

Venclexta (venetoclax) PBS listed as first line therapy for Chronic Lymphocytic Leukaemia (CLL) patients unfit for chemotherapy

- *VENCLEXTA plus obinutuzumab is a combination, fixed duration therapy for previously untreated patients with CLL who are unfit for chemotherapy¹*
- *VENCLEXTA was developed out of 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^{1,2,3}*
- *Over 1,800 people are predicted to be diagnosed with CLL in Australia this year making it the most common type of leukaemia diagnosed in Australia⁴*

Tuesday 1 December 2020, Sydney – AbbVie (NYSE: ABBV) Australia has welcomed the Government’s announcement that Venclexta® (venetoclax) in combination with obinutuzumab will be available to eligible Australians with Chronic Lymphocytic Leukaemia (CLL) as a first line therapy via the Pharmaceutical Benefits Scheme (PBS) from the 1st December 2020. This PBS listing will allow CLL patients who cannot be treated with standard chemotherapy-based treatments to have affordable access to this first line combination treatment.

Venclexta in combination with obinutuzumab is a targeted, 12-month duration treatment that is to be reimbursed for patients with previously untreated CLL, who are unfit for conventional chemotherapy.^{1,5}

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. It is an oral tablet that can be taken daily in combination with intravenous obinutuzumab.¹

The Government’s reimbursement of this combination as a first-line treatment reflects the continued effort to expand access to the range of targeted cancer treatments available to patients with blood cancer.

According to Professor Stephen Opat, Director of Clinical Haematology at Monash Health Haematology, this PBS listing widens access to affordable treatment for eligible CLL patients who cannot be treated with conventional chemo-based therapies.

“Historically chemotherapy has been the most common starting point to treat blood cancer, but unfortunately there are several patients that are unfit or can’t tolerate these agents due to side effects. Expanding the list of available treatments, especially targeted therapies, is now the focus area for healthcare. The Government’s commitment to improve access to innovative medicines means clinicians can now explore a range of options for patients,” said Professor Opat.

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.³

Professor John Seymour, MBBS, Director of Clinical Haematology at the Peter MacCallum Cancer Centre and Royal Melbourne Hospital, says the new listing for the locally discovered treatment is a positive development for cancer patients.

“This reimbursement represents another important milestone for Australia. Venclexta is the result of 30 years of research and collaboration. It is positive to see that this home grown discovery has now evolved into a medicine that more Australians can have funded access to,” said Professor Seymour.

Chris Stemple, General Manager at AbbVie Australia, commended the Government’s move to fund Venclexta in combination with obinutuzumab.

“We are proud that from today, eligible Australians with CLL will have reimbursed access to Venclexta earlier in their treatment cycle. Its listing reflects a change towards earlier use of targeted medicines in the treatment of CLL. We hope this paves the way for continued innovation of first-line therapies, not only in blood cancer but for other types of cancer,” said Mr Stemple.

About VENCLEXTA®

VENCLEXTA® is a prescription medicine used to treat adults with Chronic Lymphocytic Leukaemia (CLL) or small lymphocytic lymphoma (SLL), conditions where the blood and bone marrow or lymph nodes contain too many of a type of white blood cells. The active substance in this medicine is called venetoclax.

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 monotherapy is indicated for the treatment of:

- patients with relapsed or refractory CLL with 17p deletion, or
- patients with relapsed or refractory CLL for whom there are no other suitable treatment options.

VENCLEXTA in combination with obinutuzumab will be listed on the PBS from the 1st December 2020 for the treatment of eligible patients with CLL or small lymphocytic leukaemia (SLL) as a first line therapy who are considered unfit or unsuitable for chemo-immunotherapy^{1,5}.

All medicines have risks and benefits and may impact people in different ways. Refer to the Consumer Medicines Information (CMI) which can be located at <https://medicines.org.au/c/view/vecvenc/CMI> and your doctor for further information about VENCLEXTA.

