IBD Training Academy

Programme prospectus

April 2022 | GL-IBD-NA-202204-00001

Galápagos
Pioneering for patients

Contents

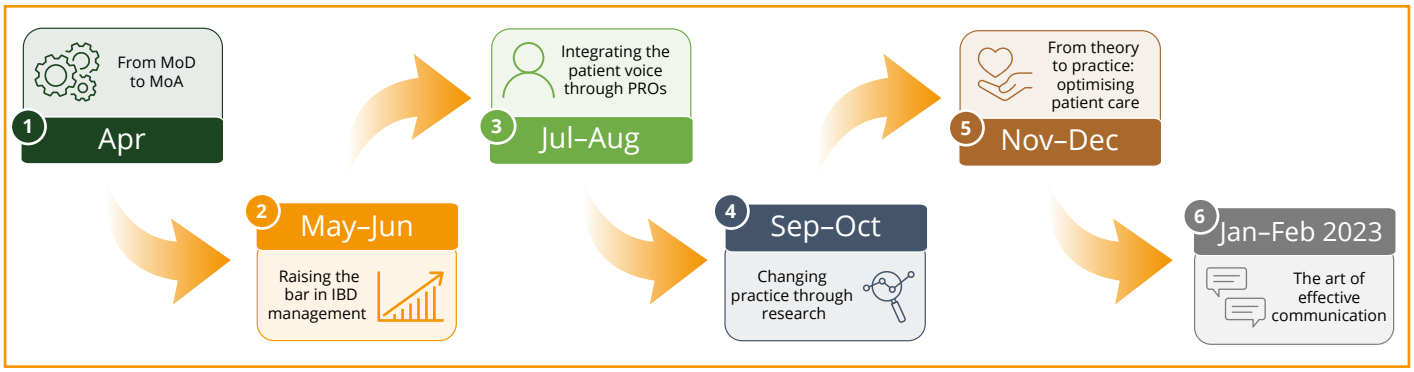
About the IBD Training Academy

Welcome!

The IBD Training Academy is a year-long educational programme, starting in March 2022, for certified gastroenterologists from across Europe with an active interest in IBD. This unique professional development programme is funded by Galapagos, with content developed by OPEN Health following guidance and endorsement from a steering committee of leading independent expert gastroenterologists. The programme aims to enhance your clinical practice and research within the field of IBD.

Module roadmap

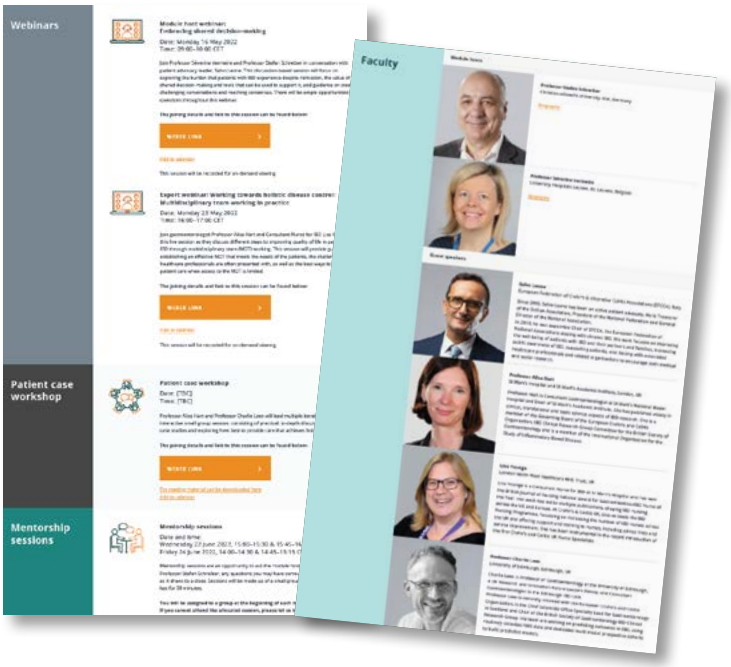
The programme, presented and hosted by the steering committee and guest faculty, comprises a series of modules made up of a mix of remote educational, mentoring and networking activities taking place over 12 months. You will also have the opportunity to join two face-to-face events at IBD Centres of Excellence.



Accessing the IBD Training Academy portal

The online portal will act as the hub for the IBD Training Academy and will host the programme content. We recommend familiarising yourself with the portal and logging in regularly as it will be updated with session dates, times, topics and guest speakers throughout the coming year. You will have received an email containing a link to access the portal. Please do not share this with anybody else.

