. Consider supportive measures including antimicrobials and growth factors (e.g., G-CSF).

Infections

- Fatal and serious infections such as pneumonia and sepsis have occurred in patients treated with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution and resume at same dose.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

VENCLEXTA dose should be modified for concomitant use with certain medications[1,8,9]

VENCLEXTA is metabolized by the CYP3A enzyme; the dose should be reduced when used with P-gp inhibitors or strong or moderate CYP3A inhibitors

Dose modifications for managing potential interactions		
Coadministered drug	**Initiation and ramp-up phase**	**Steady daily dose after ramp-up phase**
Posaconazole	Day 1: 10 mg Day 2: 20 mg Day 3: 50 mg Day 4: 70 mg	Reduce the VENCLEXTA dose to 70 mg
Other strong CYP3A inhibitors* Clarithromycin, indinavir, itraconazole, ketoconazole, lopinavir, ritonavir, voriconazole	Day 1: 10 mg Day 2: 20 mg Day 3: 50 mg Day 4: 100 mg	Reduce the VENCLEXTA dose to 100 mg
Moderate CYP3A inhibitors* Aprepitant, ciprofloxacin, conivaptan, cyclosporine, diltiazem, dronedarone, erythromycin, fluconazole, isavuconazole, verapamil	Reduce the VENCLEXTA dose by at least 50%	
P-gp inhibitors* Amiodarone, cyclosporine, dronedarone, quinidine, ranolazine, verapamil		

Scan the code to see full dosing tool

- Adjust the VENCLEXTA dose and monitor more frequently for adverse reactions. Resume the VENCLEXTA dosage that was used prior to concomitant use of a strong or moderate CYP3A inhibitor or a P-gp inhibitor 2 to 3 days after discontinuation of the inhibitor[1]
- Avoid grapefruit products, Seville oranges, and starfruit during treatment with VENCLEXTA, as they contain inhibitors of CYP3A[1]
- Concomitant use of VENCLEXTA with strong CYP3A inducers decreases VENCLEXTA exposure, which may decrease VENCLEXTA efficacy. Avoid concomitant use of VENCLEXTA with strong CYP3A inducers or moderate CYP3A inducers[1]
- Concomitant use of VENCLEXTA increases warfarin exposure, which may increase the risk of bleeding. Monitor international normalized ratio (INR) more frequently in patients using warfarin concomitantly with VENCLEXTA[1]
- Concomitant use of VENCLEXTA increases exposure of P-gp substrates, which may increase toxicities of these substrates. Avoid concomitant use of VENCLEXTA with a P-gp substrate. If concomitant use is unavoidable, separate dosing of the P-gp substrate at least 6 hours before VENCLEXTA[1]

Dose modifications for patients with severe hepatic impairment[1]

- Reduce the VENCLEXTA once daily dose by 50% for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more closely for adverse reactions

*This is not an exhaustive list and is intended only to complement, not replace, clinical judgment during treatment of patients with VENCLEXTA. Please refer to the FDA website for more examples.

CYP3A=cytochrome P450 3A; P-gp=P-glycoprotein.

Important Safety Information (cont'd)

Immunization

- Do not administer live attenuated vaccines prior to, during, or after treatment with VENCLEXTA until B-cell recovery occurs. Advise patients that vaccinations may be less effective.

Embryo-Fetal Toxicity

- VENCLEXTA may cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.

Increased Mortality in Patients with Multiple Myeloma when VENCLEXTA is Added to Bortezomib and Dexamethasone

- In a randomized trial (BELLINI; NCT02755597) in patients with relapsed or refractory multiple myeloma, the addition of VENCLEXTA to bortezomib plus dexamethasone, a use for which VENCLEXTA is not indicated, resulted in increased mortality. Treatment of patients with multiple myeloma with VENCLEXTA in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Dose modification and interruptions for cytopenias are dependent on remission status[1]

Bone marrow assessment was conducted following Cycle 1 treatment in the AML clinical trials to assess for remission

Once bone marrow assessment confirmed a remission,* VENCLEXTA or placebo was interrupted for up to 14 days or until ANC ≥500/microliter and platelet count ≥50 × 10^3/microliter.

Median time to first response of CR or CRh[1,3]

VEN+AZA 1.0 month (range: 0.6-14.3 months) **vs** **AZA** 2.6 months (range: 0.8-13.2 months)

Some patients achieved CR or CRh in later cycles (VEN+AZA vs AZA)[1,3]

For patients with resistant disease at the end of Cycle 1, a bone marrow assessment was performed after Cycle 2 or 3 and as clinically indicated.[1]

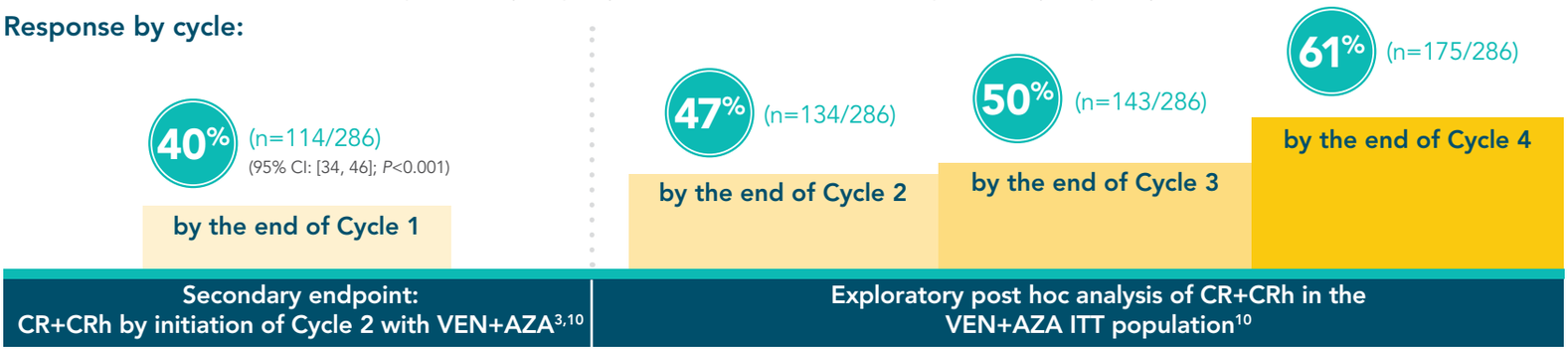
Responses for CR and CRh were reached at different times during treatment; management of Grade 4 hematologic adverse reactions differs before and after remission[1,3]

