

This website contains materials, product information, and resources prepared for an international audience and intended for healthcare professionals, excluding those from France. JYSELECA is approved but not reimbursed in Denmark.

Data are correct as of 01/06/2022.

- I acknowledge that I have read and understand the statement above.

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Prescribing Information

Study Details

Visit JYSELECA

STRENGTH OF BALANCE

Discover the key efficacy and safety data on JYSELECA from 3 clinical trials in RA



REAL-WORLD EXPERIENCE

Watch this series to learn about the discovery of JYSELECA, how it was studied, and what rheumatology experts have to say

CLINICAL DATA

Watch this series of videos to learn more about the individual clinical trials assessing the safety and efficacy of JYSELECA in RA

MOA

This video series demonstrates the mechanism of action of JYSELECA and how it strikes a balance in JAK inhibition

REAL-WORLD EXPERIENCE

Learn about the discovery of JYSELECA, how it was studied, and what rheumatology experts have to say



Talking JYSELECA Series Trailer

Discovery

Featuring René Galien, PhD

Translational Research Lead, Galapagos France

Clinical Trials

Featuring Dr David Walker

Rheumatologist and Clinical Trial Investigator, UK

Bio-IR Patients

Featuring Prof. Dr X. Baraliakos

Rheumatologist, Germany

MTX-IR Patients

Featuring Prof. Dr Torsten Witte

Rheumatologist, Germany

CLINICAL DATA

Learn more about the individual clinical trials assessing the safety and efficacy of JYSELECA in RA

FINCH 1: MTX-IR

FINCH 2: Bio-IR

FINCH 3: Monotherapy

MOA

Learn about the mechanism of action of JYSELECA and how it strikes a balance in JAK inhibition

JYSELECA: Mechanism of Action

Striking a Balance in JAK Inhibition

Featuring Dr Paqui Gonzalez Traves

Research Scientist, United States

What is the role of JAK1 in RA?

Balancing inhibition of proinflammatory cytokine signalling via JAK1 and limiting impact on JAK2- and JAK3-related physiological functions^{2,*}

Proinflammatory signalling

IFN- α and IL-6

are examples of key cytokines responsible for inflammation in RA^{1*}

Several JAKs pairs modulate the signalling of key proinflammatory cytokines that cause inflammation, bone and cartilage destruction, and autoimmunity³

JAK1

Source: [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10000000/](#)

Normal physiological functions

IFN- γ , GM-CSF, and IL-15

are some of the cytokines responsible for normal physiological functions⁴

JAKs primarily drive many physiological functions, such as haemopoiesis (JAK2), NK-cell development (JAK1), and anterior defence (JAK3)⁵

JAK2, JAK3, and TYK2

The Goal: Striking a Balance

Image is illustrative and based on in vitro findings; clinical relevance is unknown. There are currently no head-to-head trials between JAK inhibitors.

* The role of JAK1 is not limited to proinflammatory cytokine signalling. These cytokines signal via JAK pairs, though they may depend predominantly on one JAK more than another for signalling. For example, IL-6 and IFN- γ both signal through JAK1/JAK2, but IL-6 may predominantly signal through JAK1, whereas IFN- γ is more dependent on JAK2.²

† Data are normalised against IFN- α .

‡ The most frequently reported adverse reactions were nausea (3.5%), upper respiratory tract infection (3.3%), urinary tract infection (1.7%), and dizziness (1.2%).¹

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the [National reporting systems](#) and to [DrugSafety.Global@glpg.com](#).

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Adapted from Traves et al.²

Data are based on in vitro whole-blood assays; clinical relevance is unknown. There are currently no head-to-head trials between JAK inhibitors.

