Press Release

Filgotinib Shows Positive Topline Results Across Full Spectrum of Axial Spondyloarthritis in OLINGUITO Phase 3 Study

- *Alfasigma plans to submit data from the OLINGUITO Phase 3 clinical trial to European Medicines Agency (EMA) and UK's Medicines Healthcare products Regulatory Agency (MHRA) to seek market authorization for filgotinib in the treatment of adults with active axial spondyloarthritis (axSpA).*
- *Filgotinib, an oral, once-daily JAK1 preferential inhibitor, met the primary endpoint in the OLINGUITO Phase 3 clinical trial, demonstrating efficacy across the full spectrum of axSpA (r-axSpA and nr-axSpA). The safety profile was consistent with previous filgotinib studies, with no unexpected events observed.*
- *AxSpA is a chronic inflammatory disease primarily affecting young adults, typically emerging during the third decade of life, with only 40-50% of patients with axSpA achieving adequate response with current treatments.*
- *If approved, filgotinib would offer a new oral treatment option for patients with axSpA expanding the treatment landscape in a therapeutic area marked by significant unmet needs.*

Bologna, Italy, July 28, 2025 – Alfasigma S.p.A today announced positive topline results from the OLINGUITO Phase 3 clinical trial (NCT05785611; Eudra CT 2022-501354-10-01),[i] evaluating filgotinib (marketed as Jyseleca® in approved indications) to treat adult patients with active axial spondyloarthritis (axSpA).

Filgotinib, an oral, once-daily JAK1 preferential inhibitor, met the primary endpoint in the OLINGUITO Phase 3 clinical trial in active axSpA. Efficacy was demonstrated across the full spectrum of axSpA, including both radiographic (r-axSpA) and non-radiographic (nr-axSpA) forms. The safety profile was consistent with previous studies, with no unexpected events observed.[ii] Filgotinib is currently approved for the treatment of moderate to severe active rheumatoid arthritis (RA) and ulcerative colitis (UC).[iii]

"These positive OLINGUITO topline results demonstrate filgotinib's potential to address this critical unmet need for patients with axial spondyloarthritis, with only half responding adequately to current therapies," said **Daniele D'Ambrosio**, Chief Development Officer at Alfasigma. "Based on these encouraging results, we intend to submit for an extension of filgotinib's current indications, offering a potential new treatment option for patients with axial spondyloarthritis who often struggle with debilitating symptoms from a young age. We thank all patients, investigators and staff at study sites whose participation made this important achievement possible."

"These results from the OLINGUITO Phase 3 clinical trial clearly support the potential of filgotinib as a treatment option for patients living with axSpA at all stages of the disease. The burden of disease for these patients remains high as treatment options are limited. It is therefore encouraging that the primary endpoint for both axSpA indications was met in dedicated studies", said **Professor Xenofon Baraliakos**, Head of Rheumatology at the Rheumazentrum Ruhrgebiet, Herne, Germany, Professor for Internal Medicine and Rheumatology at the Ruhr-University Bochum, Germany.

AxSpA is a chronic inflammatory disease primarily affecting young adults, typically emerging during the third decade of life. It primarily affects the axial skeleton (spine and sacroiliac joints) causing significant pain, stiffness and reduced mobility.[iv] Despite several efficacious anti-inflammatory treatment options, only about 40% to 50% of patients with axSpA achieve a relevant treatment response, and an even smaller proportion (approximately 10%-20%) reach remission or an inactive disease activity state within 16 to 24 weeks of treatment initiation.[v]

About OLINGUITO

The OLINGUITO Phase 3 clinical trial (NCT05785611; Eudra CT 2022-501354-10-01) was designed – in compliance with the European Medicines Agency's (EMA) guidelines – to evaluate the efficacy and safety of filgotinib in patients with active axial spondyloarthritis (axSpA). OLINGUITO was preceded by the TORTUGA Phase 2 clinical trial (NCT03117270), a randomized, double-blind, placebo-controlled clinical trial that demonstrated the safety and efficacy of filgotinib in adult patients with moderately to severely active ankylosing spondylitis (also known as r-axSpA, i.e., the damage caused by the disease can be seen on X-rays).[vi]

The first patient entered the OLINGUITO Phase 3 clinical trial in April 2023. The trial consisted of two randomized, double-blind, multi-center, parallel-group studies of patients with active axSpA who had an inadequate response to conventional or biological treatments. Study A included 258 patients with r-axSpA, while study B included 237 patients with non-radiographic axSpA (nr-axSpA, i.e., the patient had symptoms of axSpA but damage was not yet visible on X-rays). After enrollment, patients in each study were randomized (1:1) to receive treatment with oral filgotinib 200 mg, or matching placebo, once daily for 16 weeks.

The primary endpoint for both studies was the proportion of patients who achieved an Assessment of SpondyloArthritis international Society 40% improvement (ASAS40) at week 16.[vii] Thereafter, patients without risk factors entered an open-label treatment period in which they received filgotinib 200 mg once daily up to Week 52.

Patients from study A and study B who achieved sustained low disease activity or inactive disease during the open-label period were re-randomized (1:1) at Week 52 to receive double-blind filgotinib 100 mg or 200 mg up to Week 104. In patients above 65 years of age and those with increased risk factors for cardiovascular disease or malignancies, at Week 16 in the case of achievement of disease control after treatment with 200 mg once daily, the dose was reduced to 100 mg once daily for up to Week 104.