In VIALE-A:

Select secondary endpoints: CR, CR+CRh[1,3]

- **CR:** 37% (n=105/286), 95% CI: (31, 43) in VEN+AZA **vs** 18% (n=26/145), 95% CI: (12, 25) in AZA; *P*<0.001
- **Median DOCR†:** 18 months, 95% CI: (15.3, NR) in VEN+AZA **vs** 13.4 months, 95% CI: (8.7, 17.6) in AZA
- **CR+CRh:** 65% (n=185/286), 95% CI: (59, 70) in VEN+AZA **vs** 23% (n=33/145), 95% CI: (16, 30) in AZA; *P*<0.001
- **Median DOCR+CRh†:** 17.8 months, 95% CI: (15.3, NR) in VEN+AZA **vs** 13.9 months, 95% CI: (10.4, 15.7) in AZA

Response by cycle:



*Defined as less than 5% leukemia blasts with cytopenia.

†Endpoints were not powered or tested to demonstrate a statistically significant difference between the treatment arms.

ITT=intention to treat.

Important Safety Information (cont'd)

Adverse Reactions

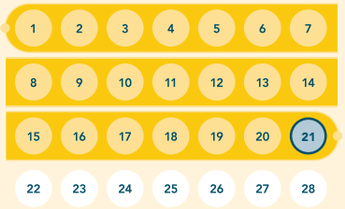
- **In patients with AML receiving combination therapy with azacitidine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia (30%), pneumonia (22%), sepsis (excluding fungal; 19%), and hemorrhage (6%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (98%), platelets decreased (94%), lymphocytes decreased (91%), hemoglobin decreased (61%), nausea (44%), diarrhea (43%), febrile neutropenia (42%), musculoskeletal pain (36%), pneumonia (33%), fatigue (31%), and vomiting (30%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with azacitidine, with the most frequent (≥2%) being pneumonia (4%), sepsis (excluding fungal; 3%), and hemorrhage (2%).
- **In patients with AML receiving combination therapy with decitabine,** the most frequent serious adverse reactions (≥10%) were sepsis (excluding fungal; 46%), febrile neutropenia (38%), and pneumonia (31%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (100%), lymphocytes decreased (100%), white blood cells decreased (100%), platelets decreased (92%), hemoglobin decreased (69%), febrile neutropenia (69%), fatigue (62%), constipation (62%), musculoskeletal pain (54%), dizziness (54%), nausea (54%), abdominal pain (46%), diarrhea (46%), pneumonia (46%), sepsis (excluding fungal; 46%), cough (38%), pyrexia (31%), hypotension (31%), oropharyngeal pain (31%), edema (31%), and vomiting (31%). One (8%) fatal adverse reaction of bacteremia occurred within 30 days of starting treatment.
- **In patients with AML receiving combination therapy with low-dose cytarabine,** the most frequent serious adverse reactions (≥10%) were pneumonia (17%), febrile neutropenia (16%), and sepsis (excluding fungal; 12%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were platelets decreased (97%), neutrophils decreased (95%), lymphocytes decreased (92%), hemoglobin decreased (63%), nausea (42%), and febrile neutropenia (32%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with LDAC, with the most frequent (≥5%) being pneumonia (6%) and sepsis (excluding fungal; 7%).

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Recommended dose modifications for cytopenias and non-hematologic adverse reactions in AML[1]

- Monitor blood counts frequently through resolution of cytopenias. Dose modification and interruptions for cytopenias are dependent on remission status

Managing Grade 4 neutropenia with or without fever or infection, or Grade 4 thrombocytopenia

Occurrence before remission*† is achieved	After remission*† is achieved: Occurrence lasting at least 7 days
STAY ON VENCLEXTA REGIMEN: In most instances, do not interrupt the VENCLEXTA regimen due to cytopenias.	**DELAY** subsequent cycle of VENCLEXTA regimen and monitor blood counts. **For 1st occurrence** **RESUME VENCLEXTA** therapy at 400 mg‡ in combination with azacitidine or decitabine or at 600 mg‡ in combination with low-dose cytarabine upon resolution to Grade 1 or 2 and resume 28-day treatment cycle. **For subsequent occurrences** **RESUME VENCLEXTA** therapy at 400 mg‡ in combination with azacitidine or decitabine or at 600 mg‡ in combination with low-dose cytarabine upon resolution to Grade 1 or 2 and reduce treatment cycle by 7 days for each subsequent cycle. *(eg, for 2nd occurrence, VENCLEXTA would be dosed for 21 days of a 28-day cycle).* 

In an exploratory post hoc analysis of VIALE-A:

- 75% of patients in remission† (139/186) had at least 1 pause in dosing lasting 7+ days[10]

*Recommend bone marrow evaluation.
†Remission is defined as less than 5% leukemia blasts with cytopenia.
‡Dose may vary based on drug-drug interactions or severe hepatic impairment.

Scan the code to see full dosing tool

Non-hematologic adverse reactions		
Grade 3 or 4 non-hematologic toxicities	Any occurrence	Interrupt VENCLEXTA if not resolved with supportive care. Upon resolution to Grade 1 or baseline level, resume VENCLEXTA at the same dose.