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The most frequently reported adverse reactions were nausea (3.5%), upper respiratory tract infection (3.3%), urinary tract infection (1.7%), and dizziness (1.2%).¹

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Summary of Product Characteristics

X

Clinical Trial Programme

Study Design

Primary Endpoint

Evaluated across a comprehensive clinical trial programme

A solid foundation of clinical evidence in RA¹⁻⁵

3

Phase 3 trials¹
FINCH 1-3

2

Phase 2b trials^{2,3}
DARWIN 1 and 2

2

Long-term extension trials^{4,5}
DARWIN 3 and FINCH 4

FINCH 1-3¹

Three Phase 3, randomised, double-blind, placebo-controlled studies in patients with moderate to severe active RA.

DARWIN 1 and 2^{2,3}

Two Phase 2b, randomised, double-blind, placebo-controlled, dose-ranging studies in patients with moderate to severe active RA.

OVER
8000 _____

patient-years of exposure⁶

RA, rheumatoid arthritis.

References: 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022. 2. Westhovens R, Taylor PC, Alten R, et al. *Ann Rheum Dis.* 2017;76(6):998-1008. 3. Kavanaugh A, Kremer J, Ponce L, et al. *Ann Rheum Dis.* 2017;76(6):1009-1019. 4. Kavanaugh A, Westhovens R, Winthrop K, et al. *J Rheumatol.* 2021;48(8):1230-1238. 5. Long term extension study to assess the safety and efficacy of filgotinib in adults with rheumatoid arthritis (FINCH 4). Clinical trials identifier: NCT03025308. Updated January 14, 2021. Accessed January 20, 2022. <https://www.clinicaltrials.gov/ct2/show/NCT03025308>. 6. Winthrop K, Tanaka Y, Takeuchi T, et al. *Arthritis Rheumatol.* 2021;73(suppl 10).



Clinical Trial
Programme

Study
Design

Primary
Endpoint

Study design

Three Phase 3, randomised, double-blind, placebo-controlled trials in adult patients with moderate to severe active RA.¹



THE FINCH 1 STUDY

Patients with inadequate response to MTX (**MTX-IR**) randomised to¹:

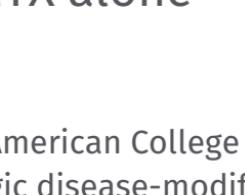
- JYSELECA 200 mg + MTX
- JYSELECA 100 mg + MTX
- Adalimumab + MTX
- Placebo + MTX



THE FINCH 2 STUDY

Patients with inadequate response to bDMARDs (**Biologic-IR**) randomised to¹:

- JYSELECA 200 mg + csDMARD
- JYSELECA 100 mg + csDMARD
- Placebo + csDMARD



THE FINCH 3 STUDY

Patients naïve to MTX therapy (**MTX-Naïve***) randomised to¹:

- JYSELECA 200 mg + MTX
- JYSELECA 100 mg + MTX
- JYSELECA 200 mg monotherapy
- MTX alone

ACR, American College of Rheumatology; bDMARD, biologic disease-modifying antirheumatic drug; csDMARD, conventional synthetic disease-modifying antirheumatic drug; DMARD, disease-modifying antirheumatic drug; IR, intolerance or inadequate response; MTX, methotrexate; RA, rheumatoid arthritis.

* JYSELECA is not indicated for use in DMARD-naïve patients.

Reference: 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022.



