

## New targeted treatment option for patients with Chronic Lymphocytic Leukaemia (CLL) now available on the Pharmaceutical Benefits Scheme

- *VENCLEXTA plus rituximab is a targeted, fixed duration therapy for patients with CLL who have received at least one prior therapy.<sup>1</sup>*
- *VENCLEXTA is based on the Australian discovery that a protein called BCL-2 helps CLL cells survive. Blocking this protein helps to kill and reduce the number of these cancer cells.<sup>2</sup>*
- *Each year in Australia around 1400 people are diagnosed with CLL<sup>3</sup> making it the most common type of leukaemia diagnosed in Australia.<sup>4</sup>*

**Sunday 24 February 2019, Sydney** – AbbVie (NYSE: ABBV) Australia welcomes the Government's announcement that patients with chronic lymphocytic leukaemia (CLL) will now have access to VENCLEXTA® (venetoclax) in combination with rituximab, from March 1<sup>st</sup> 2019 on the Pharmaceutical Benefits Scheme (PBS).

VENCLEXTA in combination with rituximab is a fixed duration treatment option for adults with chronic lymphocytic leukaemia (CLL) who have received at least one prior CLL therapy.<sup>1</sup>

VENCLEXTA was developed as part of a research collaboration between AbbVie, Genentech, a member of the Roche Group of Companies, and the Walter and Eliza Hall Institute in Melbourne, Australia.

VENCLEXTA works by blocking a protein in the body ("BCL-2") that helps these cancer cells survive. Blocking this protein helps to kill and reduce the number of cancer cells, and may slow the spread of CLL.

---

<sup>1</sup> Venclexta Product Information (PI). Prepared October 2018. <http://www.medicines.org.au/files/vepvencl.pdf>

<sup>2</sup> Venclexta Consumer Information (CMI) Prepared October 2018 <http://www.medicines.org.au/files/vecvencl.pdf>

<sup>3</sup> Australian Institute of Health and Wellness: Cancer in Australia 2017 Chronic lymphocytic leukaemia (C91.1) Cancer Council NSW.

<sup>4</sup> The Leukaemia Foundation. Blood Cancer Information; CLL <https://www.leukaemia.org.au/disease-information/leukaemias/chronic-lymphocytic-leukaemia/>

Each year in Australia around 1400 people are diagnosed with CLL,<sup>3</sup> making it the most common type of leukaemia diagnosed in Australia.<sup>4</sup>

Professor John Seymour, MBBS, Director of Clinical Haematology at the Peter MacCallum Cancer Centre and Royal Melbourne Hospital in Australia, welcomed the PBS listing.

“The reimbursement of VENCLEXTA for patients with relapsed / refractory CLL marks a major milestone in the clinical development journey that included the first patients in the world receiving this agent on clinical trials in Melbourne in 2011. It is extremely gratifying that this therapy is now available to patients with CLL nationally.”

Professor Andrew Roberts, Cancer Theme Leader at Walter and Eliza Hall Institute of Medical Research, said the listing of VENCLEXTA is testimony to the effectiveness of Australian medical innovation.

“New medicines like VENCLEXTA don’t happen by accident. They are the result of careful laboratory and clinical research over many years. The idea behind VENCLEXTA arose from a basic research discovery in Melbourne 30 years ago. Collaboration has been central to the successful development of this drug, with Australian scientists and clinical researchers playing prominent roles in taking the initial discovery all the way from the lab into this new treatment for patients.”

Kirsten O’Doherty, General Manager AbbVie Australia commended the Government for listing VENCLEXTA with rituximab on the PBS.

“Today is an exciting day for everyone involved in the discovery and development of this novel cancer treatment. Not only does it mean Australian patients with CLL have more treatment options, it marks a significant step in AbbVie’s investment in translating local R&D into addressing unmet needs through innovative new treatments.

“We are particularly proud of the global collaboration between Walter and Eliza Hall Institute of Medical Research, AbbVie and Genentech that has brought us to this moment and we will continue our focus on making a remarkable impact on patient lives,” said Ms O’Doherty.

### **About VENCLEXTA®**

VENCLEXTA® is used, in combination with rituximab or alone, to treat a condition called "Chronic Lymphocytic Leukaemia (CLL)".

VENCLEXTA in combination with rituximab will be listed on the PBS from 1 March 2019 for CLL patients who have relapsed or are refractory to at least one prior therapy and who are unsuitable for treatment or retreatment with a purine analogue.

