

DR. REDDY'S LABORATORIES LTD.

8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034. Telangana, India.

CONTACT

INVESTOR RELATIONS	MEDIA RELATIONS
AISHWARYA SITHARAM AISHWARYASITHARAM@DRREDDYS.COM	PRIYA K PRIYAK@DRREDDYS.COM

PBS listing for Zytovi®* (toripalimab), the first and only immunotherapy for a rare type of head and neck cancer

- From 1st December, Zytovi® will be available through the Pharmaceutical Benefits Scheme (PBS) as the first and only immunotherapy for eligible Australians* with nasopharyngeal cancer (NPC) that has returned or spread.¹⁻³
- NPC is a rare and aggressive head and neck cancer,⁴ three times more common in men than women,⁵ affecting approximately 200 people in Australia per year.⁶
- Until now, Australians living with this deadly cancer have had to rely on limited treatment options.^{5,7,8}

Melbourne, Australia / Hyderabad, India, December 02, 2025 – Dr. Reddy's Laboratories Ltd., today welcomes the Pharmaceutical Benefits Scheme (PBS) listing of Zytovi®* (toripalimab), the first and only immunotherapy for nasopharyngeal cancer¹⁻⁴ (a rare and aggressive type of head and neck cancer).

From 1st December 2025, Zytovi® – a next generation PD-1 inhibitor – will be available on the PBS for eligible Australians*. It is indicated as a first-line treatment option in combination with chemotherapy for nasopharyngeal cancer that has returned or spread, and as a single treatment option when the cancer has progressed during treatment with a certain type of chemotherapy or following it.²⁻³ Administered as an injection, Zytovi® works by helping the immune system better recognise and fight cancer.²

The Federal Government's subsidy for Zytovi® is a significant milestone in improving access to innovative treatments for Australians with rare cancers. Despite advances in immunotherapy and targeted medicines over the past decade, people living with rare head and neck nasopharyngeal cancer previously had only traditional treatment options available to them, including radiation, chemotherapy, and invasive surgery.⁵

"Immunotherapy transforms how we approach cancer treatment, especially for rare and difficult-to-treat cancers like nasopharyngeal carcinoma, where treatment options have been limited and the outlook for patients is often challenging," said **Professor Danny Rischin, Medical Oncologist and Head and Neck Cancer Research Lead at the Peter MacCallum Cancer Centre, Melbourne.**

"New and affordable treatment options are essential for improving the prognosis and quality of life for people with this head and neck cancer," adds **Professor Rischin.**

Nasopharyngeal cancer is a rare, aggressive and deadly type of head and neck cancer that forms in the nasopharynx – the highest part of the throat, in or behind the nose.⁴⁻⁵ An estimated 200 people in Australia are diagnosed every year,⁶ affecting three times more men than women, mainly those over 40-years old and often in the prime of their lives.⁵

Head and neck cancer presents significant psychosocial challenges, with individuals facing higher levels of anxiety, depression and emotional distress compared to those with other cancers.⁹⁻¹²

In addition, people with head and neck cancer may experience immense physical burden which can be very visible and dramatically change the way they look.¹³ Facial disfigurement is common due to the tumour itself or as a result from traditional treatments, which may involve removing parts of the face, throat or nose, or leaving redness, inflammation and scarring.¹³ People with nasopharyngeal cancer may experience nasal congestion and nosebleeds, vision and hearing problems, headaches, facial numbness, difficulty swallowing, speech impairment, bone pain, shortness of breath and chest infections.⁵

Nadia Rosin, CEO of Head and Neck Cancer Australia, the national peak body supporting people affected by head and neck cancer said, "Being diagnosed with head and neck cancer is an overwhelming and devastating experience. Unlike many other cancers, Head and Neck Cancer cannot always be concealed. The effects of treatment are visible to the world, often changing the way someone looks, eats, speaks and interacts with others. This can be deeply isolating, with many people withdrawing from social situations or unable to return to work because of ongoing challenges. The emotional and financial toll can be as significant as the physical one."

"It takes a team of people to look after someone with Head and Neck Cancer – while a surgeon or oncologist is responsible for getting rid of the cancer, recovery can be long and people rely on a team of specialist nurses, speech pathologists and dietitians to make sure they have the best possible outcomes," **Nadia adds.**

Christine Cockburn, CEO of Rare Cancers Australia, adds "For too long, patients with rare cancers have had limited treatment options and faced high costs to access the latest therapies. This listing is an important step towards equity for people with this rare cancer, providing access to immunotherapy here in Australia, without the hefty price tag."

The financial challenges faced by patients with cancer have a profound impact on their lives.¹⁴ Many are hit with unexpected "bill shock," with high out-of-pocket costs that can delay or prevent necessary treatment.⁷⁻⁸ Families often resort to borrowing, selling assets, or cutting essentials to cover expenses, which impacts their quality of life.⁷

M.V. Ramana, CEO – Branded Markets, Dr. Reddy's said, "As a company committed to advancing cancer care, we are proud to bring Zytovi® in Australia. We thank the Australian government and stakeholders for their efforts towards this reimbursement and recognise the high clinical need and financial burden for people living with nasopharyngeal cancer."

