

STRENGTH OF BALANCE

Strong RA therapy with a proven safety profile 1-5*

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).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 <u>national reporting systems</u> and to <u>DrugSafety.Global@glpg.com</u>.

EXPLORE HOW JYSELECA HELP YOUR PATIENTS







Galapagos at EULAR We look forward to seeing you at the following events June 2022

15:45 - 16:15 CEST

WED

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 decisionmaking in RA

June 2022

02 THURS

17:30 - 18:45 CEST

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

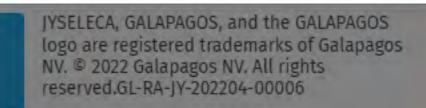
Prof. Bruno Feutrel Pitié-Salpêtrière Hospital, Paris, France Dr James Galloway King's College London, London, UK

STUDY DETAILS

Learning objectives

- · Explore efficacy and safety goals patients and physicians in the treatment of RA
- Explore the efficacy and safety profiles of JAK inhibitor; 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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RA, rheumatoid arthritis

Reference: 1. JYSELECA (fil

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

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, doseranging studies in patients with moderate to severe active RA.

RA, rheumatoid arthritis.

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

DARWIN 34

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

FINCH 45

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

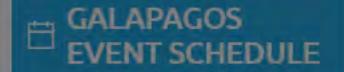
Long-term extension trials 4,5 **DARWIN 3 and FINCH 4**

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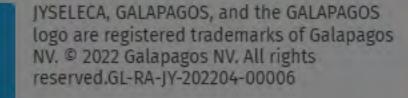
patient-years of exposure6

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):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).









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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.¹



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

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



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

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



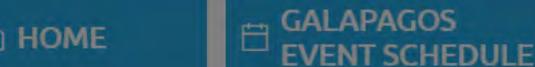
Patients naïve to MTX therapy (MTX-Naïve*) randomised to 1:

- 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, disease-modifying antirheumatic drug; DMARD, disease-modifying antirheumatic drug; CSDMARD, disease-modifying antirheumatic drug; CSDMARD, disease-modifying antirheumatic drug; DMARD, disease-modifying antirheumatic drug; CSDMARD, disease-modifying antirheumatic drug; DMARD, di

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

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



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RA, rheumatoid arthritis

Reference: 1. JYSELECA (fil

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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



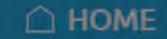
RA, rheumatoid arthritis

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, 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.



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^{*}The most frequently reported adv Reference: 1. JYSELECA (filgptinib) S Materials have been prepared for a

PRODUCT INFORMATION FOR HEALTHCARE PROFESSIONALS

This medicinal product is subject to additional monitoring. 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.

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. 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 efficacy of filgotinib have not yet been established. No data available.

Warnings and precautions: Immunosuppressants: Combination with other potent immunosuppressants such as azathioprine ciclosporin, 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: Malignancy: Malignancy: Malignancy: Malignancy: Malignancy: Malignancy: Malignancy: No. 100 when considering continuing treatment in patients who develop a malignancy. Patients at increased risk of skin cancer should have regular skin examinations. Haematological abnormalities: 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.

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

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 × 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.

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

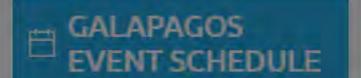


RA, rheumatoid arthriti.

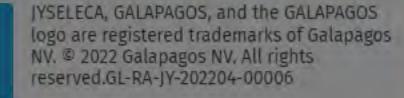
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allows s are asked to <u>l@glpg.com.</u> With JYSELECA 200 mg + MTX at Week 241:

36% 58% of patients achieved ACR50 vs 52% with of patients achieved ACR70 vs 30% with adalimumab + MTX adalimumab + MTX 888 88% 48% of patients achieved of patients had no radiographic progression remission (DAS28-CRP <2.6) vs 86% with adalimumab + MTX vs 36% with adalimumab + MTX

JYSELECA achieved nominally significant improvements vs adalimumab across key clinical outcomes¹,*

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; 202 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 1-5,*

