

# STRENGTH *of* BALANCE

## Strong RA therapy with a proven safety profile<sup>1-5\*</sup>

JYSELECA is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). JYSELECA may be used as monotherapy or in combination with methotrexate (MTX).<sup>1</sup>

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](mailto:DrugSafety.Global@glpg.com).

EXPLORE HOW JYSELECA HELP YOUR PATIENTS

RA, rheumatoid arthritis

\* 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%).<sup>1</sup>

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

Materials have been prepared for an international audience and are intended for healthcare professionals, excluding those from France. JYSELECA is approved but not reimbursed in Denmark. Data are correct as of 01/06/2022.

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STUDY DETAILS

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 **Jyseleca**  
filgotinib  
JAK1-preferential inhibitor



# Galapagos at EULAR

We look forward to seeing you at the following events

## June 2022

### 01

WED

15:45 - 16:15 CEST

#### Patient-centred care in RA: cutting through the jargon

**Dr Lars Erik Kristensen** The Parker Institute, Copenhagen University Hospital, Copenhagen, Denmark

Learning objectives

- Review the **unmet needs** experienced by patients with RA and the importance of a comprehensive approach to care
- Explore the role of **JAK inhibitors** in addressing unmet needs for patients with RA
- Consider how to facilitate a **comprehensive approach to patient care** and discuss any potential barriers to clinical implementation
- Discuss how to integrate concrete steps towards **shared decision-making** in RA

### 02

THURS

17:30 - 18:45 CEST

#### Evolving patient care in RA: can JAK inhibitors meet patient and physician expectations for RA therapy with

**Prof. Roberto Caporal** University of Milan, Milan, Italy  
**Prof. Bruno Feutrel** Pitié-Salpêtrière Hospital, Paris, France  
**Dr James Galloway** King's College London, London, UK

Learning objectives

- Explore **efficacy and safety goals** patients and physicians in the treatment of RA
- Explore the **efficacy and safety profiles of JAK inhibitors** including data from the filgotinib clinical trial programme
- Review the importance of a **comprehensive management approach** for patients with RA
- Discuss how to optimally **align patient and physician treatment goals** to achieve favourable outcomes in RA

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Clinical Trial Programme

Study Design

Primary Endpoint

## Evaluated across a comprehensive clinical trial programme

A solid foundation of clinical evidence in RA<sup>1-5</sup>

3

Phase 3 trials<sup>1</sup>  
FINCH 1-3

### FINCH 1-3<sup>1</sup>

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

### DARWIN 1 and 2<sup>2,3</sup>

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

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).

2

Phase 2b trials<sup>2,3</sup>  
DARWIN 1 and 2

### DARWIN 3<sup>4</sup>

Ongoing open-label extension trial of DARWIN 1 and 2 studies.

### FINCH 4<sup>5</sup>

Ongoing double-blind extension trial of FINCH 1-3.

2

Long-term extension trials<sup>4,5</sup>  
DARWIN 3 and FINCH 4

over

8000

*patient-years of exposure<sup>6</sup>*

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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.<sup>1</sup>



THE FINCH 1 STUDY


Patients with inadequate response to MTX (**MTX-IR**) randomised to<sup>1</sup>:

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

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: <sup>1</sup> JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022.



THE FINCH 2 STUDY

Patients with inadequate response to bDMARDs (**Biologic-IR**) randomised to<sup>1</sup>:

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



THE FINCH 3 STUDY

Patients naïve to MTX therapy (**MTX-Naïve\***) randomised to <sup>1</sup>:

