World-First Approval for Multiple Myeloma Drug Aplidin®

Singapore, 11 December 2018: Australian multiple myeloma patients 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.

Alfred Hospital Head of the Malignant Haematology and Stem Cell Transplantation Service, Professor Andrew Spencer, said: "APLIDIN provides a chance for some myeloma patients to extend their lives.

"We now have another drug to offer patients who have relapsed after being treated with existing therapies.

"This is important, because once patients become resistant to standard therapies, there have been very limited treatment options."

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.

"This really means that some patients with advanced myeloma have the possibility of improved outcomes, when previous therapies have failed."

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 distribute APLIDIN in Australia, Singapore and 12 other South East Asian countries under the terms of an exclusive arrangement with European partner, PharmaMar.

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

PharmaMar President, José María Fernández 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.”

Ends.

About APLIDIN® (plitidepsin)

Plitidepsin is an anticancer agent of marine origin, originally obtained from the ascidian *Aplidium albicans*. It specifically binds to the eEF1A2 and targets the non-canonical role of this protein, resulting in tumor cell death via apoptosis (programmed death). Plitidepsin is currently in clinical development for hematological cancers, including combination studies in relapsed or refractory multiple myeloma, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma.

About Multiple Myeloma in Australia

It is estimated that around 1800 Australians are diagnosed with MM every year and 1000 people die.[1] Fewer than 50% of patients survive five-years post diagnosis.[1]

MM accounts for between 10 and 15% of all haematological malignancies and is predominately a disease of the elderly, with median age at diagnosis 65-70 years.[2] This disease typically causes increased bone osteolysis resulting in pathological fractures, renal failure, hypercalcaemia, immune suppression, increased infection risk and bone marrow failure.[2]

Despite significant developments in frontline, maintenance and supportive therapy options, MM remains incurable, with treatment refractory relapse eventually occurring in all patients.[3]

About Specialised Therapeutics Asia

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST Asia) is an international biopharmaceutical company established to provide innovative specialist therapies and technologies to patients throughout South East Asia, as well as in Australia and New Zealand. ST Asia's existing product portfolio spans oncology, haematology, neurology, urology and ophthalmology. Additional

information can be found at www.stbiopharma.com

About PharmaMar

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in the discovery and development of innovative marine-derived anticancer drugs. The company has an important pipeline of drug candidates and a robust R&D oncology program. PharmaMar develops and commercializes YONDELIS® in Europe and has three other clinical stage programs under development for several types of solid and hematological cancers PM1183, plitidepsin, and PM60184. PharmaMar is a global biopharmaceutical company with subsidiaries in Germany, Italy, France, Switzerland and the United States. PharmaMar fully owns three other companies: GENOMICA, Spain's leading molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAI); and two other chemical enterprises, Zelnova and Xylazel. To learn more about PharmaMar, please visit us at www.pharmamar.com.

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