This is an educational programme with no promotional intentions. Mention of Jyseleca® ▼ (filgotinib) will be included as part of a fair and balanced discussion about treatment options for IBD. Jyseleca® Prescribing Information can be found on page 20 of this booklet.



The expert steering committee

Professor Raja Atreya
University Hospital Erlangen, Germany

Raja Atreya is Professor for Translational Immunology in IBD, senior physician and Head of the IBD Unit, Outpatient Clinic and Clinical Study Centre at University Hospital Erlangen, Germany. His work focusses on identifying response predictors (e.g. molecular endoscopy) and mechanisms of resistance to biological therapies in IBD. His career has been well decorated – he received the Theodor-Frerichs Award of the German Society for Internal Medicine, the Paul Ehrlich and Ludwig Darmstaedter Prize for Young Researchers from the Paul Ehrlich Foundation, and the United European Gastroenterology's Rising Star Award.

Dr Flavio Caprioli
University of Milan, Italy

Flavio Caprioli is Assistant Professor of Gastroenterology at the University of Milan, Italy. His areas of expertise are preclinical research, mucosal and systemic immunology, and translational research in IBD. His PhD focussed on mechanisms of autocrine regulation of IL-21 in humans and the role of IL-21 in inducing naïve T-cell polarisation towards effector Th17 lymphocytes. He has since studied the role of IL-21 as a promoter of systemic and intestinal inflammation and the neutralisation of this cytokine as a potential new therapeutic approach in autoimmune-related inflammatory diseases.

Professor Mathurin Fumery
University of Picardy Jules Verne, Amiens, France,
Amiens University Hospital, France

Mathurin Fumery is a consultant gastroenterologist at the University of Picardy Jules Verne and Professor of Gastroenterology at Amiens University Hospital, France. His research focusses on the epidemiology of IBD, and he is involved in the French IBD epidemiology registry, EPIMAD. Professor Fumery has published extensively in the area of IBD, particularly around biologic treatments and population-based IBD epidemiology.

Dr Ana Gutiérrez
Hospital General Alicante, Spain

Ana Gutiérrez is Head of the Gastroenterology Section at Hospital General Alicante, Spain. She is Vice President of the governing board of the Spanish IBD group, GETECCU, where she also acts as the director of training courses in IBD, and is the national representative of Spain within the European Crohn's and Colitis Organisation. Her PhD and postdoctoral research at the University of Miguel Hernández, Spain, focussed on the value of fibrinolytic tests in patients with acute upper gastrointestinal haemorrhage.

The expert steering committee

Dr Taku Kobayashi
Centre for Advanced IBD Research and Treatment, Kitasato University Kitasato Institute Hospital, Japan

Taku Kobayashi is Vice Director and Associate Professor at the Centre for Advanced IBD Research and Treatment, Kitasato University Kitasato Institute Hospital, Tokyo, Japan. He is Director of the International Exchange Committee of the Japanese Society of IBD and a Clinical Research Committee member for the Asian Organization for Crohn's and Colitis. He serves as a councillor for several Japanese gastroenterology societies. His current projects include global, prospective, randomised controlled trials and the development of prospective registries of Japanese patients with IBD.

Dr Gareth Parkes
Royal London Hospital, UK

Gareth Parkes is Clinical Lead for Gastroenterology at the Royal London Hospital, UK. His interests include IBD clinical trials, the role of the microbiota and probiotics, and the use of technology in the IBD clinic. He has sat on the British Society of Gastroenterology IBD Committee and has a range of publications in the fields of IBD, gastrointestinal microbiota and irritable bowel syndrome. He is Co-Founder and Medical Director of Ampersand Health, which developed the award-winning app 'My IBD Care', using digital technology and behavioural science to improve patients' lives.

Professor Stefan Schreiber
Christian-Albrecht University, Kiel, Germany

Stefan Schreiber gained his medical degree at the University of Hamburg, Germany. After two fellowships, he joined the Department of Gastroenterology at Charité University Hospital in Berlin and, in 1996, he became Associate Professor at Christian-Albrecht University. He became full Professor of Medicine in 1999 and, in 2004, he became Director of the Department of Internal Medicine I and Head of the Institute of Clinical Molecular Biology at Kiel University. His research interests span the genetics and pathophysiology of intestinal inflammation, IBD therapy development and human ageing. He has authored more than 1000 original publications.

Professor Séverine Vermeire
University Hospitals Leuven, KU Leuven, Belgium

Séverine Vermeire trained at KU Leuven in Belgium, the National University of Asuncion in Paraguay, the Wellcome Trust Centre for Human Genetics in Oxford, UK, and the Montreal General Hospital in Canada. Since 2003, she has been a member of the Gastroenterology Department at University Hospitals Leuven and Professor of Medicine at KU Leuven. She became Head of the Department of Chronic Diseases and Metabolism at KU Leuven in 2016. Her work has led to more than 500 peer-reviewed articles and focusses on the role of the microbiome, genetic susceptibility in IBD and signatures predictive of therapy response.

