

## Press release

### Alfasigma announces the Completion of Marketing Authorisation Transfer for Jyseleca® in the European Union

- Following a positive opinion from the EMA, the transfer of marketing authorization of Jyseleca from Galapagos NV to Alfasigma S.p.A has been approved by the European Commission.
- Alfasigma S.p.A. is responsible for providing filgotinib in Rheumatoid Arthritis and Ulcerative Colitis to patients in the European Union.

*Bologna/Milano, 29 August 2024* – Alfasigma S.p.A. today announced the completion of the transfer of marketing authorization of Jyseleca® (filgotinib) from Galapagos NV (Euronext & NASDAQ: GLPG) to the Italian pharmaceutical company in the European Union.

The marketing authorization transfer was approved by the European Commission following a positive opinion from the European Medicines Agency (EMA) on 2<sup>nd</sup> August 2024.

This update follows the transaction completed on 31<sup>st</sup> January 2024 in which Alfasigma acquired the Jyseleca® (filgotinib) business<sup>1</sup> from Galapagos. With this acquisition, Alfasigma consolidated its commitment to specialty pharmaceuticals, adding an innovative product to its portfolio in the gastrointestinal and rheumatological therapeutic areas, that addresses very important patients' unmet needs.

Jyseleca® (filgotinib) is a once-daily oral JAK1 preferential inhibitor, a class of drugs with an innovative mechanism of action and already approved for two indications: Rheumatoid Arthritis (approved in 2020) and Ulcerative Colitis (approved in 2021).

Furthermore, Alfasigma Group enhanced its presence in the European markets with the acquisition of Jyseleca®, and expanded in the Northern European markets: today Alfasigma Group has branches in Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Ireland, Italy, the Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, Switzerland, and the UK.

#### About filgotinib

Filgotinib is currently approved for the treatment of moderate to severe active RA and UC by the relevant regulatory authorities in the European Union, Great Britain, and Japan.

It is marketed as Jyseleca® in Europe and Japan for the treatment of adults with moderate to severe active RA who have responded inadequately or are intolerant to one or more disease modifying anti-rheumatic drugs. Filgotinib is also marketed as Jyseleca® in Europe and Japan for the treatment of adult patients with moderate to severe active ulcerative colitis (UC) who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. Jyseleca® 100mg and 200mg are registered in the above-mentioned territories. The European Summary of Product Characteristics for filgotinib, which includes contraindications and

---

<sup>1</sup> <https://www.alfasigma.com/corporate/alfasigma-completes-transaction-to-acquire-the-jyseleca-business-from-galapagos-for-up-to-e170-million/>



special warnings and precautions, is available at [www.ema.europa.eu](http://www.ema.europa.eu). The Great Britain Summary of Product Characteristics for filgotinib can be found at [www.medicines.org.uk/emc](http://www.medicines.org.uk/emc) and the Northern Ireland Summary of Product Characteristics for filgotinib can be found at [www.emcmedicines.com/en-GB/northernireland](http://www.emcmedicines.com/en-GB/northernireland), respectively. The interview form from the Japanese Ministry of Health, Labour and Welfare is available at [www.info.pmda.go.jp](http://www.info.pmda.go.jp).

#### About Alfasigma

Alfasigma is one of Italy's leading pharmaceutical companies with a strong international positioning. The Group has a worldwide presence in over 100 countries where about 4000 people work in research, development, production and distribution. Its historical headquarters is in Bologna, to which is added Milan, while the production sites are: in Italy, in Pomezia (RM), Alanno (PE), Sermoneta (LT) and Trezzano Rosa (MI) and abroad in Tortosa in Spain and in Shreveport (Louisiana) in the United States. The R&D laboratories are in Pomezia and in the Parco Scientifico Tecnologico Kilometro Rosso in Bergamo. Alfasigma's mission is to improve people's health and quality of life by offering caregivers and healthcare personnel therapeutic solutions according to the highest standards of quality and safety.

#### Contact:

Corporate Communication Director: Simona Gelpi – [simona.gelpi@alfasigma.com](mailto:simona.gelpi@alfasigma.com)

Press Office:

Gea Gardini - [gea.gardini@alfasigma.com](mailto:gea.gardini@alfasigma.com); +39 334 6090384

Giulia Bergami - [giulia.bergami@alfasigma.com](mailto:giulia.bergami@alfasigma.com)

Tancredi Intelligent Communication

Emma Valgimigli [emma@tancredigroup.com](mailto:emma@tancredigroup.com)

Emma Hodges [hemma@tancredigroup.com](mailto:hemma@tancredigroup.com)

[alfasigma@tancredigroup.com](mailto:alfasigma@tancredigroup.com)

+44 203 434 2330