In VIALE-A:

- In the VEN+AZA arm, among patients who achieved bone marrow clearance of leukemia, 53% (114/216)§ underwent dose interruptions for ANC <500/microliter[1]
- Once bone marrow assessment confirmed a remission, defined as less than 5% leukemia blasts with cytopenia, VENCLEXTA or placebo was interrupted up to 14 days or until ANC ≥500/microliter and platelet count ≥50 × 10^3/microliter[1]

§Of patients who achieved a morphologic leukemia-free state of response or better.[7]

Important Safety Information (cont'd)

Drug Interactions

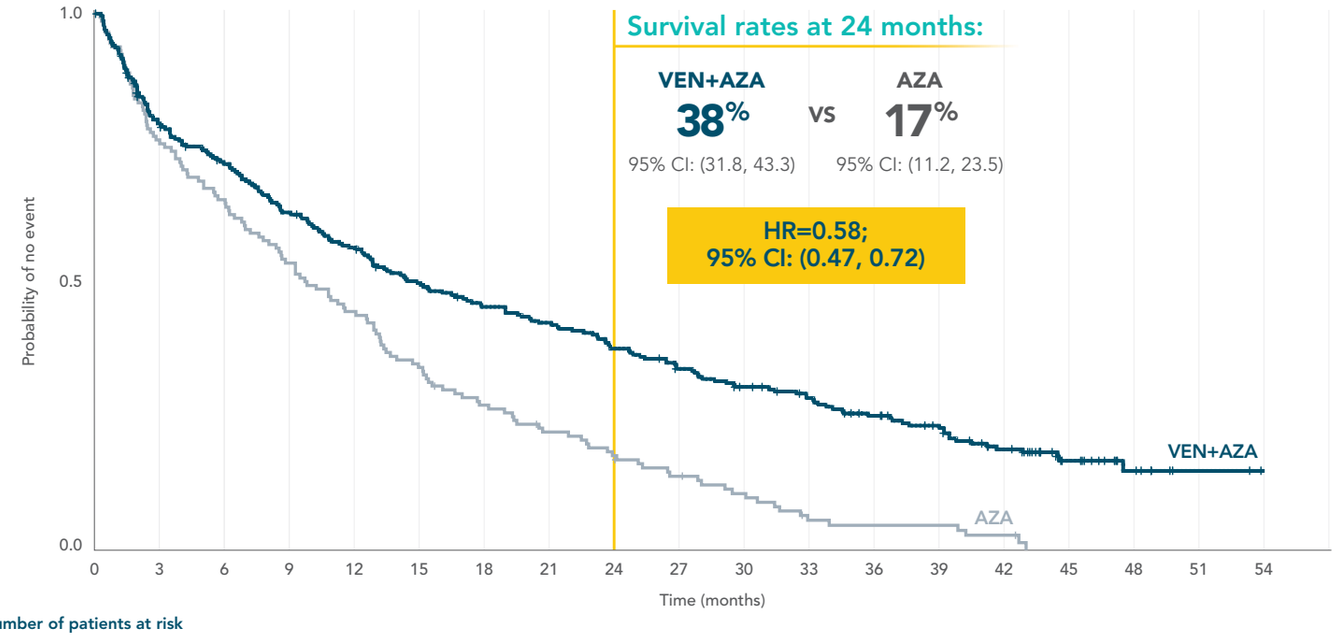
- Concomitant use with a P-gp inhibitor or a strong or moderate CYP3A inhibitor increases VENCLEXTA exposure, which may increase VENCLEXTA toxicities, including the risk of TLS. Consider alternative medications or adjust VENCLEXTA dosage and monitor more frequently for adverse reactions. Resume the VENCLEXTA dosage that was used prior to concomitant use of a P-gp inhibitor or a strong or moderate CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor.
- Patients should avoid grapefruit products, Seville oranges, and starfruit during treatment as they contain inhibitors of CYP3A.
- Avoid concomitant use of strong or moderate CYP3A inducers.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

VIALE-A long-term follow-up data: VEN+AZA vs AZA[11]

Median follow-up for OS was approximately 43.2 months (range: <0.1-53.4)[12]

Data cutoff date: December 1, 2021



Number of patients at risk

VEN+AZA	286	220	199	173	153	133	122	113	101	89	78	67	57	45	34	18	6	2	0
AZA	145	109	92	77	63	47	37	30	22	17	12	6	5	5	3	0	0	0	0

- **The rates shown are estimated and can be unreliable due to a large number of patients censored at the tail end of the curve**
- **The rates were not powered to demonstrate a statistically significant difference in survival rates**
- **No conclusions of efficacy or safety can be drawn from these data**

VIALE-A: Long-term follow-up safety[11]

- The most common adverse events (≥20%) of any grade were nausea (45% in VEN+AZA vs 37% with PBO+AZA), diarrhea (45% with VEN+AZA vs 34% with PBO+AZA), and constipation (44% with VEN+AZA vs 40% with PBO+AZA)
- Grade 3 or higher adverse events (≥10%) included thrombocytopenia (46% with VEN+AZA vs 40% with PBO+AZA), neutropenia (43% with VEN+AZA vs 29% with PBO+AZA), and febrile neutropenia (43% with VEN+AZA vs 19% with PBO+AZA)
- Serious adverse events occurred in 85% of patients with VEN+AZA vs 77% of patients with PBO+AZA
- Fatal adverse events occurred in 25% of patients with VEN+AZA vs 22% of patients with PBO+AZA
- Overall safety profiles were comparable between VEN+AZA and PBO+AZA, with no new findings

Rates of treatment-emergent adverse reactions of any grade are consistent with previous analyses[1]

Evaluating OS and CR in the real world: Study design

An ongoing retrospective real-world analysis[13]

DATA METHOD

The **A**ML **R**eal-world Eviden**C**e (ARC) Initiative is an ongoing retrospective patient medical chart review from 10 US academic sites and 4 Israeli academic sites. While the ARC study population is broader, this subgroup analysis includes only patients from the population described below.