- > Generally well tolerated1
- > Low rates of JAKi-associated AEs, including serious infections,
- > herpes zoster, and VTE, similar to adalimumab2,4,*
- > Consistent safety profile up to 6.8 years5

Throughout 1 year of treatment with JYSELECA6:

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%).1 📁

References: 1. JYSELECA (filgotinib) Summary of Product Characteristics. Galapagos NV; 2022. 2. Combe B, Kivitz A, Tanaka Y, et al. Ann en 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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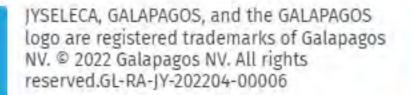
Combining JYSELECA with other potent immunosuppressants such as ciclosporin, tacrolimus, biologics, or other JAK inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. No dose adjustment required in patients with mild renal impairment or mild or moderate hepatic impairment (Child-Pugh A or B) VSELECA has not been studied in patients with end-stage renal disease (CrCl 15 mL/min) or in patients with severe hepatic impairment

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. RINVOQ (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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STUDY DETAILS

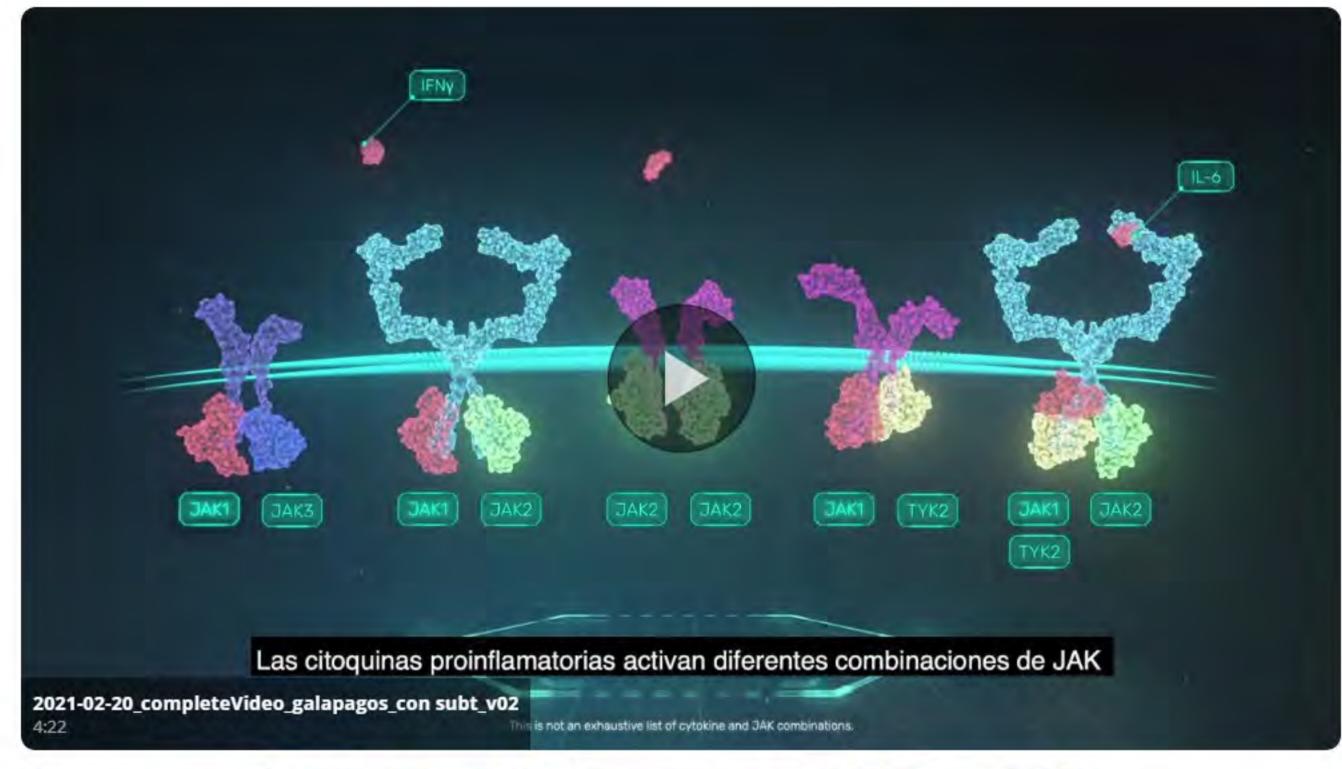


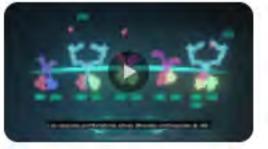


CLINICAL DATA

MOA

COMMITMENT TO INFLAMMATION





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ECCO 2022 Dr Pavlovsky



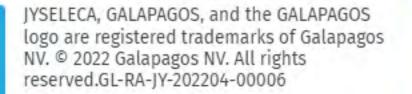
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Resources

REAL-WORLD EXPERIENCE

CLINICAL DATA

MOA

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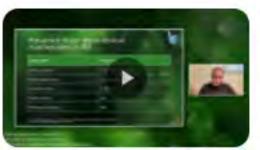




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ECCO 2022 Dr Pavlovsky



ECCO 2022 Violetta







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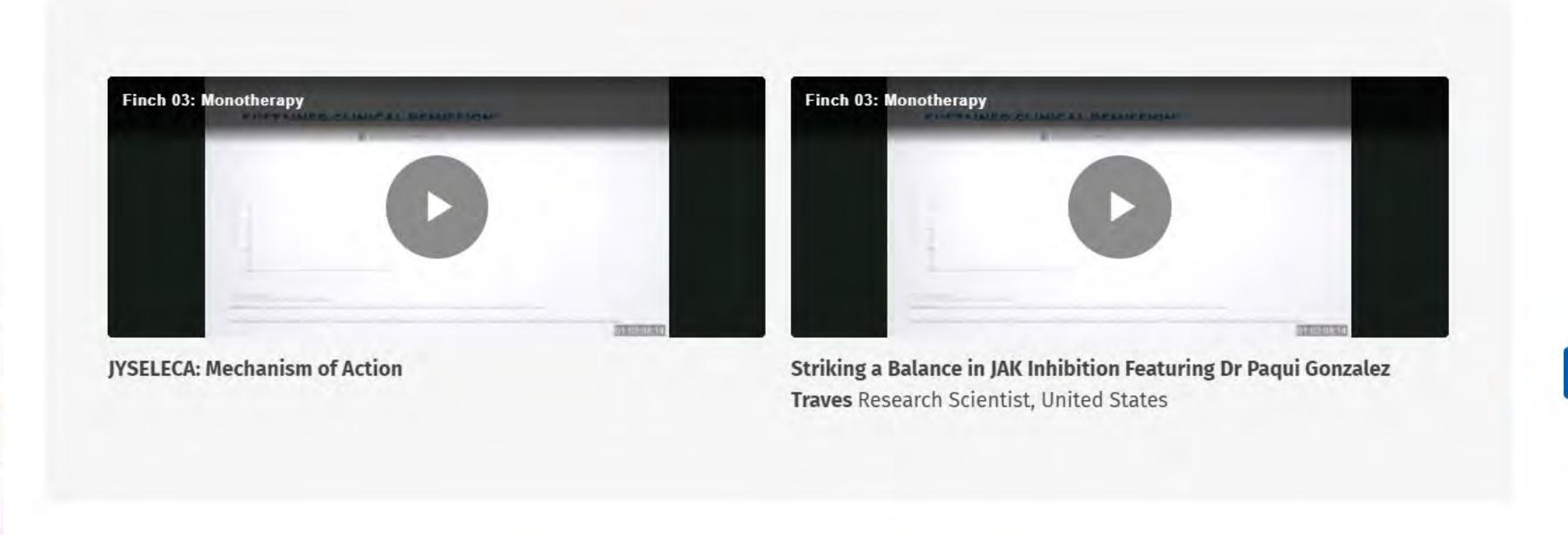
Resources

REAL-WORLD EXPERIENCE

CLINICAL DATA

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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,*}

