TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, 25 April, 2023

INSIDE INFORMATION

In compliance with the disclosure duties set out in article 226 of the consolidated text of Law 6/2023 of 17 March on Securities Markets and Investment Services, further to the information disclosed to the market and published as inside information No. 1671 on 23 November, 2022, Laboratorios Farmacéuticos ROVI, S.A. (ROVI) is reporting on the clinical development of Letrozole ISM® and, in particular, discloses that, after a number of steps with the United States Food and Drug Administration (FDA), it has decided to commence the clinical development of a new three-monthly formulation of Letrozole (hereinafter, Letrozole LEBE), rather than the initially planned annual formulation of Letrozole ISM®. The objective of this new development is to reach bioequivalence in the plasma levels of letrozole in comparison with the daily administration of oral doses of Femara® 2.5 mg.

With this new clinical programme for Letrozole LEBE, ROVI estimates it could reduce the research times in comparison to those for an annual formulation of the product, thus making it likely that the three-monthly formulation could be marketed several years earlier and, furthermore, the investment necessary to attain the objectives of this project could also be reduced.

The attached note contains further information on the aforementioned project. A press release, which can be accessed through the Company's website, will be issued today.

I remain,

Yours faithfully,

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

Press Release from ROVI

ROVI COMMENCES CLINICAL DEVELOPMENT OF A NEW THREE-MONTHLY FORMULATION OF LETROZOLE (LETROZOL LEBE)

- The objective of the new three-monthly formulation is to reach bioequivalence in the plasma levels of letrozole in comparison with the daily administration of oral doses of Femara® 2.5 mg.
- With this new clinical programme for Letrozole LEBE, ROVI estimates it could reduce the research times in comparison to those for an annual formulation, thus making it likely that the three-monthly formulation could be marketed several years earlier.
- ROVI forecasts that the investment necessary to attain the objectives of this project could be reduced.

Madrid, 25 April, 2023

The positive results of the LISA-1 trial, of which ROVI has already informed the market, showed that the first development of letrozole (annual Letrozole ISM®) allows an oestrogen suppression higher than that of Femara® to be predicted (with an initial dose of 100 mg plus a further 100 mg after 8 weeks, and annual maintenance doses of 100 mg, compared with daily oral doses of 2.5 mg), maintaining plasma levels of letrozole significantly lower than those reached with daily oral doses of 2.5 mg of Femara®, taking account of the fact that the inhibition of the enzyme aromatase and, therefore, a reduction in oestrogen synthesis is the only known pharmacological mechanism of letrozole.

ROVI sought the advice of the United States Food and Drug Administration (FDA) with a view to using the suppression of the plasma oestrogen levels (oestradiol and estrone) as a surrogate efficacy endpoint in a clinical trial on the superiority of Letrozole ISM® over Femara® in oestrogen inhibition in parallel groups of post-menopausal women with early hormone-dependent breast cancer. The proposal is based on the fact that oestrogen inhibition is letrozole's only pharmacological mechanism. However, the FDA rejected the use of this variable as a surrogate efficacy endpoint.

ROVI contacted the FDA again on 26 October, 2022 to reach an agreement on the clinical development of the product. As reported at the Capital Markets Day of November 2022, the FDA required ROVI to perform a clinical efficacy trial in women with advanced breast cancer using Progression Free Survival (PFS) or the Objective Response Rate (ORR) as the key variable. Likewise, the FDA suggested that further advice should be requested ("End of Phase 2 meeting") after completion of said clinical trial to evaluate a new study that supported registration of the product.

In the light of the advice received from the FDA, the clinical development that would foreseeably be required to obtain marketing authorisation (at least in the United States) for the annual formulation of Letrozole ISM® would entail, first, a Phase 2 clinical trial on Letrozole ISM® vs Femara®, both medicines being combined with CDK 4/6 inhibitors, in post-menopausal women with advanced breast cancer and, subsequently, a Phase 3 trial in women with early breast cancer. This clinical path would probably last more than ten years and would require an investment much higher than initially planned before the dossier to apply for marketing authorisation for the product could be

filed. As a result, the company has decided to place the clinical development of annual Letrozole ISM® on hold for the time being.
However, the knowledge acquired with the results of the LISA-1 trial have enabled ROVI to use the time to progress with the preclinical development of a new three-monthly formulation of letrozole (Letrozole LEBE), which aspires to obtain plasma levels equivalent to those obtained with daily oral doses of 2.5 mg of Femara®. Currently, this candidate has completed all the preclinical evaluation phases and is available to commence its clinical development.

Consequently, ROVI has recently applied in Europe for authorisation of a clinical trial to evaluate the safely and pharmacokinetic characterisation of single increasing doses of Letrozole LEBE in healthy post-menopausal women. This new clinical trial (LEILA-1 study) is designed in several cohorts. In each one of them, the volunteers will take 2.5 mg of Femara® daily for 14 days and, after a washout period of at least 28 days, will receive a single dose of Letrozole LEBE. This trial would last approximately two years and cost around 5 million euros.

The objective of this trial is (i) to validate the conclusions reached in the preclinical development of the product regarding its capacity to be bioequivalent to the oral formulation and (ii) to identify the dosage of Letrozole LEBE necessary for humans to obtain steady-state plasma levels equivalent to Femara®.

After completing this first clinical trial, ROVI plans to conduct a pivotal clinical trial on the bioequivalence/bioavailability of Letrozole LEBE in accordance with the requirements of the FDA's 505 (b)(2) regulatory pathway and Directive 2001/83/CE of the European Parliament. ROVI intends this clinical trial to evaluate the steady-state bioequivalence of Letrozole LEBE vs Femara®. The trial would have an estimated duration of around two years.

In accordance with the results that can be expected from the LEILA-1 study, ROVI anticipates two possible clinical paths to support to the product's marketing authorisation:

1. If the results of the LEILA-1 pharmacokinetic characterisation trial make it foreseeable that Letrozole LEBE meets bioequivalence criteria; in this case, ROVI will file a dossier applying for marketing authorisation for the product after completion of the bioequivalence/bioavailability study.

2. If the results of the LEILA-1 pharmacokinetic characterisation trial make it foreseeable that Letrozole LEBE does not meet all the bioequivalence criteria but demonstrates bioequivalence in minimum steady-state concentrations of letrozole; in this case, ROVI might need to also conduct a single clinical efficacy trial to support the product's marketing authorisation.

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 89 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its in-house developed enoxaparin biosimilar in Europe and it is now being marketed in 39 countries. 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 further information, please visit www.rovi.es

Note on forward-looking statements

This press release contains forward-looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial performance or achievements of ROVI, or its industrial results, to be materially different from any future results, performance, or achievements expressed or implied by such forward looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI clarifies that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this press release.