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

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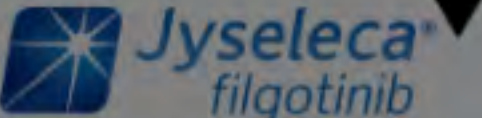
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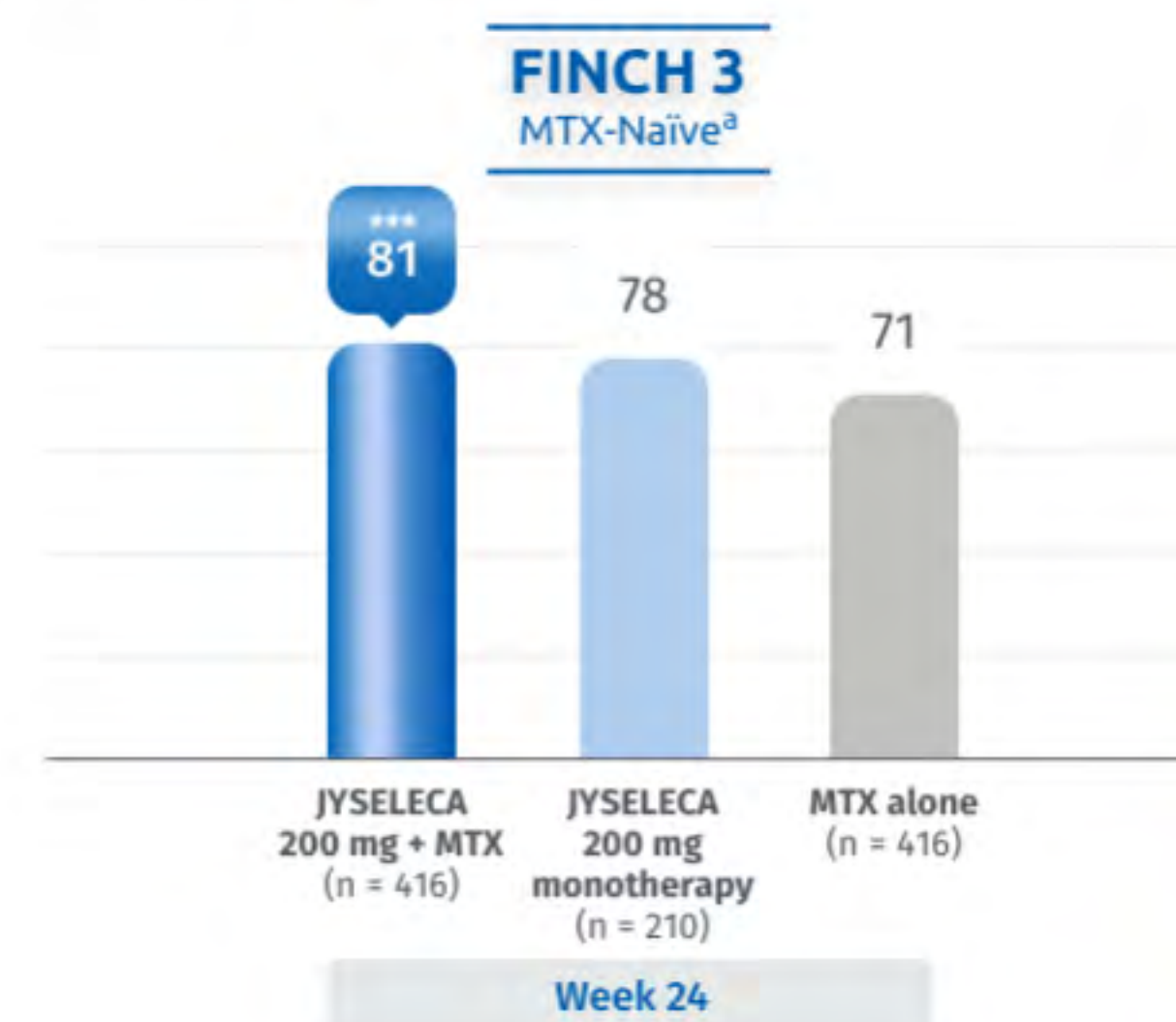
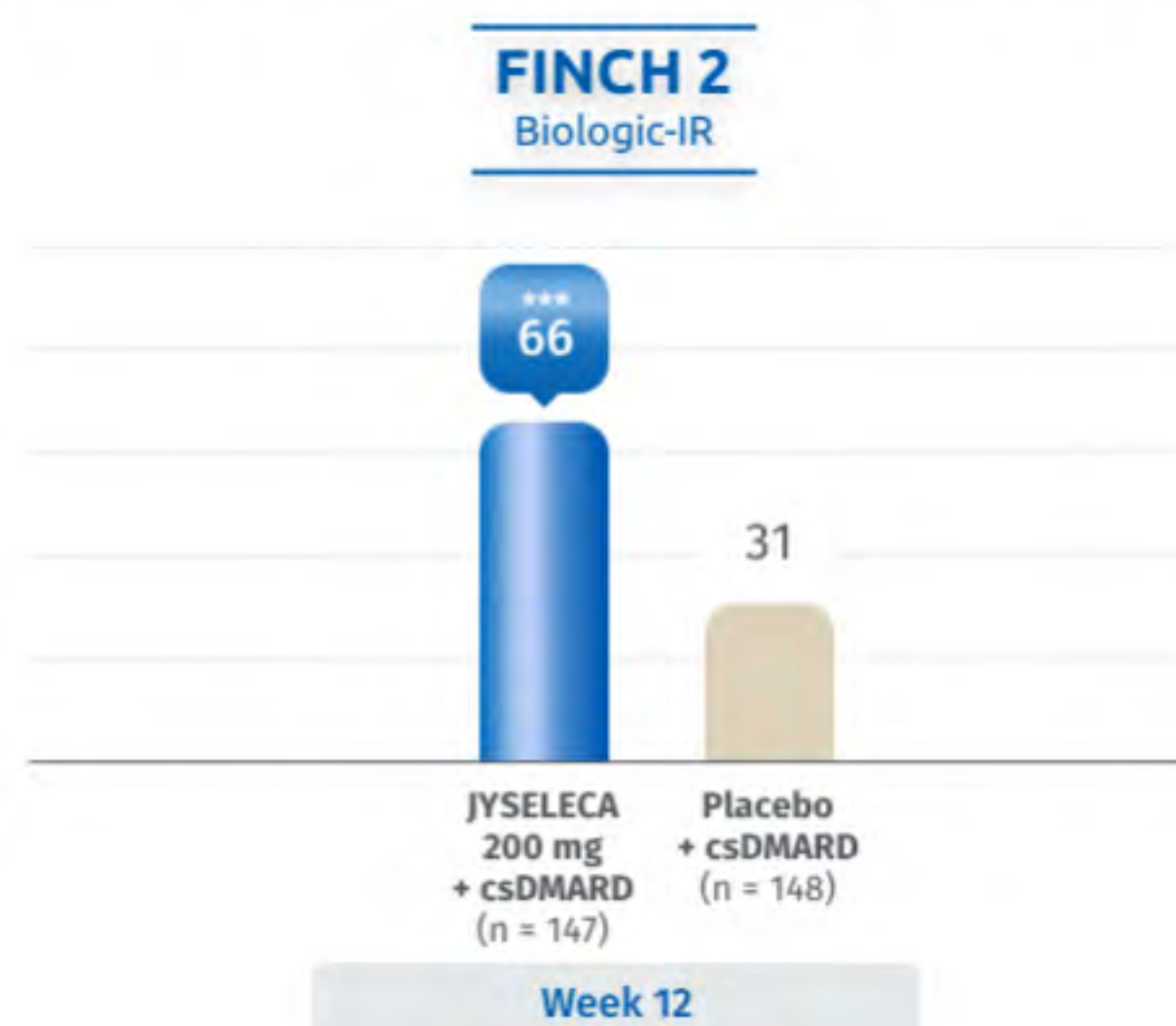
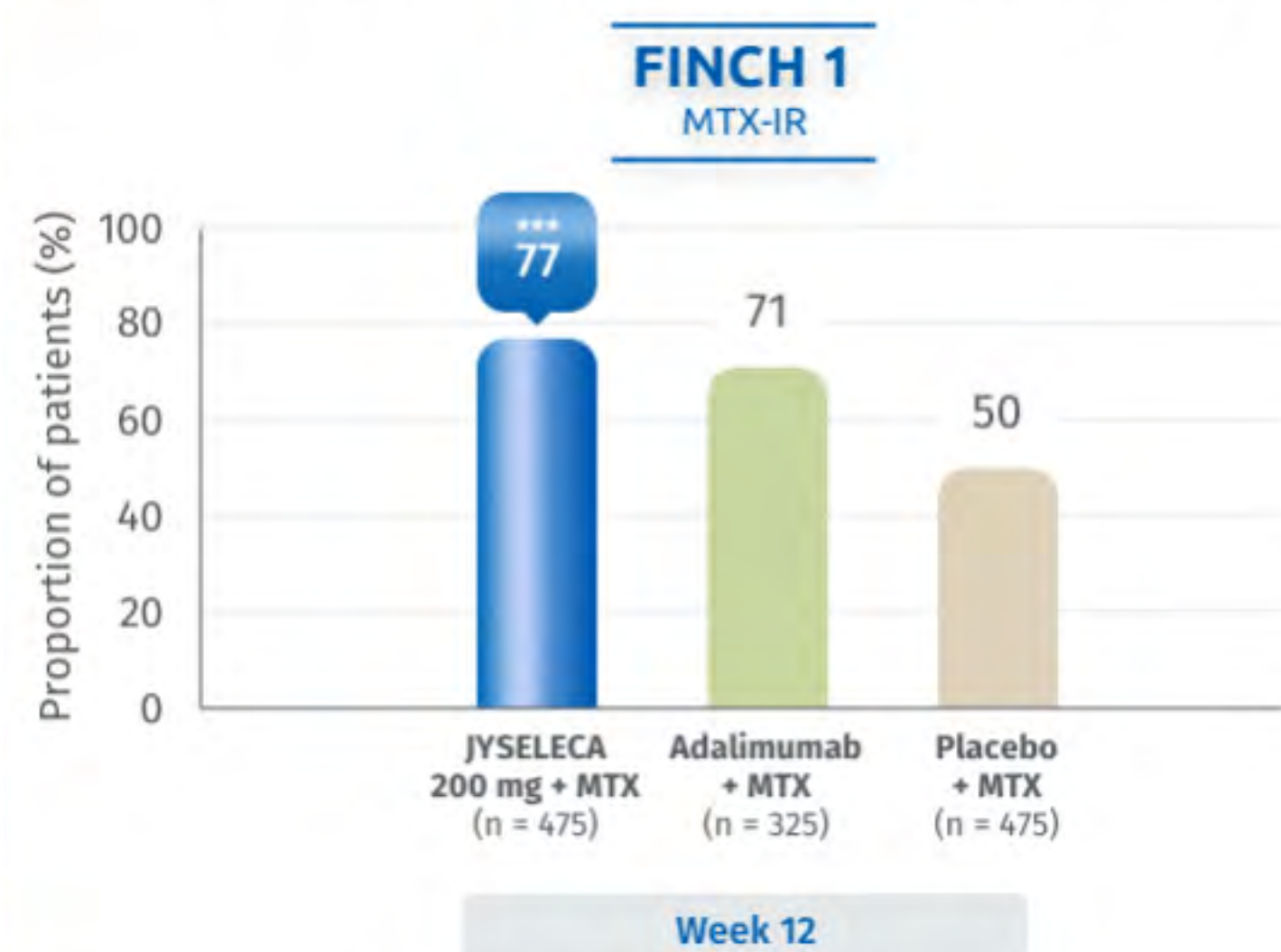
Clinical Trial Programme