POPULATION

- 90 adult patients
- Newly diagnosed with AML
- Ineligible for intensive induction chemotherapy, defined as patients ≥75 years of age, or with one of the comorbidities of interest per the Ferrara criteria and physician judgment from the study primary investigator[14]
- Treated with venetoclax in combination with azacitidine (VEN+AZA)
- No prior treatment on venetoclax
- Median age of the study population was 76 years (range: 34-89), and 24% had secondary AML

STUDY PERIOD

- VEN+AZA treatment started on April 11, 2016. Follow-up was until May 30, 2022
- Median follow-up: 10.2 months

STUDY OUTCOMES

- Complete Response (CR) Rate: complete response rate was calculated among the 87 patients with available physician-reported response data documented in patient medical records
- Median Overall Survival (mOS): median OS was estimated by the Kaplan-Meier Survival Analysis to summarize time to death

Important Safety Information (cont'd)

Drug Interactions (cont'd)

- Monitor international normalized ratio (INR) more frequently in patients receiving warfarin.
- Avoid concomitant use of VENCLEXTA with a P-gp substrate. If concomitant use is unavoidable, separate dosing of the P-gp substrate at least 6 hours before VENCLEXTA.

Lactation

- Advise nursing women not to breastfeed during treatment with VENCLEXTA and for 1 week after the last dose.

Overall survival and complete remission in a real-world study

VEN+AZA outcomes in 1L patients ineligible for chemotherapy[13]

Real-world data are observational in nature and are not based on controlled clinical studies.
Results from this study may differ from those observed and are not in the VENCLEXTA prescribing information.

Median Overall Survival

18.8 months

Complete Response

41%

Data presented do not include additional CRh

- ARC data among intensive induction chemotherapy ineligible VEN+AZA subgroup (N=90)
- VEN patients ≥75 years old or with ≥1 comorbidity of interest regardless of age (based on the Ferrara criteria for patients ineligible for intensive chemotherapy)

Specific limitations of the ARC initiative study

- Patients in this study were treated in academic centers, and results may not be generalizable to AML patients treated in the community setting
- Results in this study are based on information as recorded in patient charts by the treating physician, which may have been subject to potential data entry errors and differences in recordkeeping practices across the different centers included in this study. However, a series of data quality checks were performed to ensure that data values followed reasonable logics and expected ranges to alleviate data entry errors
- The response rate in this study was reported as recorded by the physician in the patient chart and may be subject to physician interpretation; however, the European LeukemiaNet (ELN) 2017 guidelines were provided as a guidance for definition of responses in the electronic case report form. It is unknown whether the ELN guidelines were routinely used in real-world practice to assess response
- Safety outcomes were not part of the study objectives, and this study was not powered to detect clinical meaningful changes in the safety endpoints

Important Safety Information (cont'd)

Females and Males of Reproductive Potential

- Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.
- Based on findings in animals, VENCLEXTA may impair male fertility.

Hepatic Impairment

- Reduce the dose of VENCLEXTA for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more frequently for signs of adverse reactions. No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Additional efficacy from a phase 3 clinical trial of VEN+LDAC vs LDAC[1]

VIALE-C: VENCLEXTA in combination with LDAC vs LDAC

- The efficacy and safety of VENCLEXTA in combination with low-dose cytarabine (VEN+LDAC) (N=143) versus placebo with low-dose cytarabine (PBO+LDAC) (N=68) was evaluated in VIALE-C, a double-blind randomized trial in patients with newly diagnosed AML
- At baseline, patients were ≥75 years of age, or with comorbidities that precluded the use of intensive induction chemotherapy based on at least one of the following criteria: baseline ECOG performance status of 2–3, severe cardiac or pulmonary comorbidity, moderate hepatic impairment, CrCl <45 mL/min, or other comorbidity

Dosing in VIALE-C

- Patients received VENCLEXTA 600 mg orally once daily on Days 1-28 following completion of the ramp-up dosing schedule or placebo in combination with LDAC at 20 mg/m^2 subcutaneously once daily on Days 1–10 of each 28-day cycle beginning on Cycle 1, Day 1
- During the 4-day ramp-up phase, patients received TLS prophylaxis and were hospitalized for monitoring

Bone marrow assessment in VIALE-C

- A bone marrow assessment was performed following Cycle 1 of treatment. If bone marrow assessment confirmed a remission, defined as less than 5% leukemia blasts with cytopenia, VENCLEXTA or placebo was interrupted up to 14 days or until ANC ≥500/microliter and platelet count ≥50 × 10^3/microliter
- For patients with resistant disease at the end of Cycle 1, a bone marrow assessment was performed after Cycle 2 or 3 and as clinically indicated
- LDAC was resumed on the same day as VENCLEXTA or placebo following interruption
- Patients continued to receive treatment until disease progression or unacceptable toxicity

Baseline characteristics

VEN+LDAC (N=143)

- The median age of patients treated with VEN+LDAC was 76 years (range: 36–93 years). ECOG performance status at baseline was 0-1 for 52% of patients, 2 for 44% of patients, and 3 for 4.2% of patients
- Mutations identified were as follows: *TP53*—20% (22/112); *IDH1* or *IDH2*—19% (21/112); *FLT3*—18% (20/112); and *NPM1*—16% (18/112). Intermediate or poor cytogenetic risk was present in 63% and 33% of patients, respectively

LDAC (N=68)

