



CHUGAI PHARMACEUTICAL CO., LTD.



Roche Group

## PharmaMar and Chugai Pharma Marketing Enter into a License and Commercialization Agreement in Europe for Aplidin<sup>®</sup>

**Madrid, Spain, July 14, 2014 and Tokyo, Japan, July 15, 2014** – Zeltia, and Chugai Pharmaceutical Co., Ltd. today announced that PharmaMar S.A., a wholly owned oncology subsidiary of Zeltia, and Chugai Pharma Marketing Ltd, a wholly owned subsidiary of Chugai, have entered into a license agreement where Chugai Pharma Marketing would promote PharmaMar's Aplidin<sup>®</sup> for the treatment of multiple myeloma (MM) in eight European countries (France, Germany, the UK, Belgium, the Netherlands, Luxemburg, Ireland and Austria).

Under the terms of the agreement, PharmaMar receives an upfront payment of € 5 million and will be eligible for more than € 30 million related to the regulatory, development and sales milestones. PharmaMar will retain exclusive production rights and will sell the product to Chugai for commercial use.

The Phase III trial (ADMYRE) for the treatment of relapsed and refractory MM is currently ongoing. Aplidin<sup>®</sup> showed a favorable safety profile and efficacy in combination with dexamethasone vs. dexamethasone alone in the Phase II trial. Submission of a marketing authorisation application (MAA) in Europe is expected in 4Q 2015. The dossier for EU approval will also be valid for more than 40 countries outside the EU and PharmaMar is looking into opportunities to license the compound in those territories. Aplidin<sup>®</sup> has orphan designation for multiple myeloma in Europe.

Chugai's already well-established hematologic oncology sales force in the countries covered in the agreement will help to maximise Aplidin's value in the European territory by facilitating a rapid uptake of this new treatment option in the event that Aplidin<sup>®</sup> is approved.

"This alliance is a result of a shared vision with PharmaMar to introduce a new treatment for relapsed Multiple Myeloma. Aplidin<sup>®</sup> would give physicians a totally new option that could potentially change the way they treat patients with relapsed multiple myeloma in the future." "It is Chugai's continuing commitment and dedication to bring innovative medicines to patients, and we are confident that Aplidin's novel mechanism of action and strong supporting data will lead to a successful introduction of this medicine to patients and physicians" said John Halls, Managing Director of Chugai Pharma Marketing.

Multiple myeloma is still a disease area of high unmet medical need, with no currently approved, truly effective treatment options Aplidin<sup>®</sup>, however, with its new mechanism of action has the potential to become a critical component in the management of individuals suffering from MM.

The incidence of MM in Europe is 4.5-6.0/100,000/year with a median age at diagnosis of between 65 and 70 years; the mortality is 4.1/100,000/year according to the ESMO Clinical Practice Guidelines.

### **About Aplidin®**

Aplidin® is an antitumour agent of marine origin, originally isolated from the marine tunicate *Aplidium albicans*, and currently obtained by chemical synthesis.

Aplidin® is PharmaMar's second most advanced compound. It is currently in phase II clinical trials for solid and haematological malignant neoplasias like T cell lymphoma and in phase III clinical trials for multiple myeloma.

Aplidin® has been designated an orphan drug by the European Commission (EC) and the FDA for multiple myeloma (MM).

### **About PharmaMar**

PharmaMar is a biopharmaceutical subsidiary of Grupo Zeltia; it is a world leader in discovering, developing and marketing marine-based drugs to treat cancer. Yondelis® is the first marine-based antitumour drug. PharmaMar has four other compounds in clinical development: Aplidin®, Zalypsis®, PM01183 and PM060184. PharmaMar also has a rich pipeline of pre-clinical candidates and a major R&D programme.

### **About Zeltia**

Zeltia S.A. is a world-leading biopharmaceutical company specialised in the development of marine-based drugs for use in oncology. Grupo Zeltia consists mainly of the following companies: PharmaMar, the world-leading biotechnology company in advancing cancer care through the discovery and development of innovative marine-derived medicines; Genómica, Spain's leading company in molecular diagnostics based on DNA analysis; and Sylentis, dedicated to researching therapeutic applications of gene silencing (RNAi).

### **About Chugai Pharma Marketing**

Chugai Pharma Marketing Ltd. is the headquarters of all Chugai's commercial activities throughout Europe and coordinates the European marketing operations through subsidiaries located in the UK, France, and Germany. Products which are currently marketed in those countries include "RoActemra® (tocilizumab)", a humanized anti-human IL-6 receptor monoclonal antibody, "Granocyte® (lenograstim)", a G-CSF preparation, and "Antepsin® (sucralfate)", an antiulcer agent (marketed in the UK and Ireland).

### **About Chugai**

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and Ukima is conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research was established in Singapore in January 2012 for conducting research focusing on the generation of new antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2013 of Chugai totaled 423.7 billion yen and the operating income was 79.9 billion yen. We are aiming at the consolidated revenue of 451.0 billion yen and operating profit of 71.0 billion yen in IFRS core basis, in 2014.

Additional information is available on the Internet at <http://www.chugai-pharm.co.jp/english>.

### **Important note**

PharmaMar, which is headquartered in Madrid (Spain), is a subsidiary of Zeltia, S.A. (Spanish stock exchange: ZEL), which has been listed on the Spanish Stock Exchange since 1963 and on Spain's Electronic Market since 1998. This document is a press release, not a prospectus. This document does not constitute or form part of an offering or invitation to sell or a solicitation to purchase, offer or subscribe shares of the company. Moreover, no reliance should be placed upon this document for any investment decision or contract and it does not constitute a recommendation of any type with regard to the shares of the company

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This note is also available on the Zeltia's website: [www.zeltia.com](http://www.zeltia.com) and at PharmaMar website: [www.pharmamar.com](http://www.pharmamar.com).

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