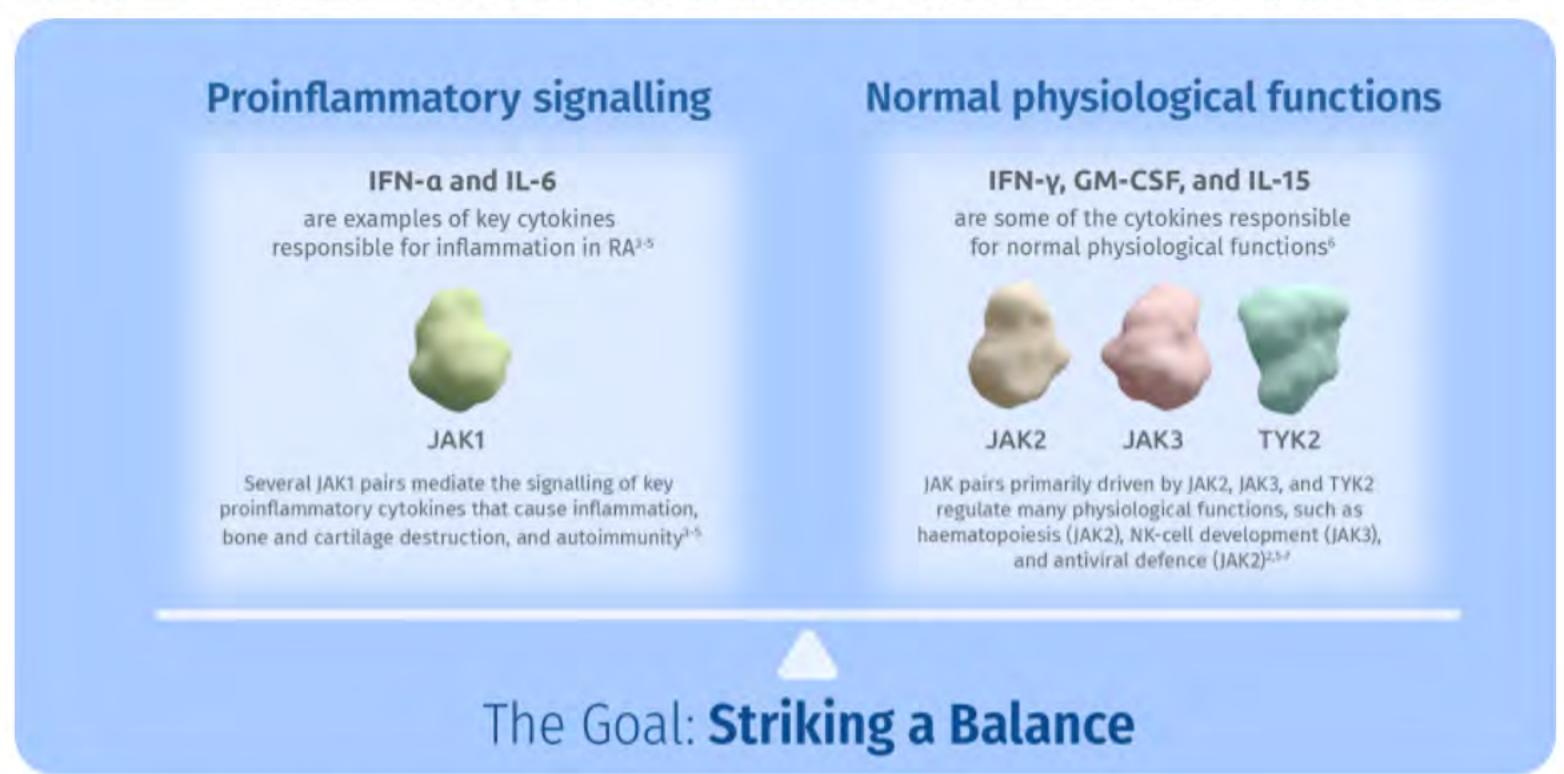