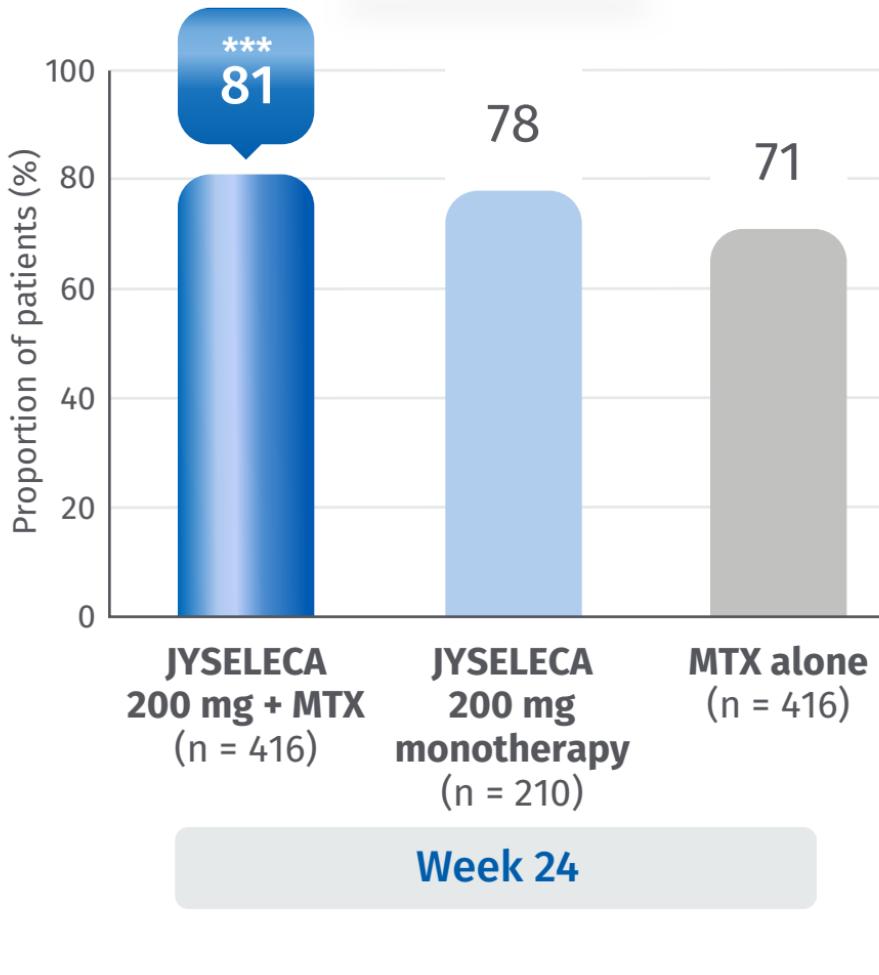
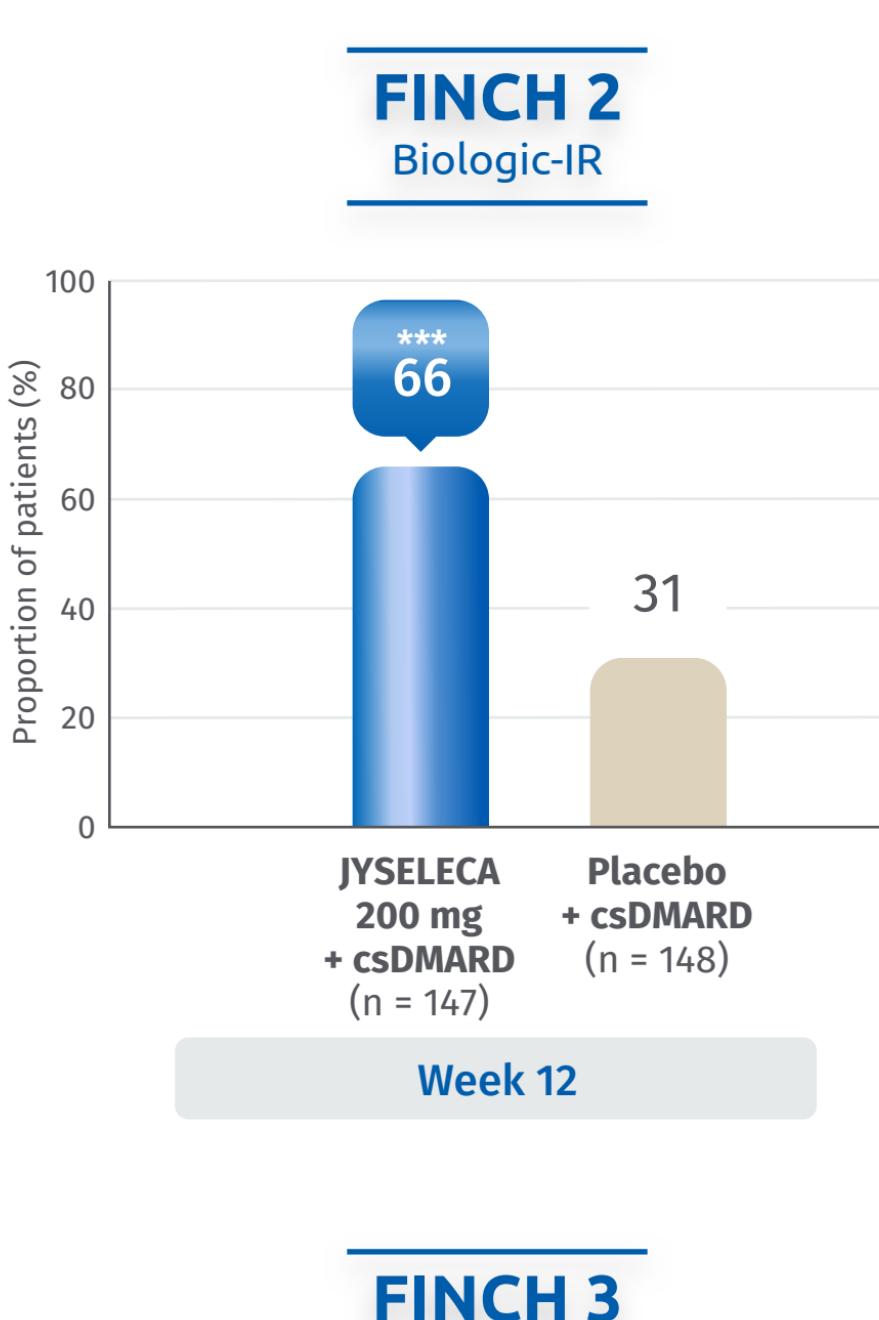
Clinical Trial Programme