Study Design

Primary Endpoint

## JYSELECA met its primary endpoint of ACR20 across all Phase 3 trials<sup>1</sup>

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.<sup>1</sup>



<sup>a</sup> 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.

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



PLEASE READ THE SUMMARY OF PRODUCT CHARACTERISTICS BEFORE PRESCRIBING. IN PARTICULAR WITH REGARD TO SIDE EFFECTS, WARNINGS, AND CONTRAINDICATIONS.



# Strong RA therapy across all key clinical outcomes<sup>1,2</sup>

With JYSELECA 200 mg + MTX at Week 24<sup>1</sup>

58%

of patients achieved **ACR50** vs 52% with  
adalimumab + MTX

36%<sup>§</sup>

of patients achieved **ACR70** vs 30% with  
adalimumab + MTX

88%

of patients had **no  
radiographic progression**  
vs 86% with adalimumab + MTX

48%<sup>§§§</sup>

of patients achieved **remission (DAS28-CRP <2.6)**  
vs 36% with adalimumab + MTX

## JYSELECA achieved nominally significant improvements vs adalimumab across key clinical outcomes<sup>1,\*</sup>

ACR, American College of Rheumatology; CRP, C-reactive protein; DAS28, Disease Activity Score 28 joints; IR, inadequate response; MTX, methotrexate; RA, rheumatoid arthritis.

§ P ≤ .05, §§§ P ≤ .001 vs adalimumab + MTX (nominal P values).

\* Patients in the study were MTX-IR. The FINCH 1 trial was not powered to detect superiority of JYSELECA vs adalimumab for ACR responses, radiographic progression, or remission.

**References:** 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2021. Combe B, Kivitz A, Tanaka Y, et al. Ann Rheum Dis. 2021;80(7):848-858.

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# JAK1-preferential inhibitor with a proven safety profile<sup>1-5,\*</sup>

- › Generally well tolerated<sup>1</sup>
- › Low rates of JAKi-associated AEs, including serious infections, herpes zoster, and VTE, similar to adalimumab<sup>2,4,\*</sup>
- › Consistent safety profile up to 6.8 years<sup>5</sup>

Throughout 1 year of treatment with JYSELECA<sup>6</sup>:

**3.0/100PY**

*Serious infections EAIR  
vs 3.4/100 PY adalimumab + MTX*

**1.2/100PY**

*Herpes zoster EAIR  
vs 0.7/100 PY adalimumab + MTX*

**0.2/100PY**

*VTE EAIR  
vs 0.3/100 PY adalimumab + MTX*

AE, adverse event; EAIR, exposure-adjusted incidence rate; JAK, Janus Kinase; JAKi, Janus kinase inhibitor; MTX, methotrexate; PY, patient-years; VTE, venous thromboembolism.

\* 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%).<sup>1</sup>

**References:** 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022. 2. Combe B, Kivitz A, Tanaka Y, et al. Ann Rheum Dis. 2021;80(7):848-858. 3. Committee for Medicinal Products for Human Use (CHMP). Jyseleca Assessment Report. European Medicines Agency; 2020:1-170

4. Genovese MC, Winthrop K, Tanaka Y, et al. Ann Rheum Dis. 2020;79:324-325. 5. Winthrop K, Tanaka Y, Takeuchi T, et al. Arthritis Rheumatol. 2021;73(suppl 10). 6. Data on file. Galapagos NV; 2019.



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# A convenient dosing regimen<sup>1,2</sup>

## Once-daily dosing<sup>1</sup>

- > Recommended dose: 200 mg daily\* with MTX or as monotherapy
- > 100 mg available for patients with moderate or severe renal impairment (CrCl 15 to 60 mL/min)† and as a starting dose for patients ≥75 years

## Low risk of drug-drug interactions<sup>1</sup>

- > JYSELECA is the **only JAK inhibitor** that is not metabolised through CYP450<sup>1,3-5</sup>

## Easy-to-open bottle cap<sup>6</sup>



Combining JYSELECA with other potent immunosuppressants such as ciclosporin, tacrolimus, biologics, or other JAK inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded.<sup>1</sup> No dose adjustment required in patients with mild renal impairment or mild or moderate hepatic impairment (Child-Pugh A or B).<sup>1</sup> JYSELECA has not been studied in patients with end-stage renal disease (CrCl 15 mL/min) or in patients with severe hepatic impairment.<sup>1</sup>

**References:** 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022. 2. Taylor PC, Betteridge N, Brown TM, et al. Patient Prefer Adherence. 2020;14:119-131. 3. RINVOO (upadacitinib) Summary of Product Characteristics. AbbVie Inc.; 2021. 4. XELJANZ (tofacitinib) Summary of Product Characteristics. Pfizer Inc.; 2021. 5. OLUMIANT (baricitinib) Summary of Product Characteristics. Eli Lilly and Company; 2021. 6. Data on file. Galapagos NV; 2019.

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# STRENGTH *of* BALANCE

- > Second-generation, JAK1-preferential inhibitor<sup>1</sup>
- > Strong RA therapy<sup>1,2</sup>
- > Proven safety profile<sup>1-5,\*</sup>

JAK, Janus kinase; RA, rheumatoid arthritis.

\* 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%).<sup>1</sup>

Reference 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022. 2. Combe B, Kivitz A, Tanaka Y, et al. Ann Rheum Dis. 2021;80(7):848-858. 3. Committee for Medicinal Products for Human Use (CHMP). Jyseleca Assessment Report. European Medicines Agency; 2020:1-170. 4. Genovese MC, Winthrop K, Tanaka Y, et al. Ann Rheum Dis. 2020;79:324-325. 5. Winthrop K, Tanaka Y, Takeuchi T, et al. Arthritis Rheumatol. 2021;73(suppl 10).