- The median age of patients treated with LDAC was 76 years (range: 41–88 years). ECOG performance status at baseline was 0–1 for 50% of patients, 2 for 37% of patients, and 3 for 13% of patients
- Mutations identified were as follows: *TP53*—17% (9/52); *IDH1* or *IDH2*—23% (12/52); *FLT3*—17% (9/52); and *NPM1*—13% (7/52). Intermediate or poor cytogenetic risk was present in 63% and 29% of patients, respectively

Efficacy was based on the rate of CR and duration of CR with supportive evidence of rate of CR+CRh, duration of CR+CRh, and the rate of conversion from transfusion dependence to transfusion independence[1]

CR

- VEN+LDAC: 27% (95% CI: 20, 35)
  mDOCR: 11.1 months
  (95% CI: 6.1, –)
- LDAC: 7.4% (95% CI: 2.4, 16)
  mDOCR: 8.3 months (95% CI: 3.1, –)

CR+CRh

- VEN+LDAC: 47% (95% CI: 39, 55)
  mDOCR+CRh of 11.1 months
- LDAC: 15% (95% CI: 7.3, 25)
  mDOCR+CRh of 6.2 months

TTFR

- The median time to first response of CR or CRh was 1.0 month (range: 0.7–5.8 months) with VEN+LDAC treatment

Transfusion conversion

- The rate of RBC and/or platelet transfusion dependence to independence* was 33% (37/111) in the VEN+LDAC arm vs 13% (7/55) in the LDAC arm

VEN+LDAC did not significantly improve OS versus LDAC. HR for OS was 0.75 (95% CI: 0.52, 1.07); *P*=0.114. The median OS for the VEN+LDAC arm was 7.2 months (95% CI: 5.6, 10.1) and for the LDAC arm was 4.1 months (95% CI: 3.1, 8.8).

*Transfusion independence was defined as no RBC and no platelet transfusion during any consecutive ≥56-day post-baseline period.
TTFR=time to first response.

Important Safety Information

Tumor Lysis Syndrome

- Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA.
- VENCLEXTA can cause rapid reduction in tumor and thus poses a risk for TLS at initiation and during the ramp-up phase in all patients. Changes in blood chemistries consistent with TLS that require prompt management can occur as early as 6 to 8 hours following the first dose of VENCLEXTA and at each dose increase.
- In patients with AML who followed the current 3-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 1.1% in patients who received VENCLEXTA in combination with azacitidine. In patients with AML who followed a 4-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 5.6% and included deaths and renal failure in patients who received VENCLEXTA in combination with low-dose cytarabine.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Safety information from VIALE-C[1]

A predictable, tolerable, and manageable safety profile

No additional warnings or precautions for VENCLEXTA were observed in the AML trials.

Serious adverse reactions (ARs)

Serious adverse reactions were reported in 65% of patients who received VEN+LDAC, with the most frequent (≥10%) being pneumonia (17%), febrile neutropenia (16%), and sepsis (excluding fungal; 12%).

Fatal ARs

Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with LDAC, with the most frequent (≥5%) being pneumonia (6%) and sepsis (excluding fungal; 7%).

Adverse reactions leading to discontinuation, dose reductions, and dose interruptions

Adverse reactions led to permanent discontinuation of VENCLEXTA in 25% of patients, dose reductions in 9%, and dose interruptions in 63%. Among patients who achieved bone marrow clearance of leukemia, 32% underwent dose interruptions for ANC <500/microliter. The most frequent adverse reaction (>2%) which resulted in permanent discontinuation of VENCLEXTA was pneumonia (6%). Adverse reactions which required a dose reduction in ≥1% of patients were pneumonia (1%) and thrombocytopenia (1%), and the adverse reactions which required a dose interruption in ≥5% of patients included neutropenia (20%), thrombocytopenia (15%), pneumonia (8%), febrile neutropenia (6%) and sepsis (excluding fungal; 6%).

Adverse reactions (≥10%) in patients with AML who received VEN+LDAC with a difference between arms of ≥5% for all grades or ≥2% for Grade 3 or 4 compared with PBO+LDAC in VIALE-C*

		VEN+LDAC (N=142)		PBO+LDAC (N=68)	
	Adverse reaction	**All Grades (%)**	**Grade 3 or 4 (%)**	**All Grades (%)**	**Grade 3 or 4 (%)**
Gastrointestinal disorders	Nausea	42	1	31	0
	Diarrhea	28	3	16	0
	Vomiting	25	<1	13	0
	Abdominal pain†	15	<1	9	3
	Stomatitis†	15	1	6	0
Blood and lymphatic system disorders	Febrile neutropenia	32	32	29	29
Infections and infestations	Pneumonia†	29	19	21	21
Vascular disorders	Hemorrhage†	27	8	16	1
	Hypotension†	11	5	4	1
Musculoskeletal and connective tissue disorders	Musculoskeletal pain†	23	3	18	0
General disorders and administration site conditions	Fatigue†	22	2	21	0
Nervous system disorders	Headache	11	0	6	0

*Patients who received at least one dose of either treatment.
†Includes multiple adverse reaction terms.

Hematologic laboratory abnormalities

New or worsening Grade 3 or 4 hematologic laboratory abnormalities (≥10%) in VIALE-C with a difference between arms of ≥2% for VEN+LDAC vs PBO+LDAC, respectively: platelets decreased 95% vs 90%, neutrophils decreased 92% vs 71%, lymphocytes decreased 69% vs 24%, hemoglobin decreased 57% vs 54%.

For dose modifications for drug-drug interactions and management of adverse reactions specific to VEN+LDAC regimen, please see section 2 of the full Prescribing Information.

