MYLOTARG™ PBS listed in Australia for patients with previously untreated, de novo, CD33-positive acute myeloid leukemia in combination with intensive chemotherapy

- *MYLOTARG is a medicine for the treatment of patients 15 years and over with previously untreated, de novo, CD33-positive acute myeloid leukemia in combination with intensive chemotherapy* [i]
- *MYLOTARG is the first treatment of its class to be approved for CD33-positive acute myeloid leukemia* [ii]
- *More than 900 Australians are expected to be newly diagnosed with acute myeloid leukemia in Australia every year* [iii]
- *Approximately 280 patients a year will be eligible for MYLOTARG in Australia.*

SYDNEY, AUSTRALIA, 1 March 2022 – Pfizer Australia has welcomed the Federal Government's announcement that MYLOTARG™ (gemtuzumab ozogamicin) will be available from 1 March 2022 to eligible Australians living with acute myeloid leukemia (AML). This PBS listing will offer patients with the condition a new and affordable treatment option.

MYLOTARG was approved by Australia's Therapeutic Goods Administration on 9 April 2020 for combination therapy with standard anthracycline and cytarabine (AraC) for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukaemia (AML), except acute promyelocytic leukaemia[iv].

MYLOTARG is an antibody drug conjugate targeting the CD-33 receptors on leukemia cells[v] and is the first of its kind for AML patients.

"Today's PBS listing of MYLOTARG provides a much-needed treatment option for patients living with acute myeloid leukemia in Australia," said Anne Harris, Pfizer Australia and New Zealand Managing Director. "In clinical trials, the addition of MYLOTARG to standard chemotherapy resulted in patients being able to live longer without their disease relapsing", Ms Harris said.

AML is a rapidly progressing, life-threatening blood and bone marrow cancer[vi]. If left untreated, patients with AML will die within months, if not weeks, of their disease. AML is the most common type of acute leukemia in adults and accounts for approximately 80% of all cases of acute leukemia[vii] About 900 people are expected to be newly diagnosed with AML in Australia annually.[viii] The goal of AML treatment is for the patient to achieve a complete, prolonged remission. Longer periods of remission prior to relapse are associated with better long-term outcomes for patients. Thus, medicines that delay the time until the disease comes back and extend life can provide meaningful clinical benefit.

Pfizer also opened a Mylotarg Experience Program for up to 50 Australian patients, which provided patients free access to MYLOTARG prior to reimbursement, and allowed clinicians the opportunity to gain clinical experience prior to its PBS listing. Putting patients at the centre of how new treatments are taken to market, Pfizer's experience program enabled patient outcomes to be improved through prolonged significant event-free survival by reducing risk of induction failure and relapse.[i]

The reimbursement of MYLOTARG reflects Pfizer Australia's ongoing effort to bring innovative treatments to market for leukemia patients.

"MYLOTARG opens up a new treatment option for a devastating disease and affords the possibility of higher rates of response and longer remission times for patients," said Dr Chun Fong, haematologist and Medical Lead for Acute Leukemias and Myelodysplasia at Austin Health, Melbourne, Australia. "It has been a long journey to get to reimbursement, but MYLOTAG is a proven and effective addition to existing chemotherapy options. Particularly interesting is the intersection of technology which allows us to use immunotherapy to selectively deliver a chemotherapy payload to leukaemia cells.

"All of the parties involved in the studies, from clinical investigators and nurses to patients, have been pivotal in achieving this milestone. Their hard work has enabled our understanding of who is best

suited for this treatment and how to deliver the treatment safely. It is a breakthrough for patient access to innovative and effective drugs," Dr Fong said.

Pfizer is advancing a broad range of therapies that leverage multiple pathways and mechanisms of action (MOAs) to address acute and chronic leukemias, myeloproliferative disorders and lymphomas. Pfizer currently has two marketed therapies in Australia for haematologic cancers, as well as several therapies in clinical development. Pfizer is also forging collaborations with a diversity of industry, academic and community partners to study multiple paths to advancing treatment. By working together, Pfizer and its partners aim to overcome the challenges of haematologic cancers and deliver meaningful benefits to patients.

Indication for MYLOTARG (gemtuzumab ozogamicin) in Australia
MYLOTARG is indicated for combination therapy with standard anthracycline and cytarabine (AraC) for the treatment of patients age 15 years and above with previously untreated, de novo CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia (APL). It is the first treatment of its class to be approved for CD33-positive acute myeloid leukemia.

Pharmaceutical Benefits Scheme (PBS) restriction for Mylotarg (gemtuzumab ozogamicin)
From 1 March 2022, Mylotarg will be PBS-listed for the treatment of patients with previously untreated, de novo CD33-positve acute myeloid leukaemia (AML) except acute promyelocytic leukaemia, who have favourable/intermediate/unknown cytogenetic risk (where the unknown risk is due to inconclusive test results), in combination with standard intensive chemotherapy.