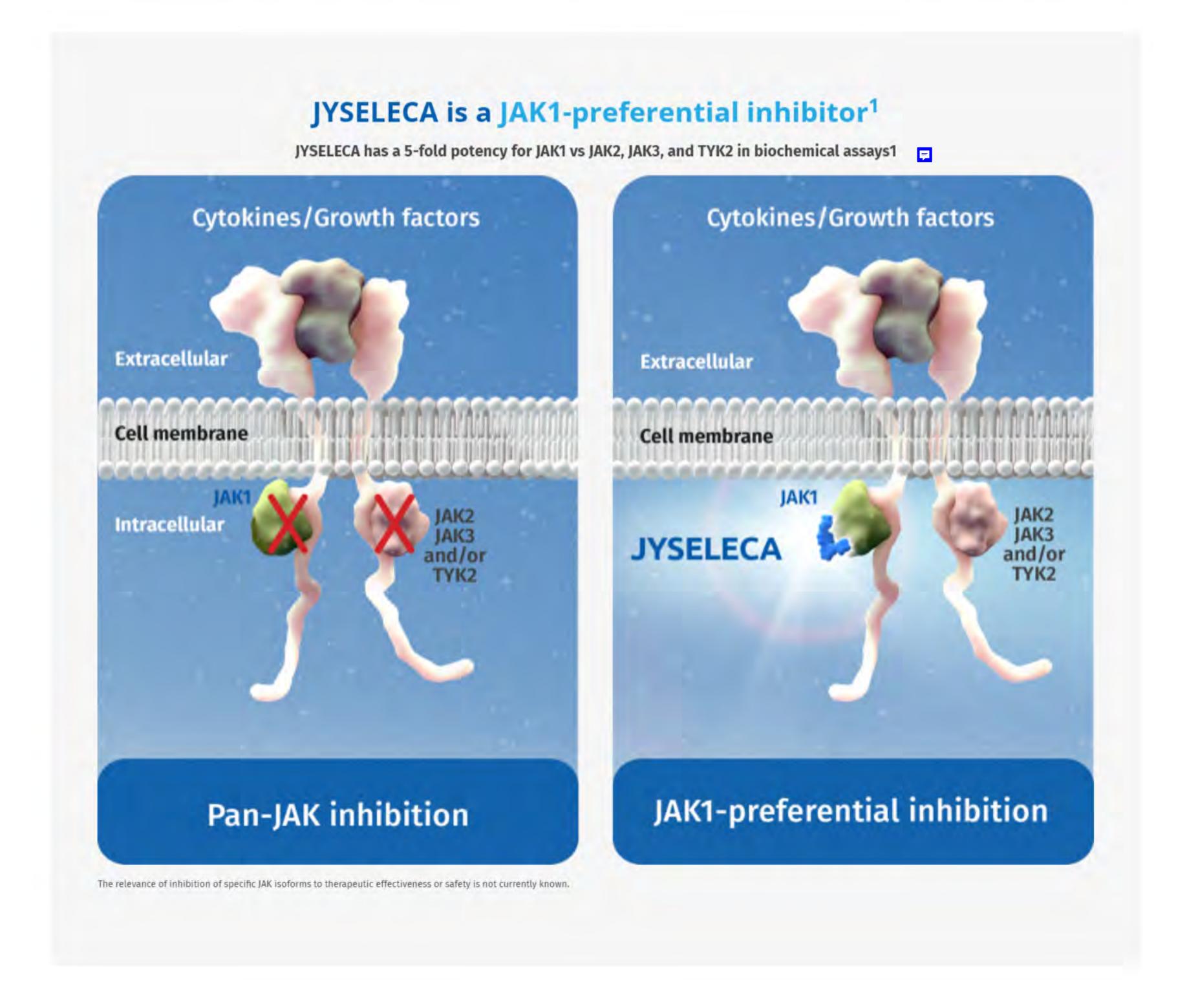


