

PharmaMar announces the approval of Aplidin® in Australia for the treatment of multiple myeloma

- **PharmaMar has licensed Aplidin® to its partner, STA, in Australia, New Zealand and several Southeast Asian countries.**
- **This approval opens the door to many other markets in South America, Mexico, Canada, Asia Pacific, Middle East and North Africa, among others.**

Madrid, 11th of December 2018.- PharmaMar (MSE:PHM) announces that the Australian Regulatory Agency (TGA) has informed STA that Aplidin® (plitidepsin) has been approved for the treatment of multiple myeloma in combination with dexamethasone.

Aplidin® will be available to patients who have failed or are resistant to other therapies, after the TGA decision to approve Aplidin® before any other country.

The indication has been approved for the treatment of patients that relapse after three lines of treatment, including proteasome inhibitors or immunomodulators. It can also be administered as 3rd line treatment, when the patient has already received two prior lines and is refractory or intolerant to proteasome inhibitors or immunomodulators.

This approval opens the door to many other markets in South America, Mexico, Canada, Asia Pacific, Middle East and North Africa, among others, that will review Aplidin® after TGA's decision, and where PharmaMar has partners for this product.

PharmaMar signed a licensing agreement with Specialised Therapeutics Asia Pte, Ltd (STA), established in Singapore, to market Aplidin® in Australia and New Zealand in August 2015, along with a new agreement for 12 other Asian countries in February 2016.

Professor Andrew Spencer, Head of the Malignant Haematology and Stem Cell Transplantation Service at The Alfred Hospital, 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."*

Professor Jeff Szer, Peter MacCallum Cancer Centre and Royal Melbourne Hospital haematologist, 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."*

Carlo Montagner, Chief Executive Officer of Specialised Therapeutics Asia, 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 recognizing the great need that exists in multiple myeloma. This disease remains incurable and patients eventually run out of treatment options."*

José María Fernández Sousa-Faro, President of PharmaMar, 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."*

Luis Mora, Managing Director of PharmaMar's Oncology Business Unit, 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."*

In Europe, as already announced, the decision of the European Medicines Agency (EMA) is being appealed to the Luxembourg Court.

Legal warning

This press release does not constitute an offer to sell or the solicitation of an offer to buy securities, and shall not constitute an offer, solicitation or sale in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of that jurisdiction.

About PharmaMar

Headquartered in Madrid, PharmaMar is a biopharmaceutical company, focused on oncology and committed to research and development which takes its inspiration from the sea to discover molecules with antitumor activity. It is a company that seeks innovative products to provide healthcare professionals with new tools to treat cancer. Its commitment to patients and to research has made it one of the world leaders in the discovery of antitumor drugs of marine origin.

PharmaMar has a pipeline of drug candidates and a robust R&D oncology program. It develops and commercializes Yondelis® in Europe and has other clinical-stage programs under development for several types of solid cancers: lurbinectedin (PM1183), PM184 and PM14. With subsidiaries in Germany, Italy, France, Switzerland, Belgium, Austria and the United States. PharmaMar wholly owns other companies: GENOMICA, a molecular diagnostics company; Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi); and a chemical enterprise, Zelnova Zeltia. To learn more about PharmaMar, please visit us at www.pharmamar.com

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 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 (programed death). Plitidepsin has received orphan drug designation in the European Union and the United States of America.

About multiple myeloma

Multiple myeloma is a relatively uncommon type of blood cancer, which accounts for 10% of all hematological malignancies, this being caused by malignant plasma cells that very rapidly multiplyⁱ. Normal plasma cells are white blood cells, which form part of the immune system, found in the bone marrow that produce the antibodies necessary for fighting infectionsⁱⁱ. Abnormal cells produce a type of antibody that does not benefit the body and accumulate, thus preventing normal cells from functioning properly. In 2016, there were about 130,000 cases of multiple myeloma worldwide and 98,437 deathsⁱⁱⁱ. In 2015, 26,850 new cases were diagnosed in the US, and about 11,200 people died from this disease^{iv}. In Europe, the incidence is 4.5–6.0 out of 100 000 diagnosed per year^v.

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ⁱ <http://www.cancer.org/cancer/multiplemyeloma/detailedguide/multiple-myeloma-what-is-it>

ⁱⁱ <http://www.myeloma.org.uk/information/what-is-myeloma/>

ⁱⁱⁱ <http://www.cancernetwork.com/multiple-myeloma/multiple-myeloma-incidence-increasing-worldwide-especially-us>

^{iv} <http://seer.cancer.gov/statfacts/html/mulmy.html>

^v <http://www.esmo.org/Guidelines/Haematological-Malignancies/Multiple-Myeloma>