

PRESS RELEASE

AbbVie Welcomes the Therapeutic Goods Administration (TGA) Regulatory Approval of VENCLEXTA® (venetoclax tablets) in Combination with Rituximab

SYDNEY, AUSTRALIA, 17 October , 2018 – AbbVie (NYSE: ABBV) announced today that the Therapeutic Goods Administration (TGA) has granted regulatory approval for VENCLEXTA® in combination with rituximab, as a fixed duration treatment option for adults with chronic lymphocytic leukaemia (CLL) who have received at least one prior CLL therapy.¹

Early in 2017, VENCLEXTA® was approved by the TGA as a monotherapy for the treatment of adult patients with relapsed or refractory (R/R) CLL in the presence of 17p deletion or those with R/R CLL for whom there are no other suitable options.¹

This extension of indication is based on results from the Phase 3 MURANO clinical trial, which evaluated the efficacy and safety of VENCLEXTA® in combination with rituximab compared with bendamustine in combination with rituximab in patients with R/R CLL who had received at least one line of prior therapy.¹

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.

CLL is a slow-growing form of leukaemia, or blood cancer, in which too many immature lymphocytes (a type of white blood cell) are found, predominantly in the blood and bone marrow.²

Each year in Australia around 1400 people are diagnosed with CLL.³ Most people have no symptoms of their disease when first diagnosed. In these cases, people often require no treatment for a long time, apart from regular check-ups with their doctor to carefully monitor their health. Others may need to be treated soon after they are diagnosed.

¹ Venclexta Approved Product Information. Date of Revision 8 October 2018

<http://www.medicines.org.au/files/vepvenc1.pdf>

² NCI dictionary. NCI Dictionary of Terms. Chronic Lymphocytic

Leukemia. <https://www.cancer.gov/publications/dictionaries/cancer-terms>. Accessed September 2018

³ Australian Institute of Health and Wellness: Cancer in Australia 2017 Chronic lymphocytic leukaemia (C91.1) Cancer Council NSW. Chronic lymphocytic leukaemia (CLL). <https://www.cancercouncil.com.au/chronic-lymphocytic-leukaemia/>. Accessed 11 Oct 2018.

While CLL is a relatively uncommon type of cancer, it is the most common type of leukaemia diagnosed in Australia.⁴

Currently, VENCLEXTA[®] (venetoclax), alone or in combination with rituximab, is not listed on the Pharmaceutical Benefits Scheme (PBS) for patients with CLL.

“Having another effective therapy for CLL is very important for patients who need an alternative treatment,” said Kirsten O’Doherty, General Manager AbbVie Australia. “This is an important step forward for patients and we are working to ensure access to this new treatment regimen on the Pharmaceutical Benefits Scheme at the earliest opportunity.”

About VENCLEXTA[®]⁵

VENCLEXTA[®] is used, in combination with rituximab or alone, to treat a condition called "Chronic Lymphocytic Leukaemia (CLL)". 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) and your doctor for further information about VENCLEXTA[®]

Important VENCLEXTA[®] (venetoclax) Safety Information⁵

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.

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

⁵ Venclexta Consumer Medicine Information (CMI). Prepared October 2018.

<http://www.medicines.org.au/product.cfm?ret=search&type=cmi&handle=vecvenc>

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 (insert link to CMI)

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/vepvencl.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.

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