ABBREVIATED SUMMARY OF PRODUCT CHARACTERISTICS

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the SmPC for how to report adverse reactions.

Jyseleca 100 / 200 mg film-coated tablets. Composition: Each film-coated tablet contains filgotinib maleate equivalent to 100 or 200 mg of filgotinib. Each 100 mg film-coated tablet contains 76 mg of lactose (as monohydrate). Each 200 mg film-coated tablet contains 152 mg of lactose (as monohydrate). For the full list of excipients, see section 6.1 of the Summary of Product Characteristics (SmPC). **Pharmaceutical form**: Film-coated tablet. *Jyseleca 100 mg film-coated tablets*: Beige 12 × 7 mm, capsule-shaped, film-coated tablet debossed with "GSI" on one side and "100" on the other side. *Jyseleca 200 mg film-coated tablets*: Beige 17 × 8 mm, capsule-shaped, film-coated tablet debossed with "GSI" on one side and "200" on the other side. **Therapeutic indications**: *Rheumatoid arthritis* 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 anti-rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). *Ulcerative colitis* Jyseleca is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to either conventional therapy or a biologic agent. **Posology and method of administration**: Treatment with filgotinib should be initiated by a physician experienced in the treatment of rheumatoid arthritis or ulcerative colitis. *Posology Rheumatoid arthritis* The recommended dose of filgotinib for adult patients is 200 mg once daily. *Ulcerative colitis* The recommended dose for induction and maintenance treatment is 200 mg once daily. For patients with ulcerative colitis who do not show an adequate therapeutic benefit during the initial 10 weeks of treatment, 12 additional weeks of induction treatment with filgotinib 200 mg once daily may provide additional relief of symptoms (see section 5.1 of the SmPC). Patients who have not shown any therapeutic benefit after 22 weeks of treatment should discontinue filgotinib. *Laboratory monitoring, and dose initiation or interruption* Guidance for laboratory monitoring, and dose initiation or interruption is provided in Table 1. Treatment should be interrupted if a patient develops a serious infection until the infection is controlled (see section 4.4 of the SmPC).

Table 1: Laboratory measures and monitoring guidance

Laboratory measure	Action	Monitoring guidance
Absolute neutrophil count (ANC)	Treatment should not be initiated, or should be interrupted, if ANC is $< 1 \times 10^9$ cells/L. Treatment may be restarted once ANC returns above this value	Before treatment initiation and thereafter according to routine patient management
Absolute lymphocyte count (ALC)	Treatment should not be initiated, or should be interrupted, if ALC is $< 0.5 \times 10^9$ cells/L. Treatment may be restarted once ALC returns above this value	
Haemoglobin (Hb)	Treatment should not be initiated, or should be interrupted, if Hb is < 8 g/dL. Treatment may be restarted once Hb returns above this value	
Lipid parameters	Patients should be managed according to international clinical guidelines for hyperlipidaemia	12 weeks after initiation of treatment and thereafter according to international clinical guidelines for hyperlipidaemia

