

## Green light to start marketing in Japan

### REIG JOFRE CERTIFIED BY THE JAPANESE AGENCY FOR THE MANUFACTURE OF A STERILE INJECTABLE FOR HOSPITAL USE

- The process is part of the agreement with Maruishi Pharma for the marketing of state-of-the-art injectables for hospital use in Japan, the second largest pharmaceutical market in the world.
- Together with the European (EMA) and American (FDA) agencies, the Japanese agency is part of the three major medicine regulatory agencies in the world.
- Reig Jofre estimates that the contract with Maruishi Pharma will contribute 10% of the annual volume of the company's non-antibiotic sterile injectables.

**Barcelona (Spain), February 23, 2016.** Reig Jofre completed successfully the process to be certified by the Japanese regulatory agency for the marketing of a sterile injectable for hospital use, co-developed with Spanish Kern Pharma, and which Reig Jofre manufactures in its facilities in Spain.

This important milestone gave green light to the start of exports to Japan as of this week, to meet the agreement signed in March 2015 with Japanese Maruishi Pharma.

Japan is the second largest pharmaceutical market in the world and the Japanese agency is one of the three most important medicine regulatory agencies in the international scene, together with the European (EMA) and the American (FDA) agencies.

Featuring three times the population of Spain, Japan has a pharmaceutical spending volume ten times higher than Spain, which makes it a market of great interest, not only for the business potential but also for the stability thereof, linked to the cultural loyalty of Japanese customer compared to other markets.



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The European, American and Japanese agencies are integrated into the International Conference on Harmonization (ICH), which formally and jointly regulates the quality standards that apply in good manufacturing practices worldwide.

To enter Japan confirms therefore the high quality standards of Reig Jofre, who trusts that the regulatory and quality requirements for this market will provide in the future new business opportunities in this and other markets in Asia, where Reig Jofre is carrying out ongoing similar certification processes.

Specifically, the company is finalizing the certification of its injectables facilities by the agencies of Korea and Indonesia, where it is estimated that Reig Jofre could get the approval in the third quarter of 2016 and the second quarter of 2017, respectively.

With 60% of sales outside Spain, Reig Jofre conveys its international presence through agreements with licensees in markets where it does not have a direct presence for the marketing of products developed by the own R&D team.

Asia and Oceania, of particular interest to Reig Jofre due to its size and growth potential, represented 5% of the 152.5 million euro in sales achieved by Reig Jofre in 2014. In those markets, the company was mainly present in the Middle East and Oceania to date, so the new contract will boost the presence of Reig Jofre in Eastern Asia.

According to Ignasi Biosca, CEO of Reig Jofre: *"In our business plan for 2015-2019 we incorporated expansion investments amounting to 8 million euros to further enhance our position and technological capacity in the development and manufacture of antibiotics and sterile injectables to meet the growing demand. These categories are our international spearhead, while we continue to develop our portfolio of dermatology, respiratory and gynaecology."*

Reig Jofre closed 2014 with sales of 152.5 million euro and net profit of 6.9 million euro. The company will disclose 2015 results on February 29.

Receive Reig Jofre's news by registering in the company's **subscription center** of the new corporate website: **[www.reigjofre.com](http://www.reigjofre.com)**



## **About Reig Jofre**

After the merger between Laboratorio Reig Jofre and Natraceutical, the new Reig Jofre is a pharmaceutical company whose business is divided into two major areas: one main for the marketing and manufacture of own developments (RJF Pharma, approximately 78% of sales in 2014) and one of specialized contract development and manufacturing (RJF CDMO, 22% of sales in 2014). At its core activity, the company focuses on the development of specialised-technology products (antibiotics and injectable); therapeutic-specialty products in the areas of dermatology, gynaecology and respiratory; and nutritional supplements and consumer healthcare. The company directs its R&D to develop new indications and/or dosage forms of known active principles, generic medicines with a special focus on beta-lactam and lyophilized injectable antibiotics, topical dermatological products, OTCs and nutritional supplements as well as the development of new innovative molecules in partnership with start-ups and research centres.

Reig Jofre trades on the Spanish stock exchange under the ticker RJF. Total outstanding shares: 63,214,220.

## **For further information**

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### **Investors and analysts**

Gloria Folch  
Head of Investor Relations  
REIG JOFRE  
Tel. +34 93 480 67 10 – ext. 1241  
gloria.folch@reigjofre.com

### **Media**

Ricardo Franco  
ATREVIA  
Tel. +34 93 419 06 30  
rfranco@atrevia.es