

Friday, July 21, 2017

You are cordially invited



to attend a clinical discussion about

VENCLEXTA™ (venetoclax) for Treatment of Previously Treated CLL With 17p Deletion

Presented by:

Javier Pinilla-Ibarz, M.D., Ph.D.

Associate Member, Department of Malignant Hematology, Moffitt Cancer Center, University of South Florida

Dr. Pinilla-Ibarz received his medical and doctoral degrees at the University of Zaragoza Medical School in Spain. He completed a residency and fellowship at La Paz University Hospital in Madrid, Spain. He was a research fellow at Memorial Sloan Kettering Cancer Center (MSKCC) in immunology, followed by a research associate position at MSKCC. He then pursued a residency at New York Presbyterian/Cornell Medical Center. He is board certified in internal medicine, hematology, and medical oncology. Dr. Pinilla-Ibarz's clinical interests are focused in the area of chronic leukemias with special interest in chronic myeloid leukemia and chronic lymphoid leukemias. He has authored or coauthored more than 80 publications in peer-reviewed journals. He is currently an investigator on several clinical trials, including A Phase I Study of Ruxolitinib in Combination With Nilotinib in CML Patients With Evidence of Molecular Disease (NCT01702064), and a principal investigator on The Life After Stopping Tyrosine Kinase Inhibitors Study (The LAST Study) (NCT02269267).

Presentation Objective

Examine the clinical trial results of VENCLEXTA™ in patients with chronic lymphocytic leukemia (CLL) with 17p deletion, who have received at least one prior therapy.

Audience

This program has been developed for health care provider discussion and participation.

Indication

- VENCLEXTA is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy.
- This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Select Important Safety Information

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up is contraindicated.
- Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in previously treated CLL patients with high tumor burden when treated with VENCLEXTA. 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 (CrCl <80 mL/min) further increases the risk. Monitor blood chemistries and manage abnormalities promptly. Employ more intensive measures (IV hydration, frequent monitoring, hospitalization) as overall risk increases.
- Avoid concomitant use of moderate CYP3A inhibitors or P-gp inhibitors. Concomitant use with strong or moderate CYP3A inhibitors and P-gp inhibitors may increase the risk of TLS at initiation and during ramp-up, and may require dose adjustment due to increases in VENCLEXTA exposure.
- Grade 3 or 4 neutropenia occurred in patients treated with VENCLEXTA.
- 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 reverse side.
Please see accompanying full [Prescribing Information](#).



Date & Time

Friday, July 21, 2017
1:00 PM



Location

Roosevelt Hotel New Orleans Waldorf Astoria
130 Roosevelt Way
New Orleans, Louisiana 70112

We look forward to seeing you there!

This is an AbbVie promotional activity.

NOTE: No continuing education (CME) credit will be awarded.

Important Safety Information

Contraindication

- Concomitant use of VENCLEXTA with *strong* CYP3A inhibitors at initiation and during ramp-up phase is contraindicated.^a

Tumor Lysis Syndrome

- Tumor lysis syndrome (TLS), including fatal events and renal failure requiring dialysis, has occurred in previously treated CLL patients with high tumor burden treated with VENCLEXTA.
- VENCLEXTA poses a risk for TLS in the initial 5-week 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 (CrCl <80 mL/min) 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 and P-gp inhibitors may increase the risk of TLS at initiation and during the ramp-up phase, and may require dose adjustment due to increases in VENCLEXTA exposure.

Neutropenia

- Grade 3 or 4 neutropenia occurred in 41% (98/240) of patients treated with VENCLEXTA. Monitor complete blood counts throughout treatment. 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. 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

- Serious adverse reactions were reported in 43.8% of patients. The most frequent serious adverse reactions ($\geq 2\%$) were pneumonia (5%), febrile neutropenia (4.6%), pyrexia (3.3%), autoimmune hemolytic anemia (2.9%), anemia (2.1%), and TLS (2.1%).^b
- The most common adverse reactions ($\geq 20\%$) of any grade were neutropenia (45%), diarrhea (35%), nausea (33%), anemia (29%), upper respiratory tract infection (22%), thrombocytopenia (22%), and fatigue (21%).^a

Drug Interactions

- For patients who have completed the ramp-up phase and are on a steady daily dose of VENCLEXTA, reduce the dose by at least 75% when used concomitantly with strong CYP3A inhibitors. Resume the VENCLEXTA dose that was used prior to initiating the CYP3A inhibitor 2 to 3 days after discontinuation of the inhibitor.
- Avoid concomitant use of moderate CYP3A inhibitors or P-gp inhibitors. If an inhibitor must be used, reduce the VENCLEXTA dose by at least 50%. Monitor patients more closely for signs of VENCLEXTA toxicities. Resume the VENCLEXTA dose that was used prior to initiating the CYP3A inhibitor or 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 narrow therapeutic index P-gp substrates. If these substrates must be used, they should be taken 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.

Please see full [Prescribing Information](#).

In accordance with the PhRMA Code on Interactions with Healthcare Professionals, attendance at this program is limited to healthcare professionals who practice in relevant specialties.

AbbVie tracks and reports payments and transfers of value to healthcare professionals under applicable state and federal reporting obligations.

Visit www.VENCLEXTA.com for more information.

^aVENCLEXTA [package insert]. North Chicago, IL: AbbVie Inc.

^bData on file, AbbVie Inc. ABVRR162926.

750-1892358

 **VENCLEXTA**[™]
venetoclax tablets 10mg, 50mg, 100mg