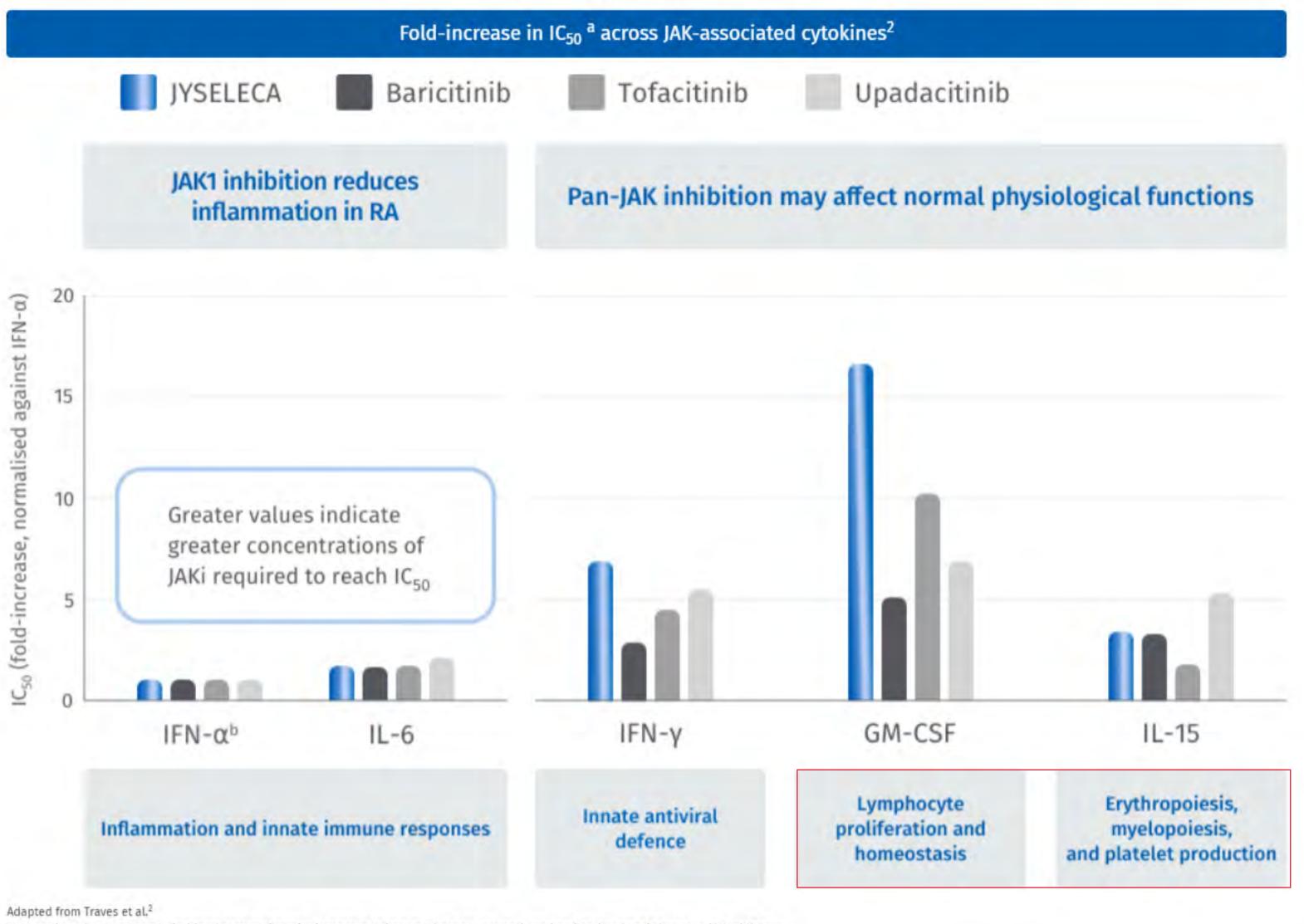
Image is illustrative and based on in vitro findings; clinical relevance is unknown. There are currently no head-to-head trials between JAK inhibitors.

