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Positive results from the ABEL trial of Bemiparin in small cell lung cancer

According to the first conclusions obtained from an interim analysis presented today in the 5th International Conference on Thrombosis and Haemostasis Issues in Cancer, the addition of bemiparin improves the clinical results of the standard anti-tumour treatment for small cell lung cancer.

Madrid – 24 April 2010 – Laboratorios Farmacéuticos Rovi S.A. (www.rovi.es) announces that the results of an interim analysis of the ABEL clinical trial (Adjuvant Bemiparin Evaluation study in small cell Lung cancer) have been reported today, which aims to assess the effectiveness and safety of bemiparin (3,500 IU/day for 26 weeks) in patients with limited small cell lung cancer (SCLC) who are receiving standard anti-tumour treatment (platinum-based chemotherapy and radiotherapy).

The analysis of the main variable of the study has shown that the median progression-free survival was 410 days in the group of patients who received bemiparin, and 249 days in the control group who did not receive bemiparin (p=0.01). In addition, after 18 months of follow-up, 77% of the bemiparin group of patients had survived, compared to 20% of the control group who did not receive bemiparin (p<0.01)., with no increase observed in the incidence of hemorrhage.

The ABEL trial is a Phase II multi-centre clinical trial, designed as a proof of concept, in which 10 Spanish hospitals are participating. In accordance with the protocol approved for the trial, an interim analysis has been carried out after 30 randomized patients had

completed 18 months of follow-up. The results of this interim analysis were presented today in one of the plenary sessions of the 5th International Conference on Thrombosis and Haemostasis Issues in Cancer which is being held from 23 to 25 April 2010 in Stresa (Italy).

Several research studies have shown that low molecular weight heparins (LMWH) have certain anti-cancer properties that could be effective in slowing the progression of certain malignant cancers, and as a result improve survival[1]. Bemiparin is a second-generation LMWH which has recently been shown to have anti-angiogenic effects *in vitro* in various cancer cell lines[2].

Positive results

Dr. Eduardo Rocha, the Coordinator Investigator of the ABEL study and the Ordinary Professor of the Faculty of Medicine of the Navarra University (Spain) said that "*the results of this interim analysis are promising, as they are not only positive in terms of the progression-free survival, but also because they show that the addition of bemiparin in standard anti-tumour therapy could increase the overall survival of patients with limited small cell lung cancer. This is encouraging, as unfortunately with this sort of treatment this patient type continues to have a poor short term prognosis*." However, Dr. Rocha noted that these results "*refer to an interim analysis with a small sample of patients and therefore we must be cautious in interpreting them*."

The ABEL trial is a project that is sponsored by the Instituto Científico y Tecnológico of Navarra, S.A., with the cooperation of Rovi. The trial is currently continuing, with the inclusion of new patients stopped because of the very slow recruitment rate. The trial is expected to be concluded in the last quarter of 2010, and then the final analysis will be carried out with all the data obtained from the 39 patients included in the trial. At the end of this year, when the new results are available to Rovi, the company will update and announce its clinical development strategy for this new indication for bemiparin.

[1] Lecumberri R., Paramo JA, Rocha E. Anticoagulant treatment and survival in cancer patients. The evidence from clinical studies. Haemotologica 2005; 90: 1258-66.

[2] Marchetti M, Vignoli A, Cantalino E, Diani E, Bonacina G, Falanga A. Very Low Molecular Weight Heparins Retain the Capacity to Inhibit Endothelial Cell Migration and Capillary-Like Tube Formation Induced by Tumor Cells. Blood (51th ASH Annual Meeting Abstracts); 114: 3047.

About small cell lung cancer

Small cell lung cancer (SCLC) 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 20 to 25% of the total number of 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[3].

About the Instituto Científico y Tecnológico of Navarra

The Instituto Científico y Tecnológico of Navarra (ICT) is a not-for-profit entity, established by the University of Navarra to facilitate cooperation between companies and the University.

Since its establishment in 1986, the mission of the ICT has been to bring together university researchers and companies in order to facilitate and encourage research and to stimulate the transfer of knowledge and of research results generated at the University of Navarra and the Clinica Universidad de Navarra.

The ICT is the Office for the Transfer of the Results of Research (OTRI) of the University of Navarra and the Clinica Universidad de Navarra.

For further information, please go to http://www.unav.es/centro/ict/

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

[3] Maghfoor I, Perry M. Lung cancer, oat cell (small cell). eMedicine, 22 May 2009. http://emedicine.medscape.com/article/280104-print

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