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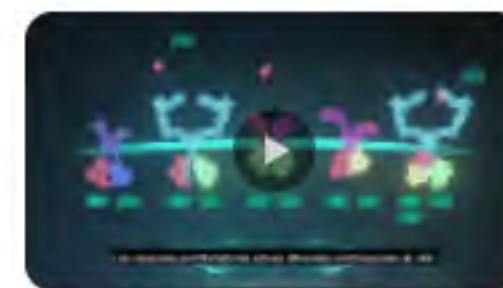
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CLINICAL DATA

MOA

COMMITMENT TO INFLAMMATION



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We see what UC- time for a holistic approach to remission-subt



ECCO 2022 Dr Pavlovsky



ECCO 2022 Violetta

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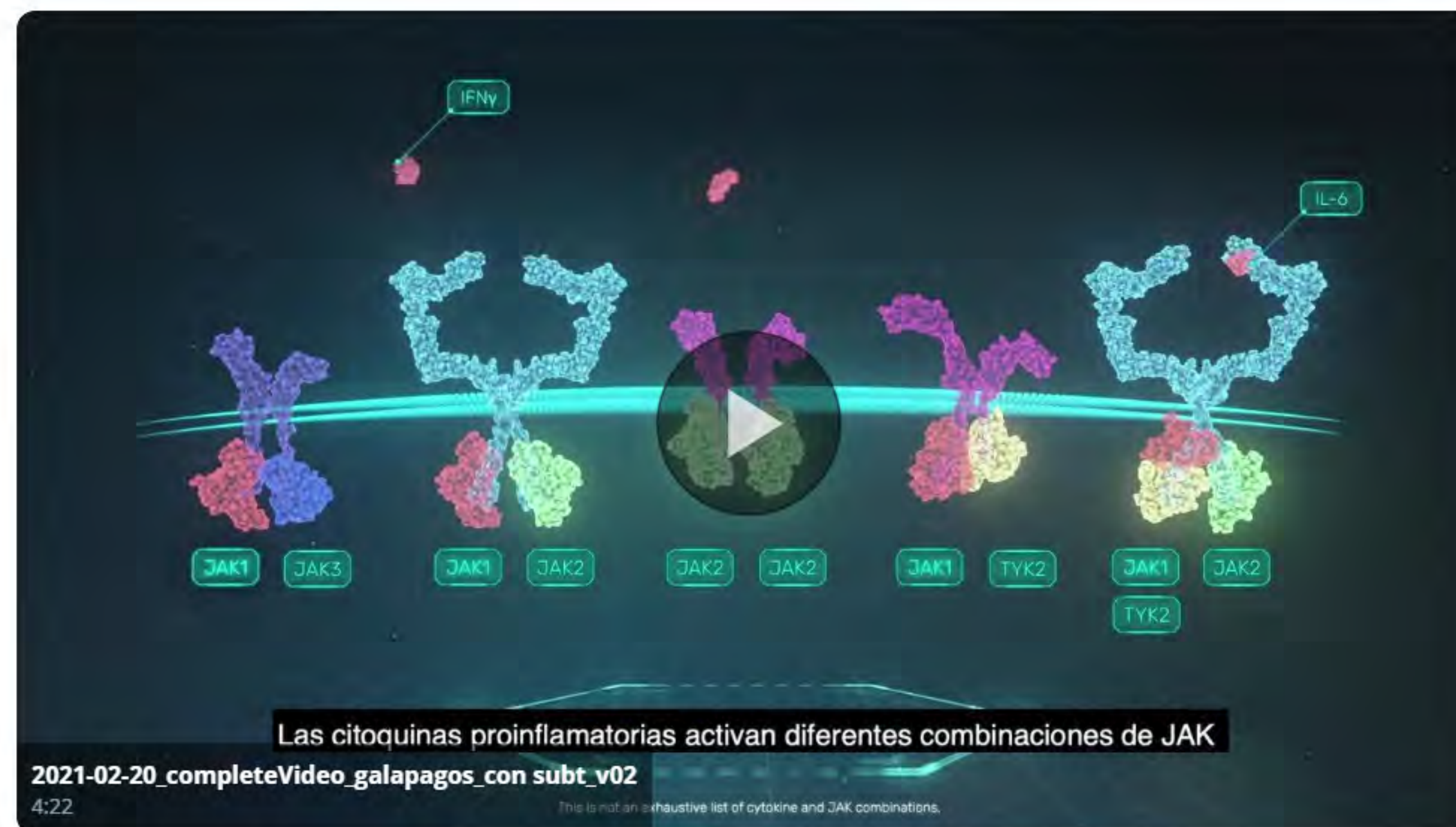
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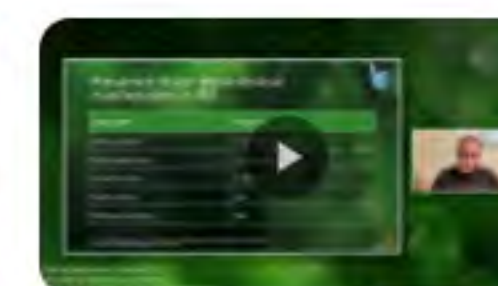
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JYSELECA: Mechanism of Action



