

NZ patients contribute to a future treatment for leukaemia in global studies

IMBRUVICA® (ibrutinib) in combination with venetoclax as first-line treatment for chronic lymphocytic leukaemia (CLL) patients.

Auckland, X December 2023 – Two major leukaemia studies presented at a recent global blood cancer conference, the American Society of Haematology (ASH) which was attended by New Zealand haematologists and investigators, has shed light on the long-term follow-up of an all-oral, fixed-duration, chemo-free, first-line treatment regimen for patients with chronic lymphocytic leukaemia (CLL).^{1,2}

Approximately 320 people are diagnosed in New Zealand each year with chronic lymphocytic leukaemia (CLL), the most common form of leukaemia in New Zealand. CLL is a type of slow-growing leukaemia that affects developing B-lymphocytes (a type of white blood cell).³ The current treatment for the majority of first-line patients is chemoimmunotherapy, which is given by intravenous infusion at the hospital.^{4,5,6} There have been no new treatments funded in New Zealand for the vast majority of first-line CLL patients for over six years despite several global advancements.^{6,7}

The GLOW Phase 3 study in the older/frailer population and the CAPTIVATE Phase 2 study in the fit and young population, both evaluated the effectiveness and safety of IMBRUVICA in combination with venetoclax as a first-line therapy.^{8,9} Across Australian and New Zealand, 98 patients were included in the CAPTIVATE study, including 20 patients from New Zealand.¹⁰ The study was conducted by a team of medical researchers, including three New Zealand hospitals and leading New Zealand investigator Dr Sharon Jackson.^{10,11}

Dr Sharon Jackson says that “the CAPTIVATE and GLOW studies showed that after 15 months of fixed-duration treatment, 97% and 84.5% of CLL patients respectively were still alive after up to five years of follow-up.”^{1,2}

“In addition, 8 out of 10 of younger CAPTIVATE patients remained treatment free for their cancer at 54 months follow-up. In the GLOW trial of older frailer patients almost 9 patients out of 10 (88%) remained treatment free for their cancer.”^{1,2}

“IMBRUVICA in combination with venetoclax is an all oral chemo-free medicine regimen that can be delivered at home in the majority of patients, reducing the need for patients to attend frequent and time-consuming hospital visits for treatment. This could be an important step forward in the New Zealand setting given the pressures on day ward infusion services.”¹²

Dr Jackson says the IMBRUVICA in combination with venetoclax combination therapy demonstrates efficacy and offers a manageable safety profile in chronic lymphocytic leukaemia.^{1,2,8,9}

IMBRUVICA in combination with venetoclax for the treatment of naïve chronic lymphocytic leukaemia is registered in New Zealand and is currently being considered for funding by Pharmac.^{13,14}

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we’re creating a future where disease is a thing of the past. We’re the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com/australia. Follow on Twitter @JanssenANZ. Janssen-Cilag Pty Ltd is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Consumer Medicine Information is available at:

https://www.janssen.com/newzealand/sites/www_janssen_com_newzealand/files/prod_files/live/imbruvica_cmi.pdf) or by contacting Janssen Medical Information on 0800 800 806. Janssen-Cilag (New Zealand) Ltd, PO Box 62185, Sylvia Park, Auckland 1644, New Zealand.

ENDS

No compensation was provided to Dr Jackson for her involvement in this media activity, and the opinions expressed are her own. Dr Jackson has served on advisory boards for which compensation was received and been involved in clinical trials sponsored by Pharmacyclics/Janssen for which compensation by the hospital was received.

For more information about the study results and future developments in CLL treatment, please contact:

Julien Leys, Pendulum Strategies, Mobile +64 21 655 598

Dr Sharon Jackson, Haematologist, Clinical Head, Head of Department, Middlemore Hospital – Sharon.jackson@middlemore.co.nz; Mobile: 021 784 182

Dr Ruth Spearing, Haematologist and CLL Advocates New Zealand Trustee – ruth.spearing@gmail.com; Mobile: 027 512 6356

Consumer Mandatories

IMBRUVICA® (ibrutinib) Capsules and Tablets Information for consumers.

IMBRUVICA is a Prescription Medicine. Your doctor will advise you if IMBRUVICA may be suitable for you. IMBRUVICA has risks and benefits. Always read the label and use strictly as directed. If symptoms continue, or if you experience side effects, contact your doctor, pharmacist or health professional. IMBRUVICA is used to treat patients with Mantle cell lymphoma (MCL) who have received at least one prior therapy, Chronic lymphocytic leukaemia (CLL) and Waldenström's macroglobulinemia (WM). The usual daily dose of IMBRUVICA for CLL and WM is 420 mg as a single dose. The usual daily dose of IMBRUVICA for MCL is 560 mg taken as a single dose. IMBRUVICA capsules and tablets should be swallowed whole with water. Do not take IMBRUVICA with grapefruit juice or Seville oranges. Your doctor may choose to also combine IMBRUVICA with other medicines. Each IMBRUVICA capsule contains 140 mg of ibrutinib and is supplied in bottles containing either 90 or 120 capsules. Each IMBRUVICA tablet may contain 140 mg, 280 mg, 420 mg or 560 mg of ibrutinib. IMBRUVICA 140 mg tablets are supplied in cartons containing 30 or 120 tablets. IMBRUVICA 280 mg, 420 mg and 560 mg tablets are supplied in cartons containing 30 tablets. IMBRUVICA should be stored below 30°C. Do not take IMBRUVICA if you are pregnant or maybe potentially pregnant. Do not breast feed.

Before taking IMBRUVICA you must tell your doctor:

- If you have problems with your liver or kidneys
- If you have ever had unusual bruising or bleeding or are on any medicines or supplements that increase your risk of bleeding
- If you have a history of high blood pressure, irregular heartbeat (atrial fibrillation, ventricular tachyarrhythmia), failure or diabetes.
- If you have recently had or are planning to have any surgery.