The approval and PBS listing of Zytovi® are supported by efficacy and safety information from two multicentre clinical trials, including an international randomised double-blind phase 3 study (JUPITER-02),^{3,15} and a single country single-arm phase 2 study (POLARIS-02),^{3,16} which together included 479 men and women with either locally advanced, previously treated, unresectable or metastatic nasopharyngeal carcinoma.¹⁵⁻¹⁶

About Zytovi®

Zytovi® is given as an injection containing the active ingredient toripalimab, a type of protein that helps the immune system fight cancer by recognising and attaching to a specific substance in the body.²⁻³

*In Australia, Zytovi® is approved for first-line treatment in combination with cisplatin and gemcitabine for adults with metastatic or recurrent, locally advanced nasopharyngeal carcinoma (NPC), and as a single treatment for adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy.¹⁻³

Toripalimab (Zytovi®) is developed by Shanghai Junshi Biosciences. Dr Reddy's entered into a license and commercialisation agreement with Shanghai Junshi Biosciences to develop and commercialise Toripalimab in the agreed countries including Australia, New Zealand and many other global markets.

Zytovi® is PBS listed for: Recurrent or metastatic nasopharyngeal carcinoma. Authority Required (Streamlined). Clinical criteria apply. Refer to PBS for full information.¹

A doctor will determine if a patient is suitable for Zytovi®. Any side effects should be reported to a doctor, or via www.tga.gov.au/reporting-problems.

As with any medicine, side effects may occur. Patients should speak with their health care professional and refer to the Customer Medicine Information (CMI) for full safety details, available online here: https://www.dreddys.au/zytovi_CMI.pdf

Zytovi® is not suitable for children and adolescents under the age of 18 years. Patients should not use Zytovi® if they have a severe allergy to toripalimab or other ingredients.²

Patients are advised to speak to a doctor if they are pregnant, could be pregnant or are planning to have a baby.² Patients are advised not to breastfeed during treatment and for at least 4 months after the last dose of Zytovi®.² Patients are advised to speak to a doctor if taking any other medicines, vitamins or supplements, or have had other medical conditions, especially immune system problems such as Crohn's disease, ulcerative colitis, or lupus, or if they have received an organ transplant.²

As with all medicines, Zytovi® is associated with some side-effects. While uncommon, the most frequent side effects are low levels of thyroid hormones, rash, fever, diarrhoea, upper respiratory infection, difficulty getting to sleep or staying asleep, itching, ulcers in mouth, lung infection and high blood pressure. A reaction may occur during an infusion of Zytovi®. Infusion reactions can sometimes be severe or life threatening. Common infusion reactions include fever, chills, itching or rash.² Other serious side effects for Zytovi® include inflammation in the lungs, heart muscle, liver, intestines, skin, kidneys, hormone glands, muscles and joints and other organ systems, as well as type 1 diabetes including acid in the blood and transplant-related complications or rejection of transplanted organ or tissue for patients who have had a solid organ, tissue, or bone marrow transplant that used donor stem cells.²

About Nasopharyngeal Cancer (NPC)

Nasopharyngeal Cancer (NPC) is a type of head and neck (throat) cancer that starts in the upper part of the throat behind the nose.⁵ It occurs when abnormal cells grow uncontrollably, forming a lump that may spread to other parts of the body.⁵ NPC is most common in people over 40, especially males and those from Southern China and Southeast Asia. Key risk factors include infection with the Epstein-Barr virus, smoking, and dietary habits like consuming salty, cured fish and meats.⁵

Common symptoms include nasal congestion, nosebleeds, ear and hearing problems, a lump in the neck, headaches, facial numbness, or vision changes.⁵ Diagnosis involves physical examinations, imaging tests and tissue biopsies.⁵

A diagnosis of NPC often carries a significant emotional burden, with patients commonly experiencing anxiety, depression, and concerns about disfigurement, or impaired abilities to speak and eat.^{5,9,11} The significant financial strain of high medical costs, ongoing treatments, and potential loss of income, can add to these challenges.⁷⁻⁸

Comprehensive care is essential for managing these burdens, including emotional support, symptom management, and access to treatment options. Ongoing support from a multidisciplinary team healthcare professionals, family, and community resources is vital throughout recovery and beyond.⁵

Disclaimers:

In relation to this media announcement, no honoraria was provided to Professor Danny Rischin, Nadia Rosin or Christine Cockburn, and the opinions expressed are their own.

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is a global pharmaceutical company headquartered in Hyderabad, India. Established in 1984, we are committed to providing access to affordable and innovative medicines. Driven by our purpose of 'Good Health Can't Wait', we offer a portfolio of products and services including APIs, generics, branded generics, biosimilars and OTC. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Our major markets include – USA, India, Russia & CIS countries, China, Brazil and Europe. As a company with a history of deep science that has led to several industry firsts, we continue to plan ahead and invest in businesses of the future. As an early adopter of sustainability and ESG actions, we released our first Sustainability Report in 2004. Our current ESG goals aim to set the bar high in environmental stewardship; access and affordability for patients; diversity; and governance.

For more information, log on to: www.drreddys.com.

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Media contacts (local PR agency): Kelly Smith: 0402 994 120