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CONFRONT R/R CLL WITH Pr VENCLEXTA® + RITUXIMAB[1]

In an open-label study, VENCLEXTA + rituximab demonstrated superior PFS compared with bendamustine + rituximab[1†]

- 81% reduction in instantaneous risk of progression or death vs. bendamustine + rituximab (HR: 0.19 [95% CI: 0.13-0.28]; $p<0.0001$).[1]
- The 2-year rates of PFS for the VENCLEXTA + rituximab and bendamustine + rituximab arms were 82.76% (95% CI: 76.62-88.90) and 39.42% (95% CI: 31.03-47.82), respectively (IRC-assessed in the ITT population).[1,2]

NCCN Guidelines‡ Category 1 recommendation:
Venetoclax + rituximab is recommended as a preferred regimen for R/R CLL[3]

Indication and clinical use:

VENCLEXTA (venetoclax) in combination with rituximab is indicated for the treatment of adult patients with CLL who have received at least one prior therapy.

No safety and efficacy data for VENCLEXTA in children and adolescents below 18 years of age are available.

Contraindication:

Concomitant use with strong CYP3A inhibitors at initiation and during ramp-up phase.

Most serious warnings and precautions:

- **VENCLEXTA should only be prescribed by a qualified physician who is experienced in the use of anti-cancer agents.**
- **VENCLEXTA is only available through specialty pharmacies and/or retail oncology pharmacies that are part of AbbVie's managed distribution program.**
- **Tumour lysis syndrome (TLS)**
  - Weekly dosage ramp-up over a period of 5 weeks, with blood chemistry monitoring on each dose ramp-up is required.
  - Patients must receive prophylaxis for TLS, including hydration and anti-hyperuricemics prior to initiating treatment.
  - Concomitant use of strong CYP3A inhibitors at initiation and during ramp-up phase is contraindicated.
- **Serious infections that may lead to hospitalization or death.**

Other relevant warnings and precautions:

- Second primary malignancies: monitor patients for the appearance of non-melanoma skin cancers.
- Neutropenia; dose interruption/reduction recommended for severe neutropenia; prophylactic use of growth factors (e.g. G-CSF) may be considered.
- Immunization using live vaccines should be avoided during treatment and thereafter until B-cell recovery.
- Monitor for signs of infection and have their complete blood counts monitored throughout treatment.
- Recommended dose not determined for patients with severe renal impairment (CrCl <30 mL/min) or on dialysis.
- Females of reproductive potential: test to exclude pregnancy before treatment; use of effective contraceptives during treatment and for at least 30 days after last dose.
- Male fertility may be compromised.
- Avoid use during pregnancy.
- Breastfeeding should be discontinued.
- No overall difference in effectiveness and safety observed in patients ≥65 years of age compared to younger patients. In the combination study (MURANO), patients ≥65 years of age experienced higher incidences of diarrhea, peripheral oedema, dizziness, blood creatinine increased, constipation, pyrexia and fall than those <65 years of age.
- Patients with hepatic impairment should be monitored more closely for signs of toxicity.
  - Severe hepatic impairment: A 50% reduction in VENCLEXTA dose is recommended throughout the initiation, ramp-up phase and steady state once daily dose.
- Monitoring and laboratory tests: tumour burden assessment; blood chemistry monitoring; signs of infection; complete blood counts; baseline renal function and hepatic status.

For more information:

Please consult the Product Monograph at abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/VENCLEXTA_PM_EN.pdf for important information relating to adverse reactions, drug interactions and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-888-704-8271 or 514-906-9771.

* VENCLEXTA is currently listed as an exception benefit on the formulary of the following provinces: Alberta (Outpatient Cancer Drug Benefit Program), British Columbia (BC Cancer – Compassionate Access Program), Manitoba (Cancer Care Manitoba), New Brunswick (New Brunswick Prescription Drug Plan), Nova Scotia (Nova Scotia Formulary Updates), Ontario (Cancer Care Ontario), Saskatchewan (Saskatchewan Cancer Agency) and Quebec (*Liste des médicaments – établissements*).

† Based on results from a randomized (1:1), multicentre, open-label, Phase 3 study that evaluated the efficacy and safety of VENCLEXTA in combination with rituximab versus bendamustine in combination with rituximab in patients with relapsed/refractory CLL who had received at least one line of prior therapy. Patients previously treated with VENCLEXTA were excluded. Patients in the VENCLEXTA + rituximab arm completed the 5-week ramp-up schedule of VENCLEXTA and received 400 mg VENCLEXTA daily for 24 months from Day 1, Cycle 1 of rituximab in the absence of disease progression or unacceptable toxicity. After the 5-week dose ramp-up, rituximab was initiated at 375 mg/m^2 for Cycle 1 and 500 mg/m^2 for Cycles 2-6. Each cycle was 28 days. Patients randomized to bendamustine + rituximab received bendamustine at 70 mg/m^2 on Days 1 and 2 for 6 cycles and rituximab at the above described dose and schedule. Following completion of the 24-month treatment in the VENCLEXTA + rituximab arm or 6 cycles of bendamustine + rituximab, patients continued to be followed for disease progression and overall survival. A total of 389 patients were randomized; 194 to the VENCLEXTA + rituximab arm and 195 to the bendamustine + rituximab arm.

R/R: relapsed/refractory; CLL: chronic lymphocytic leukemia; PFS: progression-free survival; HR: hazard ratio; CI: confidence interval; ITT: intention-to-treat; IRC: independent review committee; NCCN: National Comprehensive Cancer Network®; G-CSF: granulocyte-colony stimulating factor; CrCl: creatinine clearance.

References: 1. VENCLEXTA Product Monograph. AbbVie Corporation. April 27, 2020. **2.** 2-year PFS estimate data. Data on File. AbbVie Corporation. **3.** NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. Version 4.2020. December 20, 2019.

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