- If you have or have had Hepatitis B infection
- If you have any other medical condition

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. Please read the Consumer Medicine Information for the full list of side effects. Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well while you are being given IMBRUVICA. Common side effects of IMBRUVICA may include: diarrhoea; indigestion; feeling very tired; nausea; headache; swollen hands, ankles or feet; being short of breath; dizziness; fainting; inflamed and sore mouth; infected nose, sinuses or throat (cold); high blood pressure; irregular heart beat; urinary tract infections; infection; cough; trouble sleeping; anxiety; discharge with itching of the eyes and crusty eyelids; blurred vision; constipation; fever; vomiting; decreased appetite; bruises; nose bleed; red or purple, flat, pinhead spots under the skin; skin rash; muscle spasm; muscle and joint pain; sore stomach; low blood sodium or potassium; changes in your platelet, white or red blood cell levels or high uric acid levels. If you have diarrhoea that lasts for more than a week, your doctor may need to give you a fluid and salt replacement.

The Consumer Medicine Information can be found on the Janssen website (available from https://www.janssen.com/newzealand/sites/www_janssen_com_newzealand/files/prod_files/live/imbruvica_cmi.pdf) or by contacting Janssen Medical Information on 0800 800 806. Janssen-Cilag (New Zealand) Ltd, PO Box 62185, Sylvia Park, Auckland 1644, New Zealand.

IMBRUVICA is a fully funded medicine for monotherapy in chronic lymphocytic leukaemia, including small lymphocytic lymphoma - restrictions apply. IMBRUVICA is not funded for patients with mantle cell lymphoma or Waldenstrom's macroglobulinaemia. IMBRUVICA in combination with venetoclax is not funded in chronic lymphocytic leukaemia. You will need to pay the full cost of this medicine. A pharmacy charge and normal doctor's fees will apply. Date of Preparation: 12 April 2022

References:

1. Moreno C et al. First-Line Fixed-Duration Ibrutinib Plus Venetoclax (Ibr+Ven) Versus Chlorambucil Plus Obinutuzumab (Clb+O): 55-Month Follow-up from the Glow Study. American Society of Haematology Congress, San Diego, December 10 2023; Oral Presentation, Abstract 634.
2. Ghia P et al. Relapse after First-Line Fixed Duration Ibrutinib + Venetoclax: High Response Rates to Ibrutinib Retreatment and Absence of BTK Mutations in Patients with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) with up to 5 Years of Follow-up in the Phase2 Captivate Study. American Society of Haematology Congress, San Diego, December 10 2023; Oral Presentation, Abstract 633.
3. Leukaemia & Blood Cancer New Zealand. What is Chronic Lymphocytic Leukaemia? Available at: <https://www.leukaemia.org.nz/information/about-blood-cancers/leukaemia/chronic-lymphocytic-leukaemia/#:~:text=Every%20year%20in%20New%20Zealand,type%20of%20white%20blood%20cell>). [Accessed Dec 2023].
4. Obinutuzumab plus chlorambucil in CLL Pharmac Application Tracker. Available at <https://connect.pharmac.govt.nz/apptracker/s/application-public/a102P000008ptyu/p000389> [Accessed Dec 2023].
5. Bendamustine in CLL Pharmac Application Tracker. Available at: <https://connect.pharmac.govt.nz/apptracker/s/application-public/a102P000008puB9/p000695> [Accessed Dec 2023].
6. Fludarabine: Pharmac Hospital Medicines Schedule. Available at: <https://schedule.pharmac.govt.nz/HMLOnline.php?edition=&osq=Fludarabine+phosphate> [Accessed Dec 2023].

7. Anderson MA et al. Chronic lymphocytic leukaemia Australasian consensus practice statement. Intern Med J. 2023 Sep;53(9):1678-1691.doi: 10.1111/imj.16207.
8. Kater A et al. Fixed-Duration Ibrutinib-Venetoclax in Patients with Chronic Lymphocytic Leukemia and Comorbidities. N Engl J Med 2019 Aug 22;381(8):788-789. doi: 10.1056/NEJMc1908754.
9. Tam C et al. Fixed-duration ibrutinib plus venetoclax for first-line treatment of CLL: primary analysis of the CAPTIVATE FD cohortBlood. 2022 Jun 2;139(22):3278-3289.doi: 10.1182/blood.2021014488.
10. CAPTIVATE Clinical Study Report 2022; Janssen Data on File.
11. Ibrutinib Plus Venetoclax in Subjects With Treatment-naive Chronic Lymphocytic Leukemia /Small Lymphocytic Lymphoma (CLL/SLL) (Captivate) (NCT02910583). Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT02910583> [Accessed Dec 2023].
12. Te Aho o Te Kahu, A vision for cancer treatment in the reformed health system, July 2022 Available at: https://hcmsitesstorage.blob.core.windows.net/cca/assets/Final_Draft_Cancer_Services_Planning_full_updated_a2a614da35.pdf [Accessed Dec 2023].
13. IMBRUVICA New Zealand Data Sheet. Available at: <https://www.medsafe.govt.nz/profs/datasheet/I/Imbruvicacap.pdf> [Accessed Dec 2023]
14. Fixed duration ibrutinib plus venetoclax (IMBRUVICA) Pharmac Application Tracker. Available at <https://connect.pharmac.govt.nz/apptracker/s/application-public/a10OZ0000000aOT/p001943> [accessed Dec 2023]

Further information is available on request from Janssen-Cilag Pty Ltd, PO Box 62185, Sylvia Park, Auckland 1644, New Zealand. CP-427927. TAPS BG3570. Date of Preparation December 2023.