Special populations Elderly *Rheumatoid arthritis* A starting dose of 100 mg once daily is recommended for patients with rheumatoid arthritis aged 75 years and older as clinical experience is limited. *Ulcerative colitis* No dose adjustment is recommended for patients with ulcerative colitis up to 75 years of age. Filgotinib is not recommended in patients aged 75 years and older as there is no data in this population. Renal impairment No dose adjustment is required in patients with mild renal impairment (creatinine clearance [CrCl] ≥ 60 mL/min). A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to < 60 mL/min). Filgotinib has not been studied in patients with end stage renal disease (CrCl < 15 mL/min) and is therefore not recommended for use in these patients (see section 5.2 of the SmPC). Hepatic impairment No dose adjustment is required in patients with mild or moderate hepatic impairment (Child-Pugh A or B). Filgotinib has not been studied in patients with severe hepatic impairment (Child-Pugh C) and is therefore not recommended for use in these patients (see section 5.2 of the SmPC). Paediatric population The safety and efficacy of filgotinib in children under the age of 18 years have not yet been established. No data are available. *Method of administration* Oral use. Jyseleca can be taken with or without food (see section 5.2 of the SmPC). It has not been studied if tablets can be split, crushed, or chewed, and it is recommended that tablets are swallowed whole. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC. Active tuberculosis (TB) or active serious infections (see section 4.4 of the SmPC). Pregnancy (see section 4.6 of the SmPC). **Undesirable effects**: *Summary of the safety profile Rheumatoid arthritis* The most frequently reported adverse reactions are nausea (3.5%), upper respiratory tract infection (URTI, 3.3%), urinary tract infection (UTI, 1.7%) and dizziness (1.2%). *Ulcerative colitis* In general, the overall safety profile observed in filgotinib-treated patients with ulcerative colitis was generally consistent with the safety profile observed in patients with rheumatoid arthritis. *Tabulated list of adverse reactions* The following adverse reactions are based on clinical studies (Table 2). The adverse reactions are listed below by system organ class and frequency. Frequencies are defined as follows: common (≥ 1/100 to < 1/10) and uncommon (≥ 1/1,000 to < 1/100).

Table 2: Adverse reactions

Frequency [a]	**Adverse reaction**
Infections and infestations	
Common	Urinary tract infection (UTI) Upper respiratory tract infection (URTI)
Uncommon	Herpes zoster Pneumonia
Blood and lymphatic system disorders	
Uncommon	Neutropenia
Metabolism and nutrition disorders	
Uncommon	Hypercholesterolaemia
Nervous system disorders	
Common	Dizziness
Gastrointestinal disorders	
Common	Nausea
Investigations	
Uncommon	Blood creatine phosphokinase increased

a Frequency based on placebo-controlled pre-rescue period (week 12) pooled across FINCH 1 and 2, and DARWIN 1 and 2, for patients with rheumatoid arthritis who received filgotinib 200 mg. Frequencies reported in the SELECTION study in patients with ulcerative colitis who received filgotinib 200 mg were generally consistent with those reported in the rheumatoid arthritis studies.

Laboratory changes Creatinine An increase in serum creatinine occurred with filgotinib treatment. At week 24 in the Phase 3 studies (FINCH 1, 2, and 3), the mean (SD) increase from baseline in serum creatinine was 0.07 (0.12) and 0.04 (0.11) mg/dL for filgotinib 200 mg and 100 mg, respectively. Mean creatinine values remained within the normal range. Lipids Treatment with filgotinib was associated with dose-dependent increases in total cholesterol and HDL levels, while LDL levels were slightly increased. LDL/HDL ratios were generally unchanged. Lipid changes were observed within the first 12 weeks of filgotinib treatment and remained stable thereafter. Description of selected adverse reactions Infections *Rheumatoid arthritis* In placebo-controlled studies with background DMARDs (FINCH 1, FINCH 2, DARWIN 1, and DARWIN 2), the frequency of infection over 12 weeks in the filgotinib 200 mg group was 18.1% compared to 13.3% in the placebo group. In the MTX-controlled study FINCH 3, the frequency of infection over 24 weeks in the filgotinib 200 mg monotherapy and filgotinib 200 mg plus MTX groups was 25.2% and 23.1%, respectively, compared to 24.5% in the MTX group. The overall exposure-adjusted incidence rate (EAIR) of infections for the filgotinib 200 mg group across all seven Phase 2 and 3 clinical studies (2,267 patients) was 26.5 per 100 patient-years of exposure (PYE). In placebo-controlled studies with background DMARDs, the frequency of serious infection over 12 weeks in the filgotinib 200 mg group was 1.0% compared to 0.6% in the placebo group. In the MTX-controlled study FINCH 3, the frequency of serious infection over 24 weeks in the filgotinib 200 mg monotherapy and filgotinib 200 mg plus MTX groups was 1.4% and 1.0%, respectively, compared to 1.0% in the MTX group. The overall EAIR of serious infections for the filgotinib 200 mg group across all seven Phase 2 and 3 clinical studies (2,267 patients) was 1.7 per 100 PYE. The most common serious infection was pneumonia. The EAIR of serious infections remained stable with long-term exposure. In rheumatoid arthritis clinical studies, there was a higher incidence of serious infections in patients aged 75 years and older, although data are limited. In placebo-controlled studies with background DMARDs, the frequencies of infectious ADRs over 12 weeks for filgotinib 200 mg compared to placebo were: URTI (3.3% versus 1.8%), UTI (1.7% versus 0.9%), pneumonia (0.6% versus 0.4%), and herpes zoster (0.1% versus 0.3%). Most of the herpes zoster events involved a single dermatome and were non-serious. *Ulcerative colitis* The types of serious infections in the ulcerative colitis clinical studies were generally similar to those reported in the rheumatoid arthritis clinical studies with filgotinib monotherapy treatment groups. Across the two placebo-controlled induction studies, the frequency of serious infections was 0.6% in the filgotinib 200 mg group, 1.1% in the filgotinib 100 mg group, and 1.1% in the placebo group. In the placebo-controlled maintenance study, the frequency of serious infections in the filgotinib 200 mg group was 1%, compared to 0% in the respective placebo group. In the maintenance study filgotinib 100 mg group, the frequency of serious infections was 1.7%, compared with 2.2% in the respective placebo group. *Opportunistic infections (excluding TB)* In