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<sup>2\*</sup>

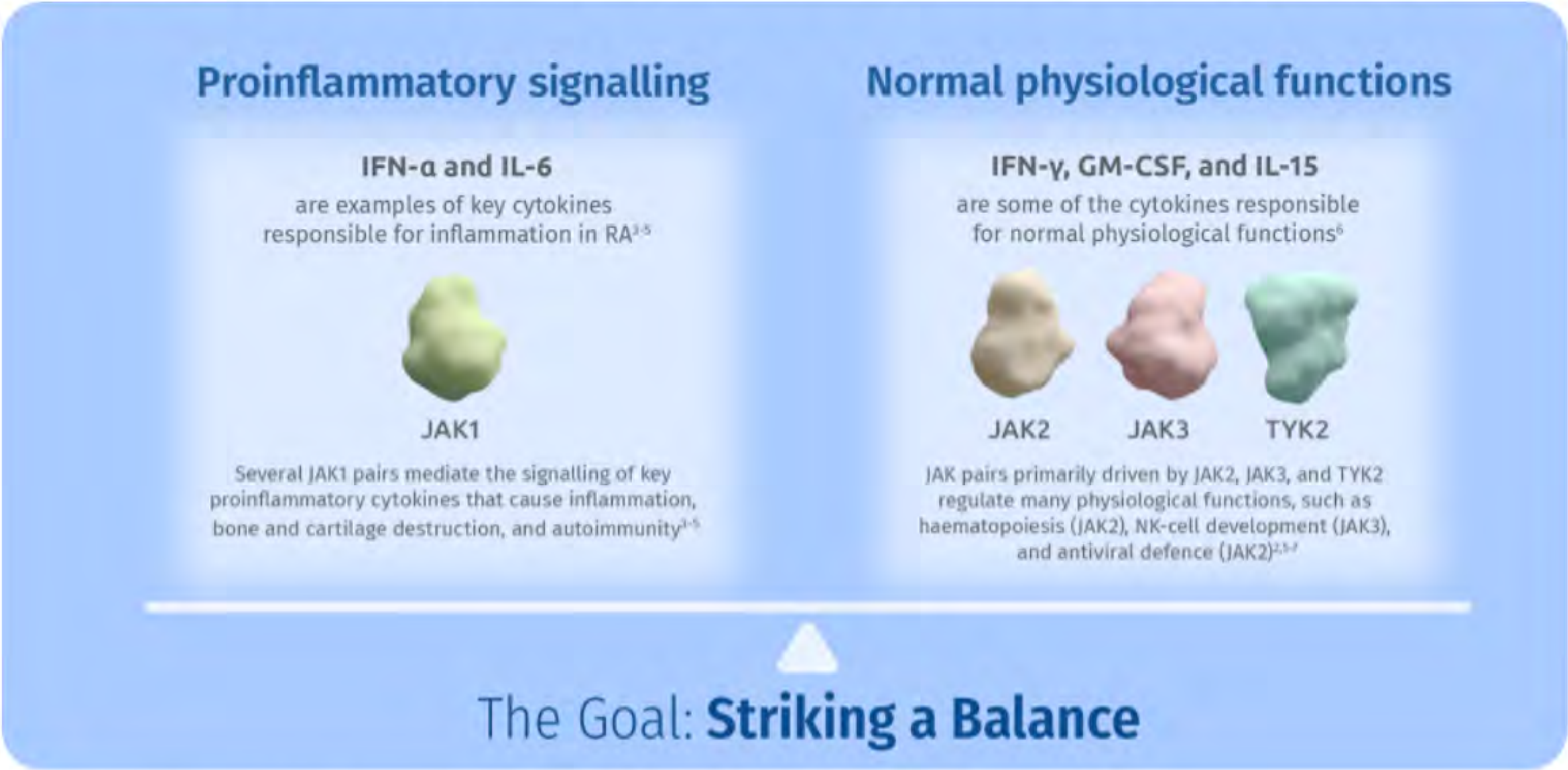
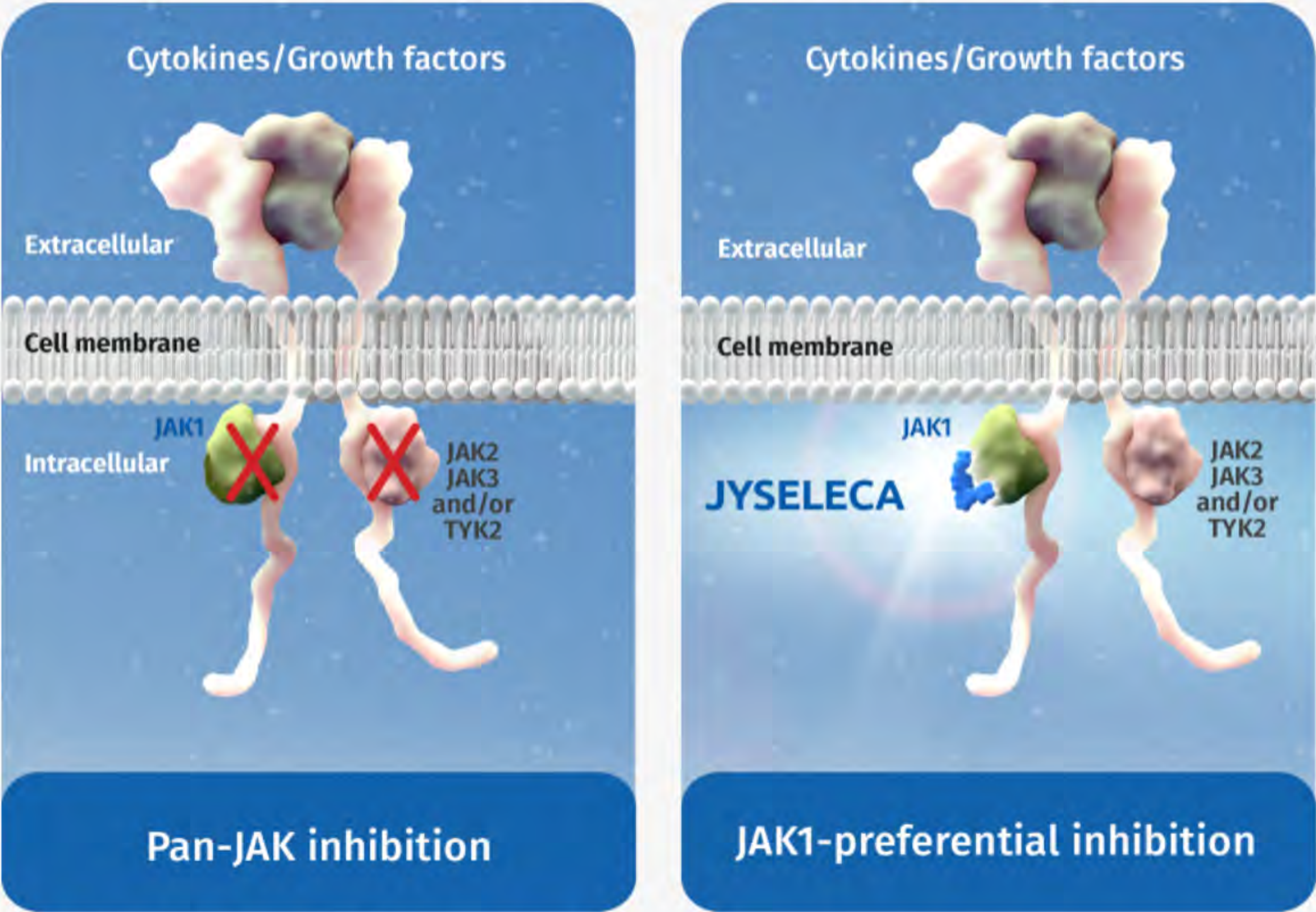