Please see page 20 for additional efficacy data.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Additional efficacy from a phase 1b trial of VEN+AZA or VEN+DEC[1,15]

Study M14-358: VENCLEXTA in combination with AZA or DEC[1]

- VENCLEXTA was studied in a non-randomized, open-label trial (NCT02203773) that evaluated the efficacy of VENCLEXTA in combination with AZA (N=84) or DEC (N=31) in patients with newly diagnosed AML
- Of those patients, 67 who received AZA combination and 13 who received DEC combination were 75 years or older, or with comorbidities that precluded the use of intensive induction chemotherapy based on at least one of the following criteria: baseline ECOG performance status of 2–3, severe cardiac or pulmonary comorbidity, moderate hepatic impairment, CrCl <45 mL/min, or other comorbidity

Dosing in M14-358[1]

- Patients received VENCLEXTA 400 mg orally once daily following completion of the ramp-up dosing schedule in combination with AZA (75 mg/m^2 either intravenously or subcutaneously once daily on Days 1–7 of each 28-day cycle beginning on Cycle 1, Day 1) or DEC (20 mg/m^2 was administered intravenously once daily on Days 1–5 of each 28-day cycle beginning on Cycle 1, Day 1)
- During the ramp-up phase, patients received TLS prophylaxis and were hospitalized for monitoring
- Treatment was continued until disease progression or unacceptable toxicity

M14-358: VEN+DEC

Baseline characteristics[1]

- The median age of patients treated with VEN+DEC was 75 years (range: 68-86 years). ECOG performance status at baseline was 0-1 for 92% of patients and 2 for 7.7% of patients
- Of the 13 patients in the VEN+DEC arm, those who had mutations identified were as follows: 31% with *TP53*, 15% with *NPM1*, 23% with *FLT3*, and no patients with *IDH1* or *IDH2*. Intermediate or poor cytogenetic risk was present in 38% and 62% of patients, respectively

First-line efficacy and fast remissions with VEN+DEC[1]

- CR was 54% (n=7); 95% CI: (25, 81)
- CRh was 7.7% (n=1); 95% CI: (0.2, 36)
- Median duration of CR was 12.7 months (95% CI: [1.4, –])
- Median time to first response (CR or CRh) was 1.9 months (range: 0.8-4.2)

Descriptive prespecified exploratory analysis of CR+CRh rates in different mutational and cytogenetic risk subgroups[15]

- CR+CRh rates were 33% (n=1/3; 95% CI: [0.8, 91]) for *FLT3*, 100% (n=2/2; 95% CI: [16, 100]) for *NPM1*, 75% (n=3/4; 95% CI: [19, 99]) for *TP53*, 60% (n=3/5; 95% CI: [15, 95]) for the intermediate cytogenetic risk group, and 63% (n=5/8; 95% CI: [25, 92]) for the poor cytogenetic risk group
- CR rates were 50% (n=2/4; 95% CI: [7, 93]) for *TP53* and 50% (n=4/8; 95% CI: [16, 84]) for the poor cytogenetic risk group. CR rates for *FLT3*, *NPM1*, and the intermediate cytogenetic risk group were the same as rates seen for CR+CRh
- No patients had an *IDH1/2* mutation
- 4 patients had insufficient sample for analysis. Patients could have expressed one or more, or none, of the identified mutations
- The subgroup analyses were not powered or tested to demonstrate a statistically significant difference in outcomes for any subgroup examined

Important Safety Information (cont'd)

Tumor Lysis Syndrome (cont'd)

- The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy.
- Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase, and requires VENCLEXTA dose reduction.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Safety information from a phase 1b trial of VEN+DEC[1]

A predictable, tolerable, and manageable safety profile

No additional warnings or precautions for VENCLEXTA were observed in the AML trials.

Adverse reactions reported in ≥30% (any grade)

- The most common adverse reactions (≥30%) were febrile neutropenia (69%), fatigue (62%), constipation (62%), musculoskeletal pain (54%), dizziness (54%), nausea (54%), abdominal pain (46%), diarrhea (46%), pneumonia (46%), sepsis (excluding fungal; 46%), cough (38%), pyrexia (31%), hypotension (31%), oropharyngeal pain (31%), edema (31%), and vomiting (31%)
- The most common hematologic laboratory abnormalities (≥30%) were neutrophils decreased (100%), lymphocytes decreased (100%), white blood cells decreased (100%), platelets decreased (92%), and hemoglobin decreased (69%)
- The median duration of exposure for patients taking VEN+DEC was 8.4 months (range: 0.5–39.0 months)

Treatment events and occurrence rates

- Serious adverse reactions were reported in 85% of patients
- The most frequent serious adverse reactions (≥10%) were sepsis (excluding fungal; 46%), febrile neutropenia (38%), and pneumonia (31%)
- One (8%) fatal adverse reaction of bacteremia occurred within 30 days of starting treatment
- Permanent discontinuation due to adverse reactions occurred in 38% of patients
- The most frequent adverse reaction leading to permanent discontinuation (≥5%) was pneumonia (8%)
- Dosage interruptions due to adverse reactions occurred in 69% of patients
- The most frequent adverse reactions leading to dose interruption (≥10%) were:
  - neutropenia (38%), febrile neutropenia (23%), leukopenia (15%), and pneumonia (15%)
- Dosage reductions due to adverse reactions occurred in 15% of patients
- The most frequent adverse reaction leading to dose reduction (≥5%) was neutropenia (15%)

For dose modifications for drug-drug interactions and management of adverse reactions specific to VEN+DEC regimen, please see section 2 of the full Prescribing Information.

Please see additional Important Safety Information on pages 22 and 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Important Safety Information

Tumor Lysis Syndrome

- Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA.
- VENCLEXTA can cause rapid reduction in tumor and thus poses a risk for TLS at initiation and during the ramp-up phase in all patients. Changes in blood chemistries consistent with TLS that require prompt management can occur as early as 6 to 8 hours following the first dose of VENCLEXTA and at each dose increase.
- In patients with AML who followed the current 3-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 1.1% in patients who received VENCLEXTA in combination with azacitidine. In patients with AML who followed a 4-day ramp-up dosing schedule and the TLS prophylaxis and monitoring measures, the rate of TLS was 5.6% and included deaths and renal failure in patients who received VENCLEXTA in combination with low-dose cytarabine.
- The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy.
- Assess all patients for risk and provide appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during the ramp-up phase, and requires VENCLEXTA dose reduction.