Study Design

Primary Endpoint

JYSELECA met its primary endpoint of ACR20 across all Phase 3 trials¹

Across all Phase 3 trials, JYSELECA demonstrated significant ACR20 response at Week 12 (FINCH 1 and FINCH 2) and Week 24 (FINCH 3) vs placebo + MTX, placebo + csDMARD, or MTX alone.¹



^a JYSELECA is not indicated for use in DMARD-naïve patients.
*** P ≤ .001 vs placebo + MTX, placebo + csDMARD, or MTX alone.

ACR, American College of Rheumatology; bDMARD, biologic disease-modifying antirheumatic drug; csDMARD, conventional synthetic disease-modifying antirheumatic drug; DMARD, disease-modifying antirheumatic drug; IR, intolerance or inadequate response; MTX, methotrexate; RA, rheumatoid arthritis.

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PRODUCT INFORMATION FOR HEALTHCARE

PROFESSIONALS

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Abbreviated Summary of Product Characteristics:

Jyseleca® (filgotinib), 100 mg or 200 mg film-coated tablets.

Indications: Treatment of moderate to severe rheumatoid arthritis in adults who have had an inadequate response to, or who are intolerant to, one or more disease-modifying anti-rheumatic drugs (DMARDs). Can be used as monotherapy or in combination with methotrexate.

Dosage: Treatment should be initiated by a physician experienced in the treatment of rheumatoid arthritis. The tablets should be swallowed whole. For guidance on laboratory monitoring and dose initiation or discontinuation, see the Summary of Product Characteristics. Treatment should be discontinued if a patient develops a serious infection until the infection is under control. Adults: 200 mg once daily. Elderly ≥75 years: Recommended starting dose: 100 mg once daily. Moderate or severe renal impairment (CrCl 15 to <60 mL/min): 100 mg once daily. End-stage renal disease (CrCl <15 mL/min): Filgotinib has not been studied and is therefore not recommended. Severe hepatic impairment (Child-Pugh C): Filgotinib has not been studied and is therefore not recommended. Children <18 years: The safety and efficacy of filgotinib have not yet been established. No data available.

