

## PharmaMar announces license agreement with TTY Biopharm for APLIDIN® (plitidepsin) in hematological cancers

**Madrid, July 23, 2015** – PharmaMar has entered into an exclusive license and commercialization agreement with the pharmaceutical company TTY Biopharm to market and distribute the drug candidate APLIDIN® (plitidepsin) in Taiwan. Under the terms of the agreement, PharmaMar will receive an upfront payment, royalties and additional remunerations for regulatory milestones achieved by APLIDIN® (plitidepsin). PharmaMar will retain exclusive production rights and will supply the finished product to TTY Biopharm for commercial use.

APLIDIN® (plitidepsin) is PharmaMar's second anticancer drug candidate obtained from a marine organism and is currently under development for the treatment of multiple myeloma and a type of T cell lymphoma. The company announced in June that [patient recruitment of the international pivotal Phase III trial](#) (ADMYRE) for APLIDIN® (plitidepsin) in refractory/relapsed multiple myeloma was successfully completed<sup>1</sup>.

“Thousands of patients are living with this disease, and it is our commitment and dedication to bring a novel and first-in-class therapy to patients in need. For this mission, we are delighted to collaborate in a partnership with one of the long-standing leaders in the field of oncology and hematology in Taiwan.” said Heiner Pieper, Vice-President of Business Development & Licensing at PharmaMar.

“Our understanding of the Taiwanese market and our capabilities to market plitidepsin along with the therapeutic value of this innovative compound will be factored into the success of this partnership”, said Hsiao Ying-Chun, Chairman of TTY Biopharm. “We are hoping to start contributing to the well-being of these patients by providing clinicians with a novel drug”.

### **About APLIDIN® (plitidepsin)**

Plitidepsin is an investigational anticancer agent of marine origin, originally obtained from the tunicate *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 a Phase III study in relapsed or refractory multiple myeloma, a Phase Ib trial in relapsed or refractory multiple myeloma as a triple combination of plitidepsin, bortezomib and dexamethasone, and a Phase II study in relapsed or refractory angioimmunoblastic T-cell lymphoma. Plitidepsin has received orphan drug designation by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).

### **About multiple myeloma**

Multiple myeloma is a relatively uncommon type of blood cancer that accounts for 10% of all hematological malignancies and that is caused by malignant plasma cells that very rapidly multiply<sup>ii</sup>. Normal plasma cells are white blood cells found in the bone marrow that form part of the immune system and produce the antibodies necessary to fight infections<sup>iii</sup>. Abnormal cells produce a type of antibody that does not benefit the body and accumulate, thus preventing normal cells from functioning properly. Almost all patients with multiple myeloma progress from an initial, asymptomatic pre-malignant stage to established disease. In 2015, 26,850 new cases will be diagnosed in the US, and about 11,200 people will die of this disease<sup>iv</sup>. In Europe, there will be 4.5–6.0 out of 100,000 people diagnosed per year<sup>v</sup>. In Taiwan, multiple myeloma is the third most common hematological malignancy and the incidence of this disease has been increasing in the last 25 years<sup>vi</sup>.

### **About PharmaMar**

Headquartered in Madrid, PharmaMar is a world-leading biopharmaceutical company in advancing cancer care through the discovery and development of innovative marine-derived anticancer drugs. The company has a rich pipeline of drug candidates and a robust R&D oncology program. YONDELIS<sup>®</sup> is the first anticancer drug of marine origin and is commercially available in 81 countries for the treatment of advanced soft tissue sarcomas as a single-agent, and for relapsed platinum-sensitive ovarian cancer in combination with DOXIL<sup>®</sup>/CAELYX<sup>®</sup>. PharmaMar develops and commercializes YONDELIS<sup>®</sup> in Europe and has three 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. To learn more about PharmaMar, please visit us at [www.pharmamar.com](http://www.pharmamar.com).

### **About TTY Biopharm**

TTY is committed to building itself as a biotech pharmaceutical company advanced in drug development and international marketing. On one hand, TTY is continuously improving its ability to gear to international developments in areas such as international technical documentation formats (CMC, CTD), execution of international clinical trials, and manufacturing process which matches EMA and FDA specifications. On the other hand, TTY continues to carefully select the most suitable collaborative partners for new drug development around the world and various target markets. Other than continuing operation in the core channels (medical centers, regional hospitals, district hospitals with development potentials) in Taiwan, TTY will enter the international market through developing high barrier and concept-proved new drugs and biologics with innovative injectable liposomal and PLA/PLGA microsphere formulations. Presently, TTY has been successful in introducing its own R&D products to regions including EU, Asian Pacific, Middle East

regions, Africa, and South America, and has become the best partner for companies which are strong in drug marketing. In the future, TTY will continue its cultivation of Asian target markets (home market) to build up its local strength to become the best partner with the best drug development and marketing capabilities for international innovation and biotech companies in target market.

#### **Disclaimer**

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<sup>i</sup> <http://www.pharmamar.com/en/press/pharmamar-completes-patient-recruitment-phase-iii-registration-trial-admyre-aplidin%C2%AE>

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

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

<sup>iv</sup> <http://seer.cancer.gov/statfacts/html/mulmy.html>

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

<sup>vi</sup> [http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(13\)70404-2/abstract](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(13)70404-2/abstract)