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## **The results of the ABEL clinical trial suggest that Bemiparin could be beneficial against small cell lung cancer**

**According to the conclusions of the final analysis of the data from a Phase II clinical trial, the addition of Bemiparin improves the clinical results of the standard anti-tumour treatment of patients with small cell lung cancer.**

**Madrid – 19 October 2011** – Laboratorios Farmacéuticos Rovi S.A. ([www.rovi.es](http://www.rovi.es)) announces that the results of the final analysis of the "ABEL" clinical trial (*Adjuvant Bemiparin Evaluation study in small cell Lung cancer*) are being presented today during the XIII National Congress of the Spanish Society of Medical Oncology<sup>1</sup>; the study was aimed to assess the effectiveness and safety of Bemiparin (3,500 IU/day for 26 weeks) in patients with limited small cell lung cancer who are receiving standard anti-tumour treatment (platinum-based chemotherapy and radiotherapy).

These final results confirm the positive results that had been seen in an interim analysis<sup>2</sup>. The disease progression-free survival time, the primary outcome of the trial, increased by 1.5-fold, and the overall survival time increased by 3.3-fold, in the group of patients who received Bemiparin, compared to the control group without Bemiparin, with no rise in the incidence of haemorrhage.

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<sup>1</sup> B. Massuti, et al. Phase II randomized CT of bemiparin in association with chemotherapy in small cell lung cancer. Final results of the ABEL study. Oral communication O-21. XIII SEOM National Congress (Málaga, 19th-21st October, 2011).

<sup>2</sup> R. Lecumberri, et al. Adjuvant bemiparin in small cell lung cancer: results from the ABEL study. *Thromb Res.* 2010. 125 (Suppl 2): S163.

The "ABEL" trial is a Phase II multi-centre clinical trial, sponsored by the *Instituto Científico y Tecnológico de Navarra, S.A.*, with the cooperation of ROVI, and designed as a proof of concept. Ten Spanish hospitals participated in the trial, with a total of 39 patients with limited stage disease of small cell lung cancer (after being stopped the inclusion of new patients because of a slow recruitment rate). The trial was directed, as principal investigator, by Prof. Eduardo Rocha, Ordinary Professor of Haematology at the Faculty of Medicine of the University of Navarra.

In the light of these results, and taking into consideration the fact that the time and resources needed to continue with the development of Bemiparin for this new therapeutic area are significant, ROVI has decided to look for a partner that specialises in oncology, with the appropriate experience and resources for undertaking the clinical development with sufficient guarantees.

### **About small cell lung cancer**

Small cell lung cancer is one of the fastest growing solid tumours, and has one of the highest tendencies for leading to distant metastases. Without treatment, the disease is fatal in a few weeks. It represents about 15% of the total number of new lung cancer cases. With treatment, the median survival time in patients with a limited stage is about 20 months, with a survival rate of 45% for 2 years and 20% for 5 years. In patients with extensive stage, the median survival time is about 12 months, with a survival rate of less than 5% for 2 years<sup>3</sup>.

### **About the Instituto Científico y Tecnológico de Navarra**

The *Instituto Científico y Tecnológico de Navarra, S.A.* is a non-profit organisation, promoted by the University of Navarra, which aims to facilitate cooperation between companies and the University.

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<sup>3</sup> Tan WW, Maghfoor I, Perry M. Small Cell Cancer. eMedicine, 20 April 2011. <http://emedicine.medscape.com/article/280104>.

Since its establishment in 1986, the mission of the *Instituto Científico y Tecnológico* has been to act as a link between university researchers and companies, in order to facilitate and promote research, and to stimulate the transfer of knowledge and research results generated at the the University of Navarra and the University of Navarra Clinic.

The *Instituto Científico y Tecnológico* is the Research Results Transfer Office (OTRI, in Spanish) of the University of Navarra and the University of Navarra Clinic.

### **About ROVI**

ROVI is a fully integrated Spanish specialty pharmaceutical company engaged in the research, development, in-licensing, manufacturing and marketing of small molecule and specialty biologic drugs. The Company has a diversified portfolio of products that it markets in Spain through its specialized sales force, calling on specialist physicians, hospitals and pharmacies. ROVI's portfolio of 27 principal marketed products is currently anchored by the internally-developed, second generation low molecular weight heparin, Bemiparin. ROVI's research and development pipeline is focused primarily on addressing currently unmet medical needs by developing new LMWH-based products and expanding applications for its existing LMWH-based products. ROVI manufactures the active biological ingredient (Bemiparin) for its principal proprietary products and for injectable pharmaceutical products developed by its in-house research team, and utilizes its state-of-the-art filling and packaging capabilities to provide a broad array of toll manufacturing services to leading international pharmaceutical companies, primarily in the area of pre-filled syringes. Additional information about ROVI is available on the company's website: [www.rovi.es](http://www.rovi.es)