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ASIA EDITION

APLIDIN gets world-first approval for Multiple Myeloma

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APLIDIN is a first-in-class anti-cancer agent approved to treat multiple myeloma, which has one of the lowest survival rates in cancer

Multiple myeloma patients from Australia will have world-first access to a new first-in-class drug developed to treat the disease, following approval by Australian regulatory authorities.

The drug, APLIDIN (plitidepsin) will be available to patients who have failed or are resistant to other therapies, after the Therapeutic Goods Administration (TGA) decision to approve APLIDIN before any other country.

Leading Australian myeloma clinicians are welcoming the decision, saying APLIDIN will provide another valuable treatment option for patients.

And Peter MacCallum Cancer Centre and Royal Melbourne Hospital haematologist, Professor Jeff Szer, who was the Australian principal investigator on the pivotal APLIDIN registration study, said APLIDIN had been shown to be effective and well tolerated.

He commented: "More Australian myeloma patients were enrolled into the pivotal international trial of APLIDIN than anywhere else in the world.These patients in the Phase 3 study known as ADMYRE have now paved the way for others to have access to a new and novel therapy."

Specialised Therapeutics will continue providing APLIDIN to eligible Australian patients at no cost via a Compassionate Access Program, prior to national reimbursement.

Chief Executive Officer of Specialised Therapeutics Asia, Carlo Montagner, said Australian regulatory authorities should be commended for ensuring Australian myeloma patients have the first opportunity to access this cutting-edge therapy.

He commented: "It is not often that Australian patients are the first in the world to access new medicines. In this case, the TGA is at the forefront, with decision-makers recognising the great need that exists in multiple myeloma. This disease remains incurable and patients eventually run out of treatment options."

The company is pursuing opportunities to provide APLIDIN to myeloma patients across South East Asia.

Specialised Therapeutics Asia has exclusive rights to market and distributes APLIDIN in Australia, Singapore and 12 other South East Asian countries under the terms of an exclusive arrangement with a European partner, PharmaMar.

APLIDIN was the first drug licensed by Specialised Therapeutics Asia for the broader SE Asian market.

PharmaMar President, Jose Maria Fernandez Sousa-Faro, said: "This approval for an incurable disease corroborates the work that the PharmaMar team has done over the years with APLIDIN®. Patients and the medical community will now have a new therapeutic alternative with a new mechanism of action that is different from the products currently in use."

Managing Director of PharmaMar's Oncology Business Unit, Luis Mora, added: "The approval of APLIDIN® is a very important step forward for the company. This increases PharmaMar's presence with a second drug on the Australian market and, together with our partners; we are initiating procedures for other markets, such as South America, Mexico, Canada, Asia and Israel."