

Venclexta® (venetoclax) – Expanded indication

- On May 16, 2019, <u>Roche announced</u> the <u>FDA approval</u> of <u>Venclexta (venetoclax)</u>, for the treatment
 of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
 - Previously, Venclexta was approved for the treatment of adult patients with CLL or SLL, with or without 17p deletion, who have received at least one prior therapy.
- Venclexta is also approved in combination with <u>azacitidine</u>, or <u>decitabine</u>, or low-dose <u>cytarabine</u> 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.
- The expanded indication for Venclexta was based on the CLL14 open-label study enrolling 432 patients with previously untreated CLL with coexisting medical conditions. Patients received Venclexta in combination with Gazyva (obinutuzumab) (VEN+G) or Venclexta in combination with Leukeran (chlorambucil) (GClb). The major efficacy outcome was progression-free survival (PFS).
 - VEN+G produced a durable and significant reduction in the risk of disease worsening or death (PFS) vs. GCIb (HR 0.33; 95% CI: 0.22, 0.51; p < 0.0001).
 - In addition, overall response rate was 85% for the VEN+G group vs. 71% for the GCIb group.
 - At the time of analysis, median overall survival (OS) had not been reached. The median duration of follow-up for OS was 28 months.
- The most common adverse reactions (≥ 20%) with Venclexta when given in combination with Gazyva or Rituxan® (rituximab) or as monotherapy in CLL/SLL were neutropenia, thrombocytopenia, anemia, diarrhea, nausea, upper respiratory tract infection, cough, musculoskeletal pain, fatigue, and edema.
- For CLL/SLL Venclexta dosing begins with a 5-week ramp-up schedule to the recommended daily dose of 400 mg. Refer to the Venclexta prescribing information for further dosing instructions when administered in combination with Gazyva, Rituxan, or as monotherapy.
- Refer to the Venclexta prescribing information for additional dosing recommendations and for use in AML.



optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum[®] trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2019 Optum, Inc. All rights reserved.