All patients receiving filgotinib 100 mg daily had the option to increase to 200 mg daily in case of flares. Week 52 visits for all patients were completed in May 2025. After week 104, select eligible patients who achieve ASAS40 response without high disease activity, per investigators' judgement, will enter the Open Label Extension (OLE) study. This OLE is designed to collect additional long-term safety and efficacy data for a duration of approximately 2.5 years.

About Filgotinib

Filgotinib (marketed as Jyseleca®) is currently approved by the relevant regulatory authorities in the European Union, United Kingdom, Japan, Taiwan, South Korea and Singapore. In Europe, United Kingdom, Japan, Taiwan, South Korea and Singapore, filgotinib is approved for the treatment of moderate to severe active rheumatoid arthritis in adults who have not responded adequately or cannot tolerate other disease modifying anti-rheumatic drugs (DMARDs). Filgotinib is also approved in Europe, United Kingdom, Japan Taiwan, South Korea and Singapore for the treatment of adult patients with moderate to severe active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. Filgotinib 100mg and 200mg are registered in the above-mentioned territories. The European Summary of Product Characteristics for filgotinib, which includes contraindications and special warnings and precautions, is available at www.ema.europa.eu. The United Kingdom Summary of Product Characteristics for filgotinib can be found at www.medicines.org.uk/emc. The interview form from the Japanese Ministry of Health, Labor and Welfare is available at www.info.pmda.go.jp. The Taiwan Food and Drug Administration Assessment Report for filgotinib can be found at www.fda.gov.tw. The Korean Ministry of Food and Drug Safety report on filgotinib can be found here www.mfds.go.kr/eng/brd. The Singapore Summary of Product Characteristics for filgotinib can be found at www.hsa.gov.sg.

About axial spondyloarthritis

Axial spondyloarthritis (axSpA) is a chronic inflammatory condition that primarily affects the axial skeleton (spine and sacroiliac joints). While persistent back pain and spinal stiffness are common initial symptoms, the disease often also presents with peripheral manifestations such as enthesitis, arthritis, and dactylitis, as well as extra-musculoskeletal features including uveitis, inflammatory bowel disease and psoriasis.[iv]

AxSpA comprises the whole spectrum of patients with and without radiographic sacroiliitis, that is, radiographic axSpA (r-axSpA; also known as ankylosing spondylitis, i.e., the damage caused by the disease can be seen on X-rays) and non-radiographic axSpA (nr-axSpA), respectively. AxSpA usually starts during the third decade of life; r-axSpA is more common in men than women, whereas there is an equal sex distribution among patients with nr-axSpA.[iv]

About Alfasigma

Alfasigma is a global pharmaceutical company founded over 75 years ago in Italy, where it is headquartered (in Bologna and Milan). The Group operates in over 100 markets spanning Europe, North and South America, Asia, and Africa. It has offices in several countries, including Italy, the US, Spain, Germany, Mexico, and China; production sites in Italy (Pomezia, RM; Alanno, PE; Sermoneta, LT; Trezzano Rosa, MI), Spain (Tortosa, Baix Ebre), and the United States (Shreveport, Louisiana); and R&D labs in Italy (Pomezia and Bergamo).

Alfasigma employs approximately 4,000 people dedicated to research, development, production, and distribution of medicinal products, contributing to its mission, *to provide better health and a better quality of life for patients, caregivers, and healthcare providers'*. It focuses on three main therapeutic areas: Gastroenterology, Vascular and Rheumatology. Its portfolio spans from primary care to specialty care, rare disease medications, and consumer health products, including medical foods and nutraceuticals.

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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Alfasigma. Various known and unknown risks, uncertainties, and other factors could lead to material differences between the actual future results, financial situation, development, or performance of the company and the estimates given here. Alfasigma assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

References

[i] OLINGUITO Clinical Trial (NCT05785611) Study Details | A Study Evaluating the Effect of Filgotinib in Participants With Active Axial Spondyloarthritis | ClinicalTrials.gov. Accessed July 2025.
[ii] The topline results of OLINGUITO Phase 3 clinical trial will become available in future scientific conferences and published in a peer-reviewed journal in due course.
[iii] https://www.ema.europa.eu/en/medicines/human/EPAR/jyseleca. Accessed July 2025.
[iv] Navarro-Compán V, et al., Axial spondyloarthritis. Lancet 2025; 405: 159–72
[v] Poddubnyy D, et al. Ann Rheum Dis 2025; 84(4): 538-546. doi: 10.1016/j.ard.2025.01.035
[vi] Van der Heijde D, et al. Lancet 2018; 392(10162): 2378-2387. doi: 10.1016/S0140-6736(18)32463-2
[vii] J. Sieper, et al. Ann Rheum Dis. 2009 Jun:68 Suppl 2:ii1-44. doi: 10.1136/ard.2008.104018. Based on the ASAS (Assessment of SpondyloArthritis International Society) assessment that includes four aspects (domains): patient global assessment, pain, function and inflammation. In order to meet ASAS40 response, 3 of the 4 domains should improve by at least 40% with a minimum 2-unit change on a scale of 0 to 10. For the remaining domain, there should be no deterioration (worsening) from baseline.