



## **TO THE NATIONAL STOCK MARKET COMMISSION (CNMV)**

Madrid, 10 February, 2015

### **REGULATORY FILING**

In accordance with article 82 of the Stock Market Act and following the Regulatory Filing with number 213748, dated 6<sup>th</sup> November 2014, related to the release of the nine-month period ended 30<sup>th</sup> September 2014 financial results, Laboratorios Farmacéuticos ROVI, S.A. (ROVI) informs that, as of yesterday's date, after the end of the validation phase, the European health authorities assessment process has been started, in order for ROVI to be granted the Marketing Authorization in Europe of a low-molecular-weight heparin, a biosimilar of enoxaparin. The European registration process for this drug is expected to take between five and twelve months. It should be noted in any case that the assessment process is subject to interruptions and extensions if the European health authorities require additional information. Likewise, it should be pointed out that the outcome of the registration process (which may be favourable or unfavourable) cannot be known until it concludes. ROVI will continue to inform on this European evaluation process, as well as on the registration process of the same drug before the FDA (U.S. Food and Drug Administration), as the calendar for registration, in both Europe and the United States, progresses.

I remain

Yours faithfully,

Juan López-Belmonte Encina  
Chief Executive Officer  
Laboratorios Farmacéuticos ROVI, S.A.