Image is illustrative and based on in vitro findings; clinical relevance is unknown. There are currently no head-to-head trials between JAK inhibitors.

\* 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.<sup>2</sup>

JYSELECA is a JAK1-preferential inhibitor<sup>1</sup>

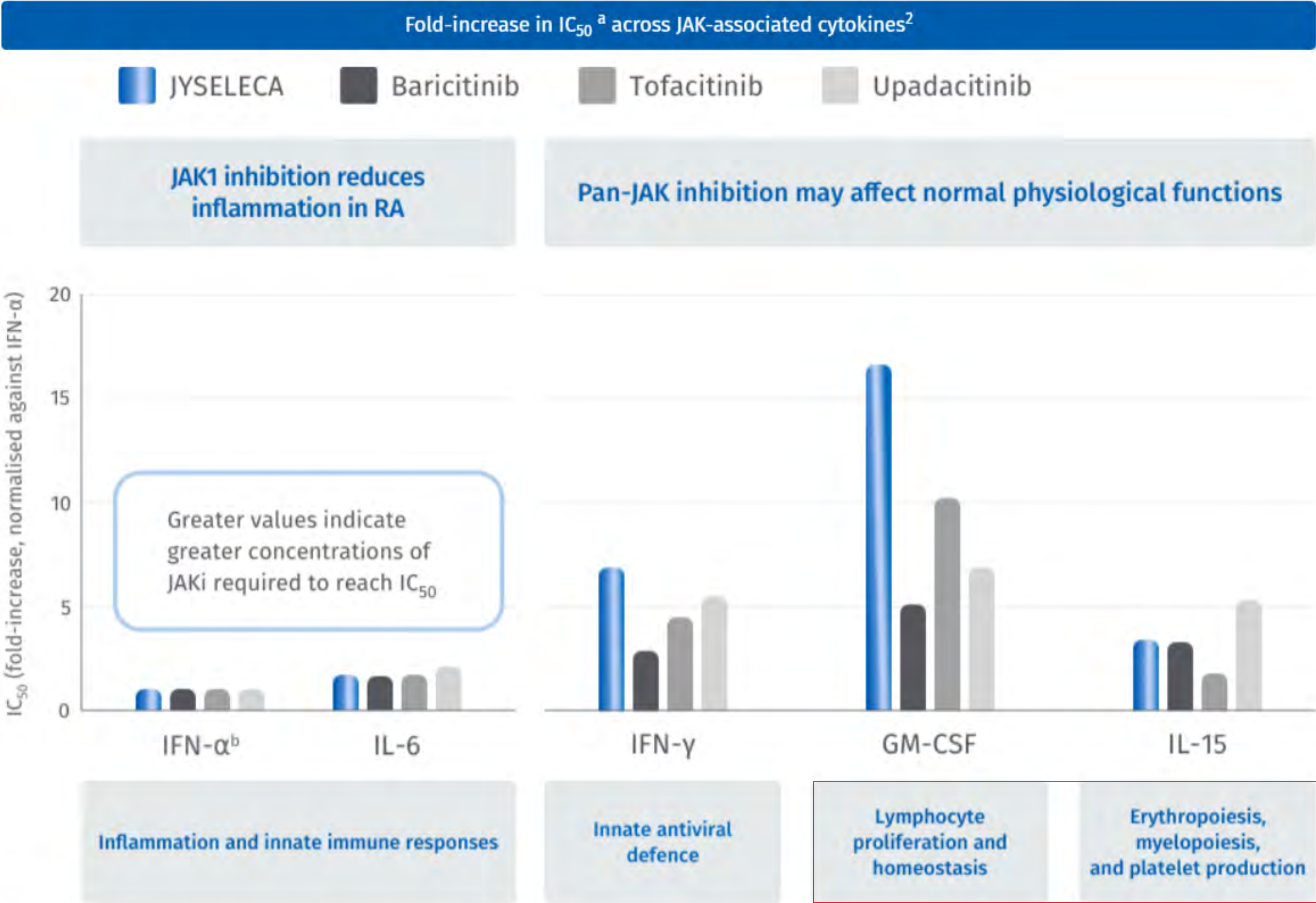
JYSELECA has a 5-fold potency for JAK1 vs JAK2, JAK3, and TYK2 in biochemical assays<sup>1</sup>



