

## **TO THE NATIONAL SECURITIES MARKET COMMISSION**

For the purposes of article 227 of Law 6/2023, of 17 March, on Securities Markets and Investment Services, and concordant provisions, Faes Farma, S.A. hereby informs the market of the following

### **OTHER RELEVANT INFORMATION**

#### **1. Approval of bilastine in China**

China's National Drug Administration (NPMA) has announced the approval of bilastine for the symptomatic treatment of urticaria in adult and adolescent patients aged 12 years and older, following the successful completion of local clinical studies.

This approval represents a new milestone in the history of bilastine and in the international expansion of Faes Farma's business, as well as a new recognition of the quality of the Group's research product.

The Chinese antihistamine market has shown a strong growth trend in recent years and is already the third largest antihistamine market worldwide (435 million euros, IQVIA, 2022). It is surpassed by Japan with €692 million and Brazil with €491 million (both IQVIA, 2022), countries where bilastine enjoys high penetration (absolute leader in the former with 24% market share and leading prescription brand also in the latter, excluding generics and OTC).

Menarini, which already successfully markets bilastine in multiple territories in Europe and Asia, will be responsible for the promotion and marketing of the product in China.

#### **2. Bilastine in USA**

Hikma Pharmaceuticals also announced its decision to terminate the bilastine licensing agreement with Faes Farma in the US. This decision was influenced by the

lengthening of the registration process with the US FDA, as well as financial reasons due to the investments required (by Hikma) during this process.

### **About bilastinee**

Bilastine is a second generation antihistamine for the treatment of seasonal allergic rhinoconjunctivitis and chronic spontaneous urticaria in adults and children.

children. Bilastine exerts its effect as a selective histamine H1-receptor antagonist and should be administered once daily. The efficacy of bilastine in clinical trials is comparable to that of cetirizine and desloratadine, with an excellent safety and tolerability profile, showing drowsiness rates not different from placebo, which means a non-sedating effect at therapeutic doses. Bilastine was developed entirely by Faes Farma, S.A. and is currently approved in 127 countries. Faes' bilastine achieved total revenues of 323 million euros in 2022 (IQVIA, Faes Farma sales + licensees), reaching a leading position in some of the world's main markets.

Leioa, 27 June 2023.