Neutropenia

- In patients with AML, baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Monitor complete blood counts. Interrupt dosing for severe neutropenia. Resume at same dose then reduce duration based on remission status and first or subsequent occurrence of neutropenia. Consider supportive measures including antimicrobials and growth factors (e.g., G-CSF).

Infections

- Fatal and serious infections such as pneumonia and sepsis have occurred in patients treated with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution and resume at same dose.

Immunization

- Do not administer live attenuated vaccines prior to, during, or after treatment with VENCLEXTA until B-cell recovery occurs. Advise patients that vaccinations may be less effective.

Embryo-Fetal Toxicity

- VENCLEXTA may cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.

Increased Mortality in Patients with Multiple Myeloma when VENCLEXTA is Added to Bortezomib and Dexamethasone

- In a randomized trial (BELLINI; NCT02755597) in patients with relapsed or refractory multiple myeloma, the addition of VENCLEXTA to bortezomib plus dexamethasone, a use for which VENCLEXTA is not indicated, resulted in increased mortality. Treatment of patients with multiple myeloma with VENCLEXTA in combination with bortezomib plus dexamethasone is not recommended outside of controlled clinical trials.

Adverse Reactions

- **In patients with AML receiving combination therapy with azacitidine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia (30%), pneumonia (22%), sepsis (excluding fungal; 19%), and hemorrhage (6%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (98%), platelets decreased (94%), lymphocytes decreased (91%), hemoglobin decreased (61%), nausea (44%), diarrhea (43%), febrile neutropenia (42%), musculoskeletal pain (36%), pneumonia (33%), fatigue (31%), and vomiting (30%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with azacitidine, with the most frequent (≥2%) being pneumonia (4%), sepsis (excluding fungal; 3%), and hemorrhage (2%).
- **In patients with AML receiving combination therapy with decitabine,** the most frequent serious adverse reactions (≥10%) were sepsis (excluding fungal; 46%), febrile neutropenia (38%), and pneumonia (31%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were neutrophils decreased (100%), lymphocytes decreased (100%), white blood cells decreased (100%), platelets decreased (92%), hemoglobin decreased (69%), febrile neutropenia (69%), fatigue (62%), constipation (62%), musculoskeletal pain (54%), dizziness (54%), nausea (54%), abdominal pain (46%), diarrhea (46%), pneumonia (46%), sepsis (excluding fungal; 46%), cough (38%), pyrexia (31%), hypotension (31%), oropharyngeal pain (31%), edema (31%), and vomiting (31%). One (8%) fatal adverse reaction of bacteremia occurred within 30 days of starting treatment.
- **In patients with AML receiving combination therapy with low-dose cytarabine,** the most frequent serious adverse reactions (≥10%) were pneumonia (17%), febrile neutropenia (16%), and sepsis (excluding fungal; 12%). The most common adverse reactions including hematological abnormalities (≥30%) of any grade were platelets decreased (97%), neutrophils decreased (95%), lymphocytes decreased (92%), hemoglobin decreased (63%), nausea (42%), and febrile neutropenia (32%). Fatal adverse reactions occurred in 23% of patients who received VENCLEXTA in combination with LDAC, with the most frequent (≥5%) being pneumonia (6%) and sepsis (excluding fungal; 7%).

Please see additional Important Safety Information on page 23.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

Important Safety Information (cont'd)

Drug Interactions

- Concomitant use with a P-gp inhibitor or a strong or moderate CYP3A inhibitor increases VENCLEXTA exposure, which may increase VENCLEXTA toxicities, including the risk of TLS. Consider alternative medications or adjust VENCLEXTA dosage and monitor more frequently for adverse reactions. Resume the VENCLEXTA dosage that was used prior to concomitant use of a P-gp inhibitor or a strong or moderate CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor.
- Patients should avoid grapefruit products, Seville oranges, and starfruit during treatment as they contain inhibitors of CYP3A.
- Avoid concomitant use of strong or moderate CYP3A inducers.
- Monitor international normalized ratio (INR) more frequently in patients receiving warfarin.
- Avoid concomitant use of VENCLEXTA with a P-gp substrate. If concomitant use is unavoidable, separate dosing of the P-gp substrate at least 6 hours before VENCLEXTA.

Lactation

- Advise nursing women not to breastfeed during treatment with VENCLEXTA and for 1 week after the last dose.

Females and Males of Reproductive Potential

- Advise females of reproductive potential to use effective contraception during treatment with VENCLEXTA and for 30 days after the last dose.
- Based on findings in animals, VENCLEXTA may impair male fertility.

Hepatic Impairment

- Reduce the dose of VENCLEXTA for patients with severe hepatic impairment (Child-Pugh C); monitor these patients more frequently for signs of adverse reactions. No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