The relevance of inhibition of specific JAK isoforms to therapeutic effectiveness or safety is not currently known.

Differential cytokine impact of JAK inhibitors

JYSELECA's inhibition of JAK1-dependent cytokines IFN-α and IL-6 is comparable to other JAK inhibitors, but with less inhibition of JAK2- and JAK3-dependent cytokines<sup>2</sup>



Adapted from Traves et al.<sup>2</sup>

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

<sup>a</sup> IC<sub>50</sub> indicates how much of a specific pharmacologic agent is required to inhibit a given biological activity by half.

<sup>b</sup> Data are normalised against IFN-α

References: 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022. 2. Traves PG, Murray B, Campigotto F, Galien R, Meng A, Di Paolo JA. *Ann Rheum Dis*. 2021;80(7):865-875. 3. Malemud CJ, Int J Sci. 2017;18(3):1-9. 4. Tan S, Xu J, Lai A, et al. *Mol Med Rep*. 2019;19(3):2057-2064. 5. Clark JD, Flanagan ME, Telliez JB. *J Med Chem*. 2014;57(12):5023-5038. 6. Schwartz DM, Kanno Y, Villarino A, Ward M, Gadina M, O'Shea JJ. *Nat Rev Drug Discov*. 2017;16(12):843-862. 7. Virtanen AT, Haikarainen T, Kivela J, Silvennoinen O. *BioDrugs*. 2019;33(1):15-32.



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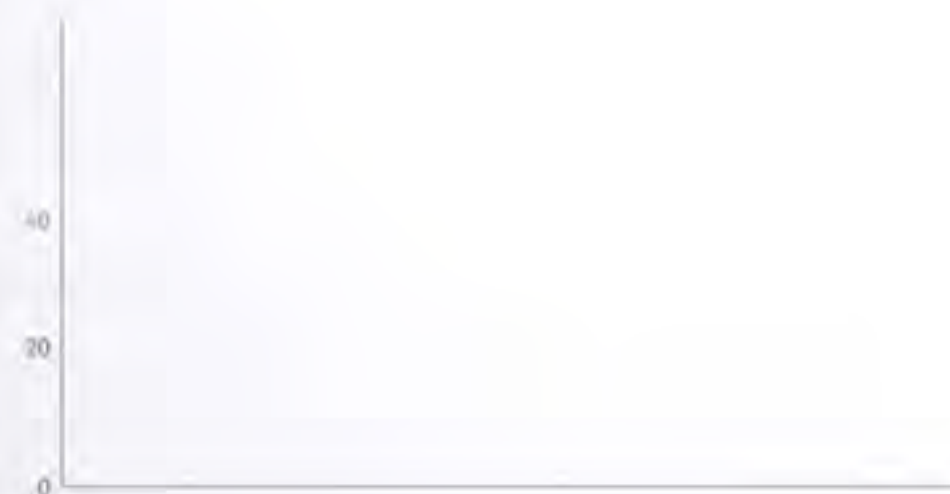
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Finch 03: Monotherapy

### SUSTAINED CLINICAL REMISSION<sup>1,2</sup>

JYSELECA 200 mg + MTX (n = 416)



\*\*\* P < .001 by ITT analysis.  
1. EULAR 2010 criteria; 2. DAS28 < 2.6 and CRP < 1 mg/dL at week 48.

Joint Definition: Sustained clinical remission was defined as DAS28 < 2.6 and CRP < 1 mg/dL at week 48.

CDAI, Clinical Disease Activity Index; CRP, C-reactive protein; DAS28, Disease Activity Score 28 joints; MTX, methotrexate; SDAI, Simplified Disease Activity Index.

01:03:08:14

## Commitment to Inflammation

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