

TGA approves chemotherapy-induced nausea and vomiting drug

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Singapore: Australian biopharmaceutical company, Specialised Therapeutics Australia (STA), and Helsinn, a Swiss group focused on building quality cancer care, have received approval from Therapeutic Goods Administration (TGA) for Akynzeo for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy.

Akynzeo is the first approved fixed dose combination oral agent that targets two critical signalling pathways associated with CINV by combining netupitant, an NK1 receptor antagonist, and palonosetron, a 5-HT3 receptor antagonist, in a single capsule for the prevention of CINV.

"Cancer patients are burdened with having to take multiple drugs, often several times per day and certainly multiple times per cycle of chemotherapy, to reduce unwanted side effects. With every increased drug/schedule there is an increased risk of mistakes and/or non-compliance," said Professor Dorothy Keefe, clinical ambassador, transforming health and professor of Cancer Medicine, University of Adelaide. "The availability of this combination of drugs, in a single capsule, allows 'once per cycle' dosing (which is even better than once per day dosing) for the benefit of the patient."

The approval was based on the submission of Phase 2 and Phase 3 trials with Akynzeo in patients undergoing treatment with moderately and highly emetogenic chemotherapy regimens for a variety of tumour types.

Mr Carlo Montagner, chief executive officer, STA said Akynzeo was a valuable addition to STA's oncology supportive care portfolio, providing patients with access to an effective and convenient antiemetic therapy. "We look forward to making this drug available to cancer patients around the country, for improved management of some of the most common side effects of chemotherapy, which can severely diminish a patient's quality of life. STA will now seek to have Akynzeo listed on the Pharmaceutical Benefits Scheme for reimbursement."