References: 1. VENCLEXTA [package insert]. North Chicago, IL: AbbVie Inc. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia V.3.2023. © National Comprehensive Cancer Network, Inc 2023. All rights reserved. Accessed April 5, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc. **3.** DiNardo CD, Jonas BA, Pullarkat V, et al. Azacitidine and venetoclax in previously untreated acute myeloid leukemia. *N Engl J Med*. 2020;383(7):617-629. **4.** Data on file, CSR_M15-656. AbbVie Inc. **5.** Data on file, ABVRRTI73540. AbbVie Inc. **6.** Data on file, ABVRRTI71272. AbbVie Inc. **7.** Data on file, ABVRRTI71500. AbbVie Inc. **8.** Drug development and drug interactions: table of substrates, inhibitors and inducers. US Food and Drug Administration website. Accessed November 30, 2022. https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm **9.** CRESEMBA [package insert]. Northbrook, IL: Astellas Pharma. **10.** Data on file, ABVRRTI71211. AbbVie Inc. **11.** Data on file, ABVRRTI75003. AbbVie Inc.**12.** Pratz KW, Jonas BA, Pullarkat V, et al. Long-term follow-up of the phase 3 VIALE-A clinical trial of venetoclax plus azacitidine for patients with treatment-naïve acute myeloid leukemia ineligible for intensive chemotherapy. Oral abstract presented at: American Society for Hematology Annual Meeting and Exposition; December 10-13, 2022. doi: https://ash.confex.com/ash/2022/webprogram/Paper158518.html **13.** Data on file, ABVRRTI74719. AbbVie Inc. **14.** Ferrara F, Barosi G, Venditti A, et al. Consensus-based definition of unfitness to intensive and non-intensive chemotherapy in acute myeloid leukemia: a project of SIE, SIES and GITMO group on a new tool for therapy decision making. *Leukemia*. 2013;27(5):997-999. **15.** Data on file, ABVRRTI67697. AbbVie Inc.

Please see additional Important Safety Information on page 22.
Please see full Prescribing Information at www.rxabbvie.com/pdf/venclexta.pdf.

VENCLEXTA + azacitidine extended overall survival

In patients with newly diagnosed AML who were ≥75 years of age, or with comorbidities that precluded the use of intensive induction chemotherapy[1]

FDA-approved regardless of mutation status.

LONGER OVERALL SURVIVAL[1]

mOS

VEN+AZA	AZA
14.7 months	**9.6 months**
95% CI: (11.9, 18.7)	95% CI: (7.4, 12.7)

- VEN+AZA improved overall survival vs AZA **(HR=0.66; 95% CI: [0.52, 0.85]; *P*<0.001)**

LASTING IMPACT[1]

CR

VEN+AZA	AZA
37%	**18%**
105/286 patients	26/145 patients
95% CI: (31, 43)	95% CI: (12, 25)

P<0.001

CR+CRh

VEN+AZA	AZA
65%	**23%**
185/286 patients	33/145 patients
95% CI: (59, 70)	95% CI: (16, 30)

P<0.001

mDOCR*

VEN+AZA	AZA
18 months	**13.4 months**
95% CI: (15.3, –)	95% CI: (8.7, 17.6)

mDOCR+CRh*

VEN+AZA	AZA
17.8 months	**13.9 months**
95% CI: (15.3, –)	95% CI: (10.4, 15.7)

- Almost 3× more remissions† and longer mDOR observed vs AZA

*Endpoints were not powered or tested to demonstrate a statistically significant difference between the treatment arms.

†Remission refers to CR+CRh.

RBC and platelet

Conversion from transfusion dependence to independence*

VEN+AZA	AZA
49%	**27%**
76/155 patients	22/81 patients

Patients were dependent on RBC and/or platelet transfusions at baseline

RBC and platelet

Transfusion independence maintenance from baseline to post-baseline*

VEN+AZA	AZA
69%	**42%**
90/131 patients	27/64 patients

Patients were independent of both RBC and platelet transfusions at baseline.

Transfusion independence was defined as no RBC and no platelet transfusion during any consecutive ≥56-day post-baseline period.

LEVERAGE A STEPWISE APPROACH FOR TREATMENT WITH VENCLEXTA REGIMENS[1]

Initiation

- Evaluate TLS risk in all patients and provide prophylactic measures
- 3-day dose ramp-up for VEN+HMA or 4-day dose ramp-up for VEN+LDAC. Monitor blood chemistries
- Dose-reduce for concomitant use with P-gp inhibitors or strong or moderate CYP3A inhibitors or for severe hepatic impairment

Assessment

- Assess and monitor for common and serious adverse reactions (ARs)
- Bone marrow assessment as clinically indicated
  - In AML clinical trials, bone marrow assessment was conducted following Cycle 1 treatment to assess for remission

Management

- Manage hematologic ARs with dose modifications based on remission status‡
  - May include VENCLEXTA pause or change in VENCLEXTA duration
- Manage non-hematologic ARs with dose modifications‡

‡See Table 6 in the full Prescribing Information for dose modifications.

NCCN Consistent with the **Principles§ of Venetoclax Use with HMA or LDAC included in the NCCN Guidelines for AML.[2]**

§See NCCN Guidelines for AML, Version 3.2023, for complete principles. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

Select Important Safety Information

- Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in patients treated with VENCLEXTA. The risk of TLS is a continuum based on multiple factors, particularly reduced renal function, tumor burden, and type of malignancy. Assess all patients for risk, including evaluation of tumor burden and comorbidities, and provide prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases. Interrupt dosing if needed; when restarting VENCLEXTA follow dose modification guidance in the Prescribing Information.
- Concomitant use of VENCLEXTA with P-gp inhibitors or strong or moderate CYP3A inhibitors increases venetoclax exposure, which may increase the risk of TLS at initiation and during ramp-up phase, and requires VENCLEXTA dose reduction.
- Grade 3 or 4 neutropenia occurred in patients treated with VENCLEXTA. Monitor blood counts and for signs of infection; manage as medically appropriate.
- Baseline neutrophil counts worsened in 95% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles.
- Fatal and serious infections such as pneumonia and sepsis have occurred in patients with VENCLEXTA. Monitor patients for signs and symptoms of infection and treat promptly. Withhold VENCLEXTA for Grade 3 and 4 infection until resolution.
- Do not administer live attenuated vaccines prior to, during, or after treatment until B-cell recovery occurs.
- VENCLEXTA may cause embryo-fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 30 days after the last dose.

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