rheumatoid arthritis placebo-controlled studies with background DMARDs, there were no opportunistic infections over 12 weeks in the filgotinib 200 mg group or the placebo group. In the MTX-controlled study FINCH 3, the frequency of opportunistic infections over 24 weeks was 0, 0.2%, and 0 in the filgotinib 200 mg monotherapy, filgotinib 200 mg plus MTX, and MTX groups, respectively. The overall EAIR of opportunistic infections for the filgotinib 200 mg group across all seven Phase 2 and 3 rheumatoid arthritis clinical studies (2,267 patients) was 0.1 per 100 PYE. Nausea Nausea was generally transient and reported during the first 24 weeks of filgotinib treatment. *Creatine phosphokinase* Dose-dependent increases in creatine phosphokinase (CPK) occurred within the first 12 weeks of filgotinib treatment and remained stable thereafter. At week 24 in the Phase 3 studies (FINCH 1, 2, and 3), the mean (SD) increase from baseline in CPK was -16 (449), 61 (260), and 33 (80) U/L for placebo, filgotinib 200 mg and 100 mg, respectively. In placebo-controlled Phase 3 studies with background DMARDs (FINCH 1 and FINCH 2) through 12 weeks, CPK elevations > 5 × upper limit of normal (ULN) were reported in 0.5%, 0.3%, and 0.3% of patients in the placebo, filgotinib 200 mg, and filgotinib 100 mg groups, respectively. Most elevations > 5 × ULN did not require treatment discontinuation. *Experience from long-term extension studies* *Rheumatoid arthritis* In the long-term extension study DARWIN 3, among patients enrolled from DARWIN 1 (N = 497), 238 patients received filgotinib 200 mg once a day for a median duration of 4.4 years; among patients enrolled from DARWIN 2 (N = 242), 234 patients received filgotinib 200 mg once a day for a median duration of 4.4 years. The safety profile of filgotinib was similar to that in the Phase 2 and Phase 3 studies. *Ulcerative colitis* In the long-term extension study (SELECTION LTE) in patients who participated in the SELECTION study, patients received filgotinib 200 mg (N = 871), filgotinib 100 mg (N = 157), or placebo (N = 133) for median durations of 55, 36, and 32 weeks, respectively. The safety profile of filgotinib was similar to that in the SELECTION induction and maintenance studies. *Reporting of suspected adverse reactions* 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. **Marketing Authorisation Holder (MAH)**: Galapagos NV, Generaal De Wittelaan L11 A3, 2800 Mechelen, Belgium **Marketing Authorisation numbers**: EU/1/20/1480/001-002-003-004. **Delivery status:** On medical prescription. **Date of revision of the text**: 12/2021.
For any safety reporting to the MAH, please email to **DrugSafety.Benelux@glpg.com**.
Detailed information on this medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.