Contraindications: Hypersensitivity to the active substance or to any of the excipients, active tuberculosis (TB), active serious infections, pregnancy.

Warnings and precautions: Immunosuppressants: Combination with other potent immunosuppressants such as azathioprine, cyclosporine, tacrolimus, biological DMARDs or other Janus kinase (JAK) inhibitors is not recommended. Infections, including severe infections (most commonly pneumonia), have been reported. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with filgotinib. Elderly ≥75 years: Caution should be exercised due to higher incidence of serious infections. Tuberculosis: Patients should be screened for TB before initiating filgotinib. Filgotinib must not be used during active TB. In latent TB, standard antimycobacterial therapy should be given before filgotinib administration. Viral reactivation (including herpesvirus reactivation) has been reported in clinical trials. If the patient develops shingles, treatment should be temporarily withheld until the episode is resolved. Malignancy: Malignancies have been observed in clinical trials with filgotinib. Risks and benefits should be considered before initiating treatment for known malignancy other than well-treated non-melanoma skin cancer (NMSC), or when considering continuing treatment in patients who develop a malignancy. Patients at increased risk of skin cancer should have regular skin examinations. Haematological abnormalities: Treatment should not be initiated or should be discontinued temporarily in patients with absolute neutrophil count (ANC) <1 x 10⁹ cells/L, absolute lymphocyte count (ALC) <0.5 x 10⁹ cells/L or haemoglobin <8 g/dL observed during routine treatment. Vaccinations: Use of live vaccines during/immediately before treatment with filgotinib is not recommended. Cardiovascular risk: Risk factors (eg, hypertension, hyperlipidaemia) should be treated as part of normal treatment. Venous thromboembolism: JAK inhibitors should be used with caution in risk factors for DVT/PE or in connection with surgery and prolonged immobilisation. In case of clinical signs of DVT/PE, treatment should be discontinued and the patient evaluated immediately, followed by appropriate treatment.

Interactions: P-gp or BCRP inhibition: Caution should be exercised when administering substrates with a narrow therapeutic index concomitantly with filgotinib.

Side effects: Common: Urinary tract infection, upper respiratory tract infection, dizziness, nausea.

Overdose: In case of overdose, the patient should be monitored for signs and symptoms of side effects.

Treatment: General supportive measures, including monitoring of vital signs as well as observation of the patient's clinical status. It is not known if filgotinib can be removed by dialysis.

Pregnancy: Filgotinib is contraindicated during pregnancy. Women of childbearing potential must use effective contraception during treatment and for at least 1 week after stopping treatment.

Breastfeeding: Jyseleca must not be used during breastfeeding.

Fertility: The potential risk of reduced fertility/infertility should be discussed with male patients before initiating treatment.

Driving/operating machinery: Filgotinib has no or negligible influence on the ability to drive and operate machinery. However, patients should be informed that dizziness has been reported during treatment with Jyseleca.

Pack sizes: 30 and 3 x 30 tablets.

Price: See current medicine prices at

www.medicinpriser.dk.

Grant status: Not eligible.

Delivery: NBS (may only be dispensed to hospitals or on the prescription of specific specialists).

Marketing authorisation number: EU/1/20/1480/003, EU/1/20/1480/004

Marketing authorisation holder: Galapagos NV, Belgium.

The product information is abbreviated in relation to the product summary approved by the European Medicines Agency (EMA) dated 16.12.2021. A complete product

summary can be requested from the marketing authorisation holder or the Danish representative:

Galapagos, tel. +800 7878 1345 or viewed on EMA's

website.