



PRESS RELEASE

New treatment for an aggressive blood cancer available on the PBS

- VENCLEXTA® (venetoclax), a first-in-class BCL-2 inhibitor is reimbursed for eligible Australian patients with Acute Myeloid Leukaemia (AML) in combination with azacitidine.^{1,2}
- Out of the 1,000 Australians who are diagnosed every year with AML,³ only around 290 will be alive in five years.⁴
- Australian scientists led the worldwide discovery of the action of a protein called BCL-2, that is blocked by venetoclax, setting in motion 30 years of research and development to provide a new treatment option for people with AML.⁵

SYDNEY AUSTRALIA, 28th November 2021 - AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, has announced that from 1 December, 2021, VENCLEXTA® (venetoclax), will be available on the Pharmaceutical Benefits Scheme (PBS) for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) in combination with azacitidine for those patients who are ineligible for intensive chemotherapy.^{1,2}

AML is an aggressive blood cancer⁶ affecting the blood and bone marrow.⁷ Abnormal leukaemia cells overwhelm other blood cells preventing them from carrying out their normal functions like fighting infection, providing oxygen and preventing bleeding.⁸ Without treatment, people may get very sick from severe infections or other serious complications.⁸

People of any age can be diagnosed with AML, but it is more common in elderly adults,⁷ with around 1,000 Australians diagnosed each year.³ Older patients have a very poor prognosis⁶ and are often ineligible for intensive chemotherapy due to age and other medical conditions.⁹ Despite advances in available therapies and care, the five-year survival rate for patients diagnosed with AML remains approximately 29 percent.⁴

Professor Andrew Wei, Clinical Haematologist at The Alfred Hospital and Monash University, Melbourne said: “The shock of an AML diagnosis and the need to make decisions quickly about treatment is incredibly difficult for patients and their families. It can be even more emotionally challenging for those who have limited treatment options, when intensive chemotherapy is not appropriate. Today’s PBS listing brings a new option for Australians with acute myeloid leukaemia who face this reality.

“It is rewarding to see the results of Australian research come to fruition for the care of those living with this difficult to-treat condition,” Prof Wei said.

Richard Vines, CEO, Rare Cancers Australia, said: “Acute myeloid leukaemia can be a devastating disease with very few treatment options. At Rare Cancers Australia we are delighted with the decision by the Federal Government to reimburse VENCLEXTA® for Australians living with AML. This will provide access to patients that have otherwise faced their cancer with very few, if any, treatment options.”

Chris Stemple, General Manager, AbbVie Australia, commended the Federal Government's new regulatory pathway that has enabled Australian patients accelerated access to medicines that provide a major therapeutic advance.

"We are pleased that Australians with AML who are ineligible for intensive chemotherapy will benefit from the registration and reimbursement pathway changes, ultimately receiving faster access to VENCLEXTA®.

"I am proud that AbbVie has been able to expand our contribution to the Australian haematology community and we remain committed to providing further treatment advances to address unmet needs in blood and other types of cancer."

The compound venetoclax was co-developed by AbbVie, Genentech and the Walter and Eliza Hall Institute (WEHI) Melbourne following a landmark research discovery made at WEHI in the late 1980s, that a protein called BCL-2 helps cancer cells survive indefinitely.⁵ More than 30 years of research and collaboration transformed this discovery into a medicine.

About VENCLEXTA® (venetoclax)

VENCLEXTA® (venetoclax) is a first-in-class BCL-2 inhibitor that selectively binds and inhibits the B-cell lymphoma-2 (BCL-2) protein. In some blood cancers, BCL-2 prevents cancer cells from undergoing their natural death or self-destruction process, called apoptosis. VENCLEXTA targets the BCL-2 protein and works to help restore the process of apoptosis.

VENCLEXTA is being developed by AbbVie and Roche. It is jointly commercialized by AbbVie and Genentech, a member of the Roche Group, in the U.S. and by AbbVie outside of the U.S. Together, the companies are committed to BCL-2 research and to studying venetoclax in clinical trials across several blood and other cancers.

Important VENCLEXTA® (venetoclax) Safety Information

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. Venclexta may cause low sperm count in men. 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. Two days before you start taking



Venclexta, drink at least 6 to 8 glasses of water each day and continue to do this throughout your treatment, especially each 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, weight loss, a sore inside mouth, low blood pressure, bleeding, 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 at [this link](#).

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 at [this link](#).

About AbbVie in Oncology

At AbbVie, we are committed to transforming standards of care for multiple blood cancers while advancing a dynamic pipeline of investigational therapies across a range of cancer types. Our dedicated and experienced team joins forces with innovative partners to accelerate the delivery of potentially breakthrough medicines. We are evaluating more than 20 investigational medicines in over 300 clinical trials across some of the world's most widespread and debilitating cancers. As we work to have a remarkable impact on people's lives, we are committed to exploring solutions to help patients obtain access to our cancer medicines. For more information, please visit <http://www.abbvie.com/oncology>.

About AbbVie

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 80 years and we employ more than 400 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. In 2020 we acquired Allergan which immediately diversified our business across several therapeutic areas: Immunology, Oncology, Virology, Neuroscience and 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](#), [Instagram](#) or our [LinkedIn](#) page.

###

Professor Wei has participated in advisory boards and undertaken consultancy for AbbVie Australia for which compensation has been received. In relation to this media announcement, no compensation was provided to Professor Wei, and the opinions expressed are their own. Professor Wei has been briefed by AbbVie Australia on the approved use of this product. Professor Wei is also a former employee of the Walter and Eliza Hall Institute (WEHI) and is eligible for financial benefits associated with payments which WEHI receives in relation to venetoclax.

Media enquiries:

- Julia Herbert, Red Havas – julia.herbert@redhavas.com | 0412 473 333
- Simone McKay, Red Havas – simone.mckay@redhavas.com | 0430 551 906
- Sarah Aldridge, AbbVie Australia – sarah.aldridge@abbvie.com | 0481 467 985

References:

1. VENCLEXTA Product Information. [Available online](#). Accessed Nov 2021
2. Pharmaceutical Benefits Scheme. [Available online](#). Accessed Nov 2021
3. Cancer Council. 2020. Acute myeloid leukaemia (AML). [Available online](#). Accessed Nov 2021
4. National Cancer Institute. 2018. Acute Myeloid Leukemia - SEER Stat Fact Sheets. [Available online](#). Accessed Nov 2021
5. WEHI. 2021. Venetoclax. [Available online](#). Accessed Nov 2021
6. Zjablovskaja P and Florian M.C. 2019. Acute Myeloid Leukemia: Aging and Epigenetics. *Cancers (Basel)*; 12(1):103.
7. Leukemia Foundation. 2020. Acute Myeloid Leukaemia (AML). [Available online](#). Accessed Nov 2021
8. Leukemia Foundation. 2019. State of the Nation: Blood Cancer in Australia. [Available online](#). Accessed Nov 2021
9. Wei, AH et al. 2020. Venetoclax plus LDAC for newly diagnosed AML ineligible for intensive chemotherapy: a phase 3 randomized placebo-controlled trial. *Blood*. 135(24):2137-2145.