AbbVie Limited  
241 O’Riordan Street  
MASCOT NSW 2020

Date Prepared: 14 February 2019  
AU-VNCCLL-190014

The active substance in this medicine is called venetoclax. VENCLEXTA works by blocking a protein in the body ("BCL-2") that helps these cancer cells survive. Blocking this protein helps to kill and reduce the number of cancer cells, and may slow the spread of CLL. This medicine is available only with a doctor's prescription.

**All medicines have risks and benefits and may impact people in different ways. Refer to the safety information below, the Consumer Medicines Information (CMI) which can be located at <http://www.medicines.org.au/files/vecvenc1.pdf> and your doctor for further information about VENCLEXTA**

### **Important VENCLEXTA® (venetoclax) Safety Information<sup>5</sup>**

**Venclexta has risks and benefits.** You must not take it if you are allergic to venetoclax or to any of the inactive ingredients. Do not take it if you are taking certain medicines broken down in the liver, including: ketoconazole, posaconazole, voriconazole, itraconazole, clarithromycin, ritonavir, indinavir or lopinavir. Do not drink grapefruit juice, or eat grapefruit, starfruit or Seville oranges or marmalades. Do not give Venclexta to children and adolescents under 18 years of age. Do not take Venclexta if you are pregnant or plan to become pregnant, or if you are breastfeeding or plan to breastfeed. Tell your doctor if you have or have had heart, kidney or liver problems. Tell your doctor if you recently received or are scheduled for any vaccinations.

**Venclexta can cause tumour lysis syndrome**, which is caused by the fast breakdown of cancer cells. Tumour lysis syndrome is a very serious side effect that can be fatal. To help prevent this side effect it is important to start on a low dose of Venclexta and gradually increase this each week during the first five weeks of treatment, and to stay well hydrated. Tell your doctor immediately if you experience: fever or chills, nausea or vomiting, confusion, shortness of breath, irregular heartbeat, dark or cloudy urine, fits or seizures, feeling unusually tired, or muscle pain or discomfort while on treatment with Venclexta. Ensure you follow all your doctor's instructions carefully when taking Venclexta. Tell your doctor immediately if you have signs of an infection before or while taking Venclexta, including fever, chills, feeling weak or confused, cough, or pain or burning feeling when passing urine. Some of the more common side effects of Venclexta include: decreased white blood cell count, diarrhoea, nausea, anaemia, upper respiratory tract infection, fatigue, high blood phosphate, vomiting and constipation. Tell your

doctor or pharmacist if you notice anything else that is making you feel unwell. Some medicines and Venclexta may interfere with each other, so tell your doctor if you are taking medicines containing any of the following (refer also to the list of medicines above): fluconazole, ciprofloxacin, erythromycin, azithromycin, nafcillin, rifampicin, carbamazepine, phenytoin, efavirenz, etravirine, captopril, carvedilol, felodipine, bosentan, verapamil, diltiazem, modafinil, St John's wort (*Hypericum perforatum*), warfarin, amiodarone, ticagrelor, digoxin, dronedarone, everolimus and sirolimus. Tell your doctor about all of the medicines you are taking, including those bought without a prescription from a pharmacy, supermarket, or health food store. Tell any other doctors, pharmacists, dentists, or surgeons treating you that you are taking Venclexta, and remind them before you start any new medicines.

If you have any questions about using Venclexta, ask your doctor, nurse or pharmacist, or refer to the Consumer Medicine Information. The Consumer Medicine Information is available here <http://www.medicines.org.au/files/vecvenc1.pdf>

Healthcare Professionals should review the full Product Information for further details and before prescribing. The Product Information is available here <http://www.medicines.org.au/files/vepvenc1.pdf>

### **About AbbVie in Australia**

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. Our heritage in Australia reaches back more than 75 years and we employ more than 280 people with our therapies currently benefiting more than 32,000 Australians. For further information please visit <http://www.abbvie.com.au>. Follow [@abbvie\\_AU](#) or follow us on [Facebook](#) or our [LinkedIn](#) page.

#### **Media Enquiries: Palin Communications**

Karina Durham  
0402 307 056  
[karina@palin.com.au](mailto:karina@palin.com.au)

#### **AbbVie Australia**

Libby Noble  
0409 876 468  
[Libby.noble@abbvie.com](mailto:Libby.noble@abbvie.com)