



Speaker:
Dr. Mary Ann Anderson
Consultant Haematologist
The Royal Melbourne Hospital and
Peter MacCallum Cancer Center

Chairperson:
Dr. Ng Soo Chin
Consultant Haematologist

A CHANCE TO BREAK FREE

Finite Treatment Duration in R/R CLL^{1,2}

Time	Topic
6:30 PM – 7:00 PM	Registration
7:00 PM – 7:10 PM	Welcome Remarks
7:10 PM – 7:50 PM	Breaking Free - Finite Treatment Duration In R/R CLL
7:50 PM – 8:10 PM	Case Presentation: The Australian Experience
8:10 PM – 8:30 PM	Q & A
8:30 PM	Dinner

For RSVP, please contact Vivienne Teh +60163804800 or Joleen Tay +60102219233.
Kindly advise if vegetarian meal is preferred.

R/R = Relapsed / Refractory
CLL = Chronic Lymphocytic Leukaemia



Date **19th July 2019** (Friday) | Time **6:30 PM – 8:30 PM** | Venue **Le Meridien Hotel, KL**

I N V I T A T I O N



Dr. Mary Ann Anderson (MBBS, FRACP, FRCPA, PhD)
 Consultant Haematologist, The Royal Melbourne Hospital and Peter MacCallum Cancer Center
 Clinician Researcher, The Walter and Eliza Hall Institute

Doctor Anderson is a haematologist at the Royal Melbourne Hospital and Peter MacCallum Cancer center specializing in high- and low-grade lymphomas with a particular interest in early phase clinical trial development. She holds a joint position at the Walter and Eliza Hall Institute as a post-doctoral clinician scientist. Doctor Anderson's research since 2011 has focused on the development of targeted therapy for the treatment of B cell malignancies. As part of this, she has been involved in the development of venetoclax, the first targeted BCL2 inhibitor, for the use in B cell malignancies. Her work is now focused on identifying biomarkers for venetoclax efficacy, as well as understanding mechanisms for the development of resistance to the agent and identifying rational drug combinations for clinical trial testing.

For Healthcare Professionals Only.

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 **VENCLEXTA™**
 venetoclax tablets

MY-VEN-190004 15 Jun 2019

References: 1. DCA Approval Letter dated 14 May 2019. 2. Kater AP, et al. Fixed Duration of Venetoclax-Rituximab in Relapsed/Refractory Chronic Lymphocytic Leukemia Eradicates Minimal Residual Disease and Prolongs Survivals: Post-Treatment Follow-up of the MURANO Phase III Study. J Clin Oncol 2018;37:269-277.

ABBREVIATED PRESCRIBING INFORMATION. VENCLEXTA™. Active Ingredient: Tablets: Venetoclax 10mg, 50mg, 100mg. **Indication:** VENCLEXTA in combination with rituximab is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy. VENCLEXTA is indicated as monotherapy for the treatment of patients with chronic lymphocytic leukemia (CLL) with 17p deletion who have received at least one prior therapy, or patients with CLL without 17p deletion who have received at least one prior therapy and for whom there are no other suitable treatment options. **Dosage and Administration:** Venetoclax should be taken orally once daily until disease progression or unacceptable toxicity is observed. Instruct patients to take Venetoclax tablets with a meal and water at approximately the same time each day. Venetoclax tablets should be swallowed whole and not chewed, crushed, or broken prior to swallowing. The starting dose of Venetoclax is 20 mg once daily for 7 days (week 1), 50mg once daily for week 2, 100mg once daily for week 3, 200mg once daily for week 4, 400mg once daily for week 5 and beyond. The 5-week ramp-up dosing schedule is designed to gradually reduce tumor burden (debulk) and decrease the risk of tumor lysis syndrome (TLS). Venetoclax in Combination with Rituximab: Start rituximab administration after the patient has completed the ramp-up schedule with Venetoclax and has received the 400 mg dose of Venetoclax for 7 days. Patients should continue Venetoclax 400 mg once daily for 24 months from Cycle 1 Day 1 of rituximab. Venetoclax as Monotherapy: The starting dose of Venetoclax is 20 mg once daily for 7 days. The Venetoclax dose must be administered according to a weekly ramp-up schedule to the recommended daily dose of 400 mg over a period of 5 weeks. Perform tumor burden assessments, including radiographic evaluation. Assess blood chemistry in all patients and correct pre-existing abnormalities prior to initiation of treatment with Venetoclax. For prophylaxis of TLS and dose modifications, please refer to the full prescribing information. **Contraindications:** Concomitant use of VENCLEXTA with strong CYP3A inhibitors is contraindicated at initiation and during ramp-up phase. **Warning & Precautions: Tumor Lysis Syndrome (TLS).** VENCLEXTA can cause rapid reduction in tumor, and thus poses a risk for TLS in the initial 5-week ramp-up phase. Changes in electrolytes consistent with TLS that require prompt management can occur as early as 6-8 hours following the first dose of Venetoclax and at each dose increase. Reduced renal function (CrCl <80 mL/min) further increases the risk. Patients should be assessed for risk and should receive appropriate prophylaxis for TLS, including hydration and anti-hyperuricemics. Monitor blood chemistries and manage abnormalities promptly. Interrupt dosing if needed. Employ more intensive measures (intravenous hydration, frequent monitoring, hospitalization) as overall risk increases. Concomitant use of VENCLEXTA with strong or moderate CYP3A inhibitors may increase the risk for TLS at initiation and during ramp-up phase. **Neutropenia:** Grade 3 or 4 neutropenia have occurred in patients treated with Venetoclax. Monitor complete blood counts throughout the treatment period. Dose interruptions or dose reductions are recommended for severe neutropenia. Consider supportive measures including antimicrobials for any signs of infection and prophylactic use of growth factors (e.g., G-CSF). **Immunization:** The safety and efficacy of immunization with live attenuated vaccines during or following Venetoclax therapy have not been studied. Live vaccines should not be administered during treatment with VENCLEXTA and thereafter until B-cell recovery. **Adverse Reactions:** In clinical trials, the most common adverse reactions (≥20%) were neutropenia (including decreased neutrophil count), diarrhea, nausea, anemia (including decreased hemoglobin), upper respiratory tract infection, fatigue, hypophosphatemia, vomiting, and constipation. The most frequently reported serious adverse reactions (≥2%) were pneumonia, febrile neutropenia, and TLS. **Available pack:** Starter pack: Consist of Week 1 carton (14 x 10mg tablets); Week 2 carton (7 x 50mg tablets); Week 3 carton (7 x 100mg tablets); Week 4 carton (14 x 100mg tablets). Maintenance Pack: A bottle containing 120 x 100mg tablets.

Ref: PI dated 27 July 2018; DCA Approval Letter dated 14 May 2019.
 Full prescribing information is available upon request.