PRESS RELEASE

VENCLEXTA® (venetoclax) has now received full registration for adult patients with newly diagnosed Acute Myeloid Leukaemia who are ineligible for intensive chemotherapy[1]

- *VENCLEXTA (venetoclax) in combination with azacitidine or low-dose cytarabine is now fully registered in the ARTG for the treatment of adult patients with newly diagnosed acute myeloid leukemia who are ineligible for intensive chemotherapy.[1]*
- *Acute Myeloid Leukaemia (AML) is an aggressive[2] and difficult-to-treat blood cancer[3] with around 1000 Australians diagnosed with the condition each year[4]*
- *Despite advances in available therapies and care, the five-year survival rate for patients diagnosed remains below 30 per cent[5]*

SYDNEY AUSTRALIA, 28 September 2021 – AbbVie (NYSE: ABBV) has today announced that the provisional registered indication for VENCLEXTA® (venetoclax) in combination with azacitidine or low-dose cytarabine has received full registration in the Australian Register of Therapeutic Goods (ARTG) *(ARTG number 267441, 267442, 267443, 267444, 267445*) for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are ineligible for intensive chemotherapy. [1]

VENCLEXTA received provisional approval in Australia for this indication in February 2020 and has become the first medicine to have the provisional registration converted to full registration on the ARTG.

AML is an aggressive haematological disorder[2] affecting the blood and bone marrow.[4] It results in accumulation of poorly differentiated myeloid stem cells preventing blood cells from carrying out their normal function.[3] It can occur at any age but is more common in adults over 60,[4] with around 1000 Australians diagnosed each year. [4]

The disease progresses rapidly without treatment[3] and due to age and comorbidities,[6] many patients are often ineligible for chemotherapy.[7] Older patients have a very poor prognosis[7], and effective treatments are limited.[7] Despite advances in available therapies and care, the five-year survival rate for patients diagnosed with AML remains approximately 29 percent.[5]

Chris Stemple, Vice President and General Manager at AbbVie Australia, welcomed the VENCLEXTA registration and said that new treatment options for patients are vital.

“This registration for VENCLEXTA in acute myeloid leukemia is a welcome development due to the current prognosis of AML for patients who are ineligible for intensive chemotherapy, and the limitations around effective treatments already available for this patient population.

“Following a recent positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC)[9], we will continue to work with the Department of Health on the post PBAC processes to ensure eligible Australian patients with AML receive timely, funded access to this treatment option,” he said.

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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, quercertin, 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 on Twitter, Facebook, Instagram or our LinkedIn page.

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Issued on behalf of AbbVie Australia by Red Havas. For further information please contact:

Red Havas
Emma Shipley
emma.shipley@redhavas.com / 0434 623 510

Simone McKay
simone.mckay@redhavas.com / 0430 551 906

AbbVie
Edwina Elliott, Communications Manager
edwina.elliott@abbvie.com / 0439 578 865

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