

## **Modelling and simulation in biomedicine save time and resources in drug development**

- **PharmaMar, a biopharmaceutical company in the Zeltia Group, is organising the Seminar on Modelling and Simulation in Biomedicine for the first time. The event, now in its fifth edition, will be held at PharmaMar's headquarters in Colmenar Viejo (Madrid) on 20-22 November**
- **Modelling involves using a mathematical model to represent a reality—a biological phenomenon in the specific case of Biomedicine; once the model has been defined, it can be used in experiments instead of the actual system (simulation)**
- **These techniques have contributed notably to the foundations of personalized medicine, under which each patient receives the right dose of the right medicine**
- **Spain currently has numerous trained scientists and considerable scope for innovation in this field**
- **Modelling and simulation techniques should be applied to all activity and safety data obtained in clinical trials, instead of the classic approach of applying them only to define a drug's activity or safety**

**Madrid, 19 November 2013:** Modelling involves using a mathematical model to represent a reality—a biological phenomenon in the specific case of Biomedicine. Once the model has been defined, it can be used in experiments instead of the actual system (simulation). This approach "offers major savings in development time, lab animal use and trials in human subjects," said Dr. Arturo Soto, Head of Clinical Development at PharmaMar, the Zeltia Group company which is hosting the Seminar on Modelling and Simulation in Biomedicine for the first time. The event, now in its fifth edition, will be held at PharmaMar's headquarters in Colmenar Viejo (Madrid) on 20-22 November.

Since PharmaMar is a world leader in the discovery and development of antitumor drugs of marine origin, this edition of the Seminar will focus on the application of modelling to the various phases of oncological drug development, from initial preclinical trials up to authorization. "Modelling efficacy and toxicity data obtained in animals enables us to rationalize the administration pattern and dosage the first time the drug is administered to humans." In general, these techniques "have made a very important contribution to the foundations of personalized medicine, enabling each patient to receive the right dose of the right medicine."

Simulation and modelling are leading-edge tools in clinical research in the area of medicine. "For many years, these techniques were confined almost exclusively to countries that lead the field in R&D, such as the United States, the United Kingdom and Germany," said Regina Múzquiz, Head of Institutional Relations at PharmaMar. "Spain currently has numerous trained scientists and considerable scope for innovation in this field." At the Fifth Seminar on Modelling and Simulation in Biomedicine, educators, students, researchers, opinion leaders, pharmacists and modelling professionals will discuss the latest tools and methodologies and share their impressions about ongoing research.

According to Regina Múzquiz, they will address topics such as "including genetic data in models, evaluating accurate measures of tumour size reduction after treatment, establishing the prognosis of patients with lung cancer using a model based on biological markers, and developing models which evaluate the tumour response triggered by immunostimulant agents; the Spanish Medicines Agency will provide the regulator's point of view."

According to the Head of Clinical Development at PharmaMar, modelling and simulation techniques "should be applied to all activity and safety data obtained in clinical trials, instead of the classic approach of applying them only to define a drug's activity or safety. If we can accurately predict the probability of trial success through a more precise evaluation of the preparatory phases, the savings in terms of time and resources would be extraordinary." The objective of the biomedical application of these techniques is "to achieve a greater understanding of how drugs work and the factors which result in not all patients exhibiting the same benefits or adverse effects, even when receiving the same dose."

According to Ángel Gil, Vice-Rector of Research and International Relations at King Juan Carlos University (URJC) in Madrid: "Modelling and simulation in biomedicine are clear examples of innovation aligned with the objectives of the Health Innovation and Communication Chair at the URJC. Our department supports all the Zeltia Group's innovation initiatives and contributes to publicizing them in the general and specialized media source to raise awareness generally of the progress which is being made in biomedicine; in this case, the fact that modelling and simulation are producing considerable progress and change in the way we address the emerging challenges in biomedicine."

### **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).

### **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.

### **For more information +34 91 444 4500**

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