

# **Specialized Therapeutics Grants Sublicense for Anti-Emetic Products to Mundipharma for Australia and New Zealand Anti-emetic Products Covered Under the Sublicense Agreement Include ALOXI® (palonosetron hydrochloride) and AKYNZEO® (netupitant/palonosetron).**

**Melbourne, Australia, 7 March 2016:** Specialized Therapeutics Pty Ltd and Mundipharma Pty Limited today announce a sublicense agreement enabling Mundipharma to assume all commercialisation responsibilities for the anti-emetic products ALOXI® (palonosetron hydrochloride) and AKYNZEO® (netupitant/palonesetron).

Under the terms of the arrangement, Specialized Therapeutics grants Mundipharma exclusive marketing, promotion, distribution and sales rights for the anti-nausea and vomiting pharmaceutical products ALOXI® and AKYNZEO® in Australia and New Zealand markets.

ALOXI® is indicated for the prevention of acute nausea and vomiting associated with chemotherapy<sup>1</sup> and has been commercially available in Australia since 2010 under license from Helsinn Healthcare SA, a Swiss pharmaceutical company which has consented to the sublicense agreement.

AKYNZEO® is the first fixed combination oral agent targeting two critical signalling pathways associated with chemotherapy induced nausea and vomiting

(CINV) by combining netupitant, an NK1 receptor antagonist, and palonosetron, a 5-HT<sub>3</sub> receptor antagonist, in a single capsule.<sup>2</sup>

AKYNZEO<sup>®</sup> is also supplied by Helsinn, and was approved by Australia's Therapeutic Goods Administration in May 2015. A submission for reimbursement on the Pharmaceutical Benefits Scheme (PBS) was submitted in 2015 and is nearing completion.

## **About ALOXI<sup>®</sup> (palonosetron hydrochloride)**

ALOXI<sup>®</sup> (palonosetron hydrochloride) is a second generation 5-HT<sub>3</sub> receptor antagonist, developed for the prevention of chemotherapy-induced nausea and vomiting (CINV) in patients with cancer, with a long half-life of 40 hours.

ALOXI<sup>®</sup> has been developed by the Helsinn Group in Switzerland and today it is marketed as Aloxi<sup>®</sup>, Onicit<sup>®</sup> and Paloxi<sup>®</sup> in more than 50 countries worldwide. In Australia, Aloxi<sup>®</sup> is PBS listed for the management of nausea and vomiting associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.<sup>3</sup>

For more information about ALOXI<sup>®</sup>, please visit the website: [www.aloxi.com](http://www.aloxi.com)

## **About AKYNZEO<sup>®</sup> (netupitant/palonosetron)**

AKYNZEO<sup>®</sup> is an oral, fixed combination of an NK1 receptor antagonist, netupitant, and a 5-HT<sub>3</sub> receptor antagonist, palonosetron, in a single capsule, that targets two critical signalling pathways associated with chemotherapy-induced nausea and vomiting (CINV).<sup>2</sup>

AKYNZEO<sup>®</sup> was approved by the US Food and Drug Administration (FDA) in October 2014 and by the European Commission in May 2015. In Australia,

AKYNZEO® was approved by the Therapeutic Goods Administration in May 2015. It is indicated in adult patients for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy and for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy.<sup>2</sup> An application to New Zealand's regulatory authority MEDSAFE has been submitted and is under review. Additional regulatory submissions for netupitant/palonosetron fixed combination are underway worldwide.

## **About Specialized Therapeutics Pty Ltd**

Specialized Therapeutics Pty Ltd, a wholly owned subsidiary of Specialised Therapeutics Australia Pty Ltd, is a biopharmaceutical company dedicated to working with leading international pharmaceutical companies to provide patient access to innovative healthcare solutions.

For more information, please visit [www.specialisedtherapeutics.com.au](http://www.specialisedtherapeutics.com.au).

## **About the Helsinn Group**

Helsinn is a privately owned cancer supportive care pharmaceutical group with an extensive portfolio of marketed products and a broad development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality, through a unique integrated licensing business model working with long standing partners in pharmaceuticals, medical devices and nutritional supplement products. Helsinn is headquartered in Lugano, Switzerland, with operating subsidiaries in Ireland and the US (Helsinn Therapeutics), a representative office in China, as well as a product presence in about 90 countries globally.

For more information, please visit [www.helsinn.com](http://www.helsinn.com).

# About Mundipharma

Mundipharma's global network of companies are privately owned entities covering the world's pharmaceutical markets. Mundipharma provides patients across 6 continents with a growing portfolio of 19 products in 5 therapeutic areas, which include moderate-to-severe pain, consumer healthcare, oncology, respiratory disease, rheumatoid arthritis, antiseptics and laxatives. Mundipharma is a prime example of a company that consistently delivers high quality products while standing by the values that represent the company. Our mission is to alleviate the suffering of patients and to substantially improve their quality of life.

For more information, please visit: [www.mundipharma.com.au](http://www.mundipharma.com.au)

## References

1. ALOXI<sup>®</sup> Approved Product Information available at: [http://www.specialisedtherapeutics.com.au/assets/files/d-aloxi\\_pi.pdf](http://www.specialisedtherapeutics.com.au/assets/files/d-aloxi_pi.pdf)
2. AKYNZEO<sup>®</sup> Approved Product Information available at: [http://www.specialisedtherapeutics.com.au/assets/files/d-akynzeo\\_pi.pdf](http://www.specialisedtherapeutics.com.au/assets/files/d-akynzeo_pi.pdf)
3. The Pharmaceutical Benefits Scheme available at: <http://www.pbs.gov.au/pbs/home>, Accessed March 2016.