You are cordially invited to attend a clinical discussion about the use of VENCLEXTA in the treatment of acute myeloid leukemia (AML)

Tuesday

September 24

Presented by:

Jonathan Abbas, MD

Banner MD Anderson Cancer Center, Gilbert, AZ

Dr. Jonathan Abbas is a physician at Banner MD Anderson in Gilbert, Arizona. He specializes in hematologic malignancies, primarily acute leukemia, and cellular therapy including autologous and allogeneic stem cell transplantation and CAR-T therapy. He is an investigator on over a dozen clinical trials focusing on stem cell transplantation, acute myeloid leukemia, and CAR-T therapy.

Presentation Objective

- Examine the clinical trial results of VENCLEXTA in combination with azacitidine, decitabine, or low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy

Audience

- This program is designed to facilitate discussion and participation among physicians, nurses, pharmacists, and other healthcare professionals

Indication

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

This indication is approved under accelerated approval based on response rates. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Tuesday, September 24, 2019

6:00 PM

Fleming's Prime Steakhouse
180 El Camino Real
Palo Alto, California 94304

Please RSVP by **September 19, 2019**

Sharon McCarthy

(650) 388-2369

We look forward to seeing you there!

Select Important Safety Information

- Anticipate tumor lysis syndrome (TLS). Assess risk in all patients, including evaluation of tumor burden and comorbidities. Patients should receive appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases.
- Concomitant use with strong or moderate CYP3A inhibitors or P-gp inhibitors: Adjust dosage of VENCLEXTA.
- Grade 3 or 4 neutropenia occurred in patients treated with VENCLEXTA. Monitor blood counts and for signs of infection; manage as medically appropriate.
- 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 avoid pregnancy during treatment.

Please see additional Important Safety Information on the reverse side.

Please see accompanying full Prescribing Information or visit www.rxabbvie.com/pdf/venclexta.pdf.

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

Important Safety Information

Contraindication

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up phase is contraindicated in patients with CLL/SLL due to the potential for increased risk of tumor lysis syndrome (TLS).

Tumor Lysis Syndrome

- Tumor lysis syndrome, including fatal events and renal failure requiring dialysis, has occurred in patients with high tumor burden when treated with VENCLEXTA.
- In patients with CLL, with the current (5 week) dose ramp-up, TLS prophylaxis and monitoring, the rate of TLS was 2% in the VENCLEXTA CLL monotherapy studies. The rate of TLS remained consistent with VENCLEXTA in combination with rituximab. With a 2 to 3 week dose ramp-up and higher starting dose in patients with CLL/SLL, the TLS rate was 13% and included deaths and renal failure.
- VENCLEXTA poses a risk for TLS at initiation and during the ramp-up phase. 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.
- Patients should be assessed for TLS risk, including evaluation of tumor burden and comorbidities, and should receive appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Reduced renal function further increases the risk. Monitor blood chemistries and manage abnormalities promptly. Interrupt dosing if needed. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases.
- Concomitant use of VENCLEXTA with strong or moderate CYP3A inhibitors or P-gp inhibitors may increase the risk of TLS at initiation and during the ramp-up phase, and requires dose adjustment due to increases in VENCLEXTA exposure.

Neutropenia

- In patients with CLL, Grade 3 or 4 neutropenia developed in 64% of patients and Grade 4 neutropenia developed in 31% of patients treated with VENCLEXTA in combination with rituximab. Grade 3 or 4 neutropenia developed in 63% of patients and Grade 4 neutropenia developed in 33% of patients treated with VENCLEXTA monotherapy. Febrile neutropenia occurred in 4% of patients treated with VENCLEXTA in combination with rituximab and in 6% of patients treated with VENCLEXTA monotherapy.
- In patients with AML, baseline neutrophil counts worsened in 97% to 100% of patients treated with VENCLEXTA in combination with azacitidine or decitabine or low-dose cytarabine. Neutropenia can recur with subsequent cycles of therapy.
- Monitor complete blood counts throughout the treatment period. Interrupt dosing or reduce dose for severe neutropenia. Consider supportive measures including antimicrobials for signs of infection and use of growth factors (e.g., G-CSF).

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 avoid pregnancy during treatment.

Adverse Reactions

- **In patients with CLL receiving combination therapy with rituximab,** the most frequent serious adverse reaction (≥5%) was pneumonia (9%). The most common adverse reactions (≥20%) of any grade were neutropenia (65%), diarrhea (40%), upper respiratory tract infection (39%), fatigue (22%), cough (22%), and nausea (21%).
- **In patients with CLL/SLL receiving monotherapy,** the most frequent serious adverse reactions (≥5%) were pneumonia (9%), febrile neutropenia (5%), and sepsis (5%). The most common adverse reactions (≥20%) of any grade were neutropenia (50%), diarrhea (43%), nausea (42%), upper respiratory tract infection (36%), anemia (33%), fatigue (32%), thrombocytopenia (29%), musculoskeletal pain (29%), edema (22%), and cough (22%).
- **In patients with AML receiving combination therapy with azacitidine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia, pneumonia (excluding fungal), sepsis (excluding fungal), respiratory failure, and multiple organ dysfunction syndrome. The most common adverse reactions (≥30%) of any grade were nausea (58%), diarrhea (54%), constipation (49%), neutropenia (49%), thrombocytopenia (49%), hemorrhage (46%), peripheral edema (46%), vomiting (40%), fatigue (36%), febrile neutropenia (36%), rash (33%), and anemia (30%).
- **In patients with AML receiving combination therapy with decitabine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia, sepsis (excluding fungal), pneumonia (excluding fungal), diarrhea, fatigue, cellulitis, and localized infection. The most common adverse reactions (≥30%) of any grade were febrile neutropenia (69%), constipation (62%), fatigue (62%), thrombocytopenia (54%), abdominal pain (46%), dizziness (46%), hemorrhage (46%), nausea (46%), pneumonia (excluding fungal) (46%), sepsis (excluding fungal) (46%), cough (38%), diarrhea (38%), neutropenia (38%), back pain (31%), hypotension (31%), myalgia (31%), oropharyngeal pain (31%), peripheral edema (31%), pyrexia (31%), and rash (31%).
- **In patients with AML receiving combination therapy with low-dose cytarabine,** the most frequent serious adverse reactions (≥5%) were febrile neutropenia, sepsis (excluding fungal), hemorrhage, pneumonia (excluding fungal), and device-related infection. The most common adverse reactions (≥30%) of any grade were nausea (64%), thrombocytopenia (59%), hemorrhage (49%), febrile neutropenia (46%), neutropenia (46%), diarrhea (44%), fatigue (44%), constipation (33%), and dyspnea (31%).

Drug Interactions

- Concomitant use with a strong or moderate CYP3A inhibitor or a P-gp inhibitor increases VENCLEXTA exposure, which may increase VENCLEXTA toxicities, including the risk of TLS. Adjust VENCLEXTA dosage and closely monitor patients for signs of VENCLEXTA toxicities. 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.
- 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.
- 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.
- Monitor international normalized ratio (INR) closely in patients receiving warfarin.

Lactation

- Advise nursing women to discontinue breastfeeding during treatment with VENCLEXTA.

Females and Males of Reproductive Potential

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

This is an AbbVie promotional activity.
NOTE: No continuing education (CME) credit will be awarded.

Please see accompanying full Prescribing Information or visit www.rxabbvie.com/pdf/venclexta.pdf.

VISIT **VENCLEXTAHCP.COM** FOR MORE INFORMATION

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