



ROVI signs a co-operation agreement for a clinical trial to study the efficacy and safety of bemiparin in patients hospitalised with pneumonia caused by COVID-19

- **The project will be coordinated and managed by *Fundación de Investigación HM Hospitales***

Madrid – 14 April, 2020 – Laboratorios Farmacéuticos Rovi, S.A. (“ROVI”) has signed a co-operation agreement with *Fundación de Investigación HM Hospitales* to fund a clinical trial aimed to analyse the efficacy and safety of bemiparin in patients hospitalised with pneumonia caused by COVID-19 and D-dimer higher than 500 ng/mL.

The exploratory, single-arm Phase 2 clinical trial will be managed and coordinated by Dr. Antonio Cubillo Gracián of the HM Sanchinarro Hospital. Its objective will be to evaluate the effect of therapeutic doses of bemiparin on the evolution of patients hospitalised with pneumonia caused by COVID-19 and underlying coagulopathy.

By funding this clinical trial, ROVI, in co-operation with *Fundación HM Hospitales*, wishes to help to generate clinical evidence that facilitates the appropriate treatment of patients infected with coronavirus SARS-Cov-2. In the light of recent results of clinical trials conducted with patients in the Wuhan area of China the D-dimer, a marker of thrombin generation and fibrinolysis, might constitute a significant mortality prognostic index associated with COVID-19.

The fact that a coagulopathy is present in these patients has led to antithrombotic strategies being considered, particularly in patients admitted to ICUs and/or those who show organic damage or ischemic attacks, as described above. Although the best antithrombotic strategy has not yet been established, it seems that low-molecular-

weight heparins should be indicated in these patients, especially after they have been admitted to an ICU and/or when the D-dimer values are particularly high.

Therefore, this study focuses on the exploratory analysis and evaluation of the safety and efficacy of the use of bemiparin, hoping that the results will provide sufficient clinical evidence to improve the selection of patients who can receive antithrombotic therapies with which to improve their prognoses and reduce the mortality associated to COVID-19.

About ROVI

ROVI is a pan-European pharmaceutical company specializing and engaging in the research, development, contract manufacturing and marketing of small molecules and biological specialties. The company, in a continuous international expansion process, has subsidiaries in Portugal, Germany, the United Kingdom, Italy France and Poland, and has a diversified marketing portfolio of more than 40 products, among which its flagship product, Bemiparin, which is already marketed in 56 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its in-house developed enoxaparin biosimilar in Europe. ROVI continues to develop the ISM® Platform technology, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit www.rovi.es.