IMPORTANT MYLOTARG™ (gemtuzumab ozogamicin) SAFETY INFORMATION in Australia

The overall safety profile of MYLOTARG is based on data from patients with acute myeloid leukaemia from the combination therapy study ALFA-0701, monotherapy studies, and from post-marketing experience.

Hepatotoxicity, including life-threatening, and sometimes fatal hepatic failure and VOD/SOS have been reported in patients treated with MYLOTARG. Other special warnings and precautions include myelosuppression and infusion-related reactions.

In the combination therapy study ALFA-0701, clinically relevant serious adverse reactions were hepatotoxicity, including VOD/SOS (3.8%), haemorrhage (9.9%), severe infection (41.2%), and tumour lysis syndrome (1.5%). In monotherapy studies, clinically relevant serious adverse reactions also included infusion related reactions (2.5%), thrombocytopenia (21.7%), and neutropenia (34.3%).

The most common adverse reactions (> 30%) in the combination therapy study were haemorrhage and infection. In monotherapy studies the most common adverse reactions (> 30%) included pyrexia, nausea, infection, chills, haemorrhage, vomiting, thrombocytopenia, fatigue, headache, stomatitis, diarrhoea, abdominal pain, and neutropenia.

The most frequent (≥ 1%) adverse reactions that led to permanent discontinuation in the combination therapy study were thrombocytopenia, VOD, haemorrhage and infection. The most frequent (≥ 1%) adverse reactions that led to permanent discontinuation in monotherapy studies were infection, haemorrhage, multi-organ failure, and VOD.

Mylotarg Product Information

https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2020-PI-01422-1&d=20220224172310101

About MYLOTARG™ (gemtuzumab ozogamicin)
MYLOTARG is an antibody-drug conjugate (ADC) composed of the cytotoxic agent calicheamicin, attached to a monoclonal antibody (mAB) targeting CD33, an antigen expressed on the surface of myeloblasts in up to 90 percent of AML patients. When MYLOTARG binds to the CD33 antigen on the cell surface it is absorbed into the cell and calicheamicin is released causing cell death.

About Pfizer Oncology
Pfizer Oncology is committed to pursuing innovative treatments that have a meaningful impact on people living with cancer. Our growing pipeline of biologics, small molecules, and immunotherapies is focused on identifying and translating the best scientific breakthroughs into clinical application for patients across a diverse array of solid tumors and hematologic cancers. Today, we have 13 approved oncology medicines and more than 20 assets currently in clinical development. By maximizing our internal scientific resources and collaborating with other companies, government and academic institutions, as well as non-profit and professional organizations, we are bringing together the brightest and most enterprising minds to take on the toughest cancers. Together we can accelerate breakthrough treatments to patients around the world and work to redefine life with cancer.

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer. For more information, visit: www.pfizer.com.au

DISCLOSURE NOTICE: The information contained in this release is as of 1 March 2022. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.
This release contains forward-looking information about MYLOTARG (gemtuzumab ozogamicin), an antibody-drug conjugate, and Pfizer's oncology portfolio, including their potential benefits, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of MYLOTARG; the uncertainties inherent in research and development, including the ability to meet anticipated clinical trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when applications for MYLOTARG may be filed in any other jurisdictions and whether and when applications for any other oncology products may be filed in any jurisdictions; whether and when any such applications for MYLOTARG or any such other oncology products that may be pending or filed may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted, and, if approved, whether such products will be commercially successful; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of MYLOTARG or any such other oncology products; and competitive developments.
A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

References

[i] Mylotarg (gemtuzumab ozogamicin) Product Information v. 10122.

[ii] Mylotarg (gemtuzumab ozogamicin) Product Information v. 10122.

[iii] Leukemia Foundation (Australia), Acute Myeloid Leukemia. Patient number is validated using AIHW age-specific incidence rates for AML applied to ABS population data. Accessed February 2022. https://www.leukaemia.org.au/blood-cancer-information/types-of-blood-cancer/leukaemia/acute-myeloid-leukemia

[iv] Mylotarg (gemtuzumab ozogamicin) Product Information v. 10122.

[v] Mylotarg (gemtuzumab ozogamicin) Product Information v. 10122.

[vi] Orpha.net. The portal for rare diseases and orphan drugs. Accessed December 2017: http://www.orpha.net/consor4.01/www/cgi-bin/OC_Exp.php?lng=EN&Expert=519

[vii] Leukemia & Lymphoma Society, Acute Myeloid Leukemia Booklet. Developed 2011. Accessed July 2017. https://www.lls.org/sites/default/files/file_assets/aml.pdf

[viii] Leukemia Foundation (Australia), Acute Myeloid Leukemia. Patient number is validated using AIHW age-specific incidence rates for AML applied to ABS population data. Accessed February 2022: https://www.leukaemia.org.au/blood-cancer-information/types-of-blood-cancer/leukaemia/acute-myeloid-leukemia

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