



## STATEMENT

**SYDNEY, NSW**, Friday 20 April 2018 – AbbVie (NYSE: ABBV) Australia:

AbbVie announces we have been unable at this stage to reach an agreement with the Department of Health to list Venclexta™ (venetoclax) on the Pharmaceutical Benefits Scheme (PBS).

In July 2017, the PBAC recommended Venclexta™ monotherapy for listing on the PBS for the treatment of relapsed or refractory (R/R) chronic lymphocytic leukaemia (CLL) in patients who have failed a kinase inhibitor.

We acknowledge that this is a disappointing outcome as patients with R/R CLL will not have reimbursed access to Venclexta™ on the PBS at this stage.

Following the recent publication of a randomised controlled trial for Venclexta™ in R/R CLL<sup>1</sup>, AbbVie will submit this data later this year to the PBAC for consideration to enable PBS reimbursement for eligible R/R CLL patients on Venclexta™.

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<sup>1</sup> March 22, 2018, N Engl J Med 2018; 378:1107-1120

## 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 [LinkedIn](#) page.

## IMPORTANT INFORMATION ABOUT VENCLEXTA®

Venclexta is a prescription medicine containing venetoclax, which blocks a protein that helps cancer cells survive. It is used to treat chronic lymphocytic leukaemia. You will begin treatment with Venclexta at a low dose for 1 week. Your doctor will gradually increase your dose over the next four weeks to the full standard dose. Use strictly as directed.

**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 or ritonavir. 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 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. Let your healthcare provider know 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. Tell your doctor immediately if you have signs of an infection 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. Some medicines and Venclexta may interfere with each other, so tell your doctor if you are taking medicines containing any of the following: fluconazole, ciprofloxacin, erythromycin, nafcillin, rifampicin, carbamazepine, phenytoin, efavirenz, etravirine, bosentan, verapamil, modafinil, St John's wort (*Hypericum perforatum*), warfarin, digoxin.

**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 from your

pharmacist, from AbbVie Pty Ltd by calling 1800 043 460, or from the TGA website [www.tga.gov.au](http://www.tga.gov.au).  
Ask your doctor if Venclexta is right for you. Venclexta is not available on the PBS.