Important VENCLEXTA® (venetoclax) Safety Information¹

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 Venclexta if you are taking any of the following medicines, including: medicines used to treat or prevent fungal infections, including ketoconazole, posaconazole, voriconazole, itraconazole; clarithromycin (an antibiotic); conivaptan (a medicine used to treat low sodium levels); medicines used to treat HIV or hepatitis C, including 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. If you are a woman of child-bearing age, you must use a highly effective form of contraception during treatment with Venclexta and for at least 30 days after your last dose. Tell your doctor, nurse or pharmacist if you have or have had heart, kidney or liver problems. Tell your doctor if you recently received or are scheduled for any vaccinations. Do not stop using Venclexta or change the dose without checking with your doctor.

Venclexta can cause tumour lysis syndrome, which is caused by the fast breakdown of cancer cells. Tumour lysis syndrome, which can be fatal, has occurred rarely in patients receiving Venclexta. To help prevent this side effect it is important to follow all your doctor's instructions carefully, especially when you start treatment with Venclexta and make sure you drink plenty of water (6 to 8 glasses or 1.5 to 2 L per day) as instructed throughout your treatment and every time your dose is increased. Tell your doctor immediately if you experience, especially at the beginning of treatment, symptoms such as: fever or chills, feeling sick or vomiting, being short of breath, changes in your heart rate, feeling unusually tired, dark or cloudy urine, joint or muscle pain, feeling confused, convulsions or fits. Ensure you follow all your doctor's instructions carefully and keep all your appointments, including those for blood tests. You may experience a low number of neutrophils, a type of white blood cells – this can be severe and need treatment. Your doctor will check your blood counts during treatment with Venclexta. You may experience infections during treatment with Venclexta. Some infections can be very serious or even fatal. Your doctor will closely monitor and treat you right away if you have fever or any signs of infection during treatment with Venclexta. Tell your doctor immediately if you have signs of an infection before or while taking Venclexta, including fever or chills; feeling weak or confused; cough, runny nose, sore throat; congestion on the chest; or pain or burning feeling when passing urine. Some of the less serious side effects of Venclexta include: diarrhoea, tummy pain, constipation, nausea (feeling sick), vomiting, reduced appetite, swelling of the arms, legs and feet, looking pale, feeling tired, having little or no energy, shortness of breath when exercising, feeling dizzy, headache, trouble sleeping. 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, quinidine, ciclosporin, quercetin, ranolazine, everolimus and sirolimus. Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop. 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, including its risk and benefits, how much to use, how and when to use it, ask your healthcare professional and refer to the Consumer Medicine Information. The Consumer Medicine Information is available from your pharmacist, by calling AbbVie Pty Ltd on 1800 043 460 or here: <https://medicines.org.au/c/view/vecvenciCMI> Healthcare Professionals should review the full Product Information for further details and before prescribing. The Product Information is available by calling AbbVie Pty Ltd on 1800 043 460 or here: <https://medicines.org.au/i/view/vepvenciPI>

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. Our heritage in Australia reaches back more than 75 years and we employ more than 320 people with our therapies currently benefiting more than 40,000 Australians. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments. Recently, we acquired Allergan which immediately diversified our business across several therapeutic areas: Immunology, Hematologic Oncology, Neuroscience and Allergan Aesthetics.

Our commitment to making a remarkable impact doesn't end at developing medicines; it begins there. We provide broader support to our patients and help address the health needs of underserved communities. We strive to protect our environment and to make a positive impact in the areas where we live and work.

For further information please visit www.abbvie.com.au. Follow [@abbvie_AU](https://twitter.com/abbvie_AU) on Twitter, [Facebook](https://www.facebook.com/abbvie) or our [LinkedIn](https://www.linkedin.com/company/abbvie) page.

For all media enquiries:

Palin Communications Karina Durham 0402 307 056 karina@palin.com.au	AbbVie Australia Jarrod Miles 0434 602 382 jarrod.miles@abbvie.com
--	---

¹ Venclexta Product Information (PI).

² Venclexta Consumer Information (CMI)

³ AbbVie data on File CLA-AU-190019

⁴ Australian Institute of Health and Welfare 2019. Cancer in Australia 2019. Cancer series no.119. Cat. no. CAN 123. Canberra: AIHW.

⁵ PBS Schedule <https://www.pbs.gov.au/pbs/search?term=venclexta>