* 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-y both signal through JAK1/JAK2, but IL-6 may predominantly signal through JAK1, whereas IFN-y is more dependent on JAK2.



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 cytokines²



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.

 $^{\circ}$ IC₅₀ indicates how much of a specific pharmacologic agent is required to inhibit a given biological activity by half. $^{\circ}$ 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 Kneum 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.

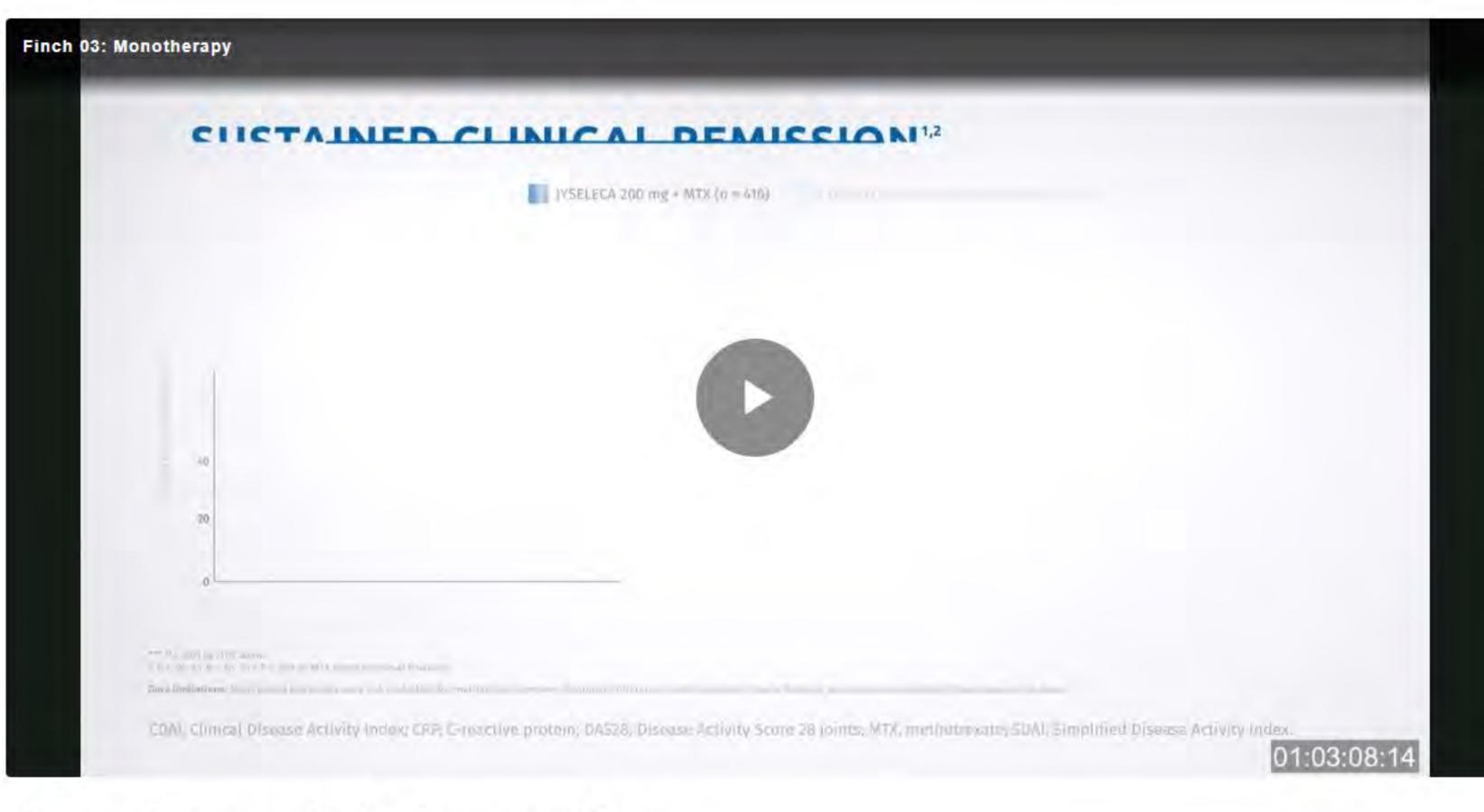
7. Virtanen AT, Haikarainen T, R Ja Ja J, Silvennoinen O. BioDrugs. 2019;33(1):15-32.

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Commitment to Inflammation







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