Learning activities

Launch meeting	The IBD Training Academy will hold a live, online launch meeting as an opportunity for you to meet and hear from the expert steering committee as well as your fellow trainees. We will take a tour of what content to expect and who you'll be hearing from, and give you an overview of the interactive session formats.
eLearning	A self-paced, interactive eLearning course will be one of the common threads across each of the modules in the IBD Training Academy. Online quizzes can be used to assess your knowledge at the end of each module.
Webinars	Hear from leading gastroenterologists, consultant IBD nurses, patient advocates and many more as part of the expert-led webinar series. The webinars are an opportunity for you to discuss the latest data on hot topics in IBD and how these might be applied in your own clinical practice.
Masterclass videos & podcasts	Watch and listen to an eclectic range of short videos and podcasts featuring experts in the field who will share their expertise and knowledge as part of your self-paced learning.
Journal club	Discuss the latest publications in IBD and how these may inform clinical practice with your peers. The journal club sessions will help to develop your critical appraisal skills and improve literature awareness.
Patient case workshop	Hosted by leading clinical experts, these practical, in-depth sessions will cover a variety of patient case studies. Explore investigative, diagnostic and treatment-based decision-making in small groups and gain practical tips for achieving holistic disease control for patients in daily clinical practice.
Small-group mentoring	Join the steering committee experts in these mentoring sessions alongside a small number of your peers. Your questions will shape the discussion, so be sure to make the most of your time by asking any questions you have throughout the modules to consolidate your knowledge.

See the tips and tricks section for advice on how to get the most out of the IBD Training Academy

Centres of Excellence

Join your peers, the steering committee and other experts in up to two exciting, **face-to-face** Centres of Excellence as part of the programme. These meetings will be an opportunity for you to hear directly from leading experts, network with your peers and discuss the latest research within the field. You will also receive practical guidance to implement within your own research activities and clinical practice.

Keep an eye on the portal as more information will be available soon!

Tips and tricks

Reflective learning

To help get the most out of the IBD Training Academy, think about your personal goals and objectives prior to the launch meeting in March. Some examples include:

- What was your main motivation for applying to the programme?
- What goals would you like to achieve through the programme?
- At the end of the programme, what changes do you hope to have made in your clinical practice?

Completing the learning activities

To ensure you are able to gain the most benefit from the content provided, we recommend the following:

- **Complete the eLearning first**. This activity is self-paced and may take the most time as it broadly covers many of the themes of the modules. The other sessions, including webinars, masterclass videos and patient case studies, will draw on some of the key topics covered in more detail, so starting with the eLearning will ensure you are up to speed in advance
- **Find the right time**. Find a time that works for you and when you can focus without distractions
- **Take notes**. We recommend taking notes during each session to summarise your key learnings and note any outstanding questions you may have. You can then discuss these in more detail at the mentorship sessions or email any questions to the team if needed. Use the handy notes pages within this booklet to jot anything down
- **Pre-read**. Make sure you read the papers ahead of the journal club sessions. This is a great way to ensure you have sufficient background information and are able to participate in discussions. Note down anything that catches your eye and prepare a couple of questions
- **Be organised.** Get the most from the programme by not missing anything! Be sure to add session invites to your calendar and keep an eye on your inbox for any important updates. The IBD Training Academy portal is where module content is updated, including overviews of upcoming activities, key dates and times, so make sure you check in regularly
- **Get to know your fellow trainees**. Networking is a key part of the Academy and is a way to create more connections, and share experiences and learnings

Gaining the most from your mentorship sessions

Mentorship sessions are a great way to build on your professional development by engaging with the experts. They will be available to provide guidance that will help you achieve your objectives, offer specific answers to questions and aid in developing critical skills. To get the full benefit from these, try to do the following:

- Think about your goals and objectives, and write them down
- Come to sessions prepared – write down a list of questions you want to ask ahead of the session
- Ask your mentor about their experiences with the module topic – you can learn a lot from drawing on others' expertise

Module overview

Module 1: From MoD to MoA

Module 1, hosted by Dr Flavio Caprioli and Professor Stefan Schreiber, will kick off the programme. The module will explore the rationale for different treatment targets in IBD and patient populations that may benefit from different treatment classes. By the end of the module, you should be able to summarise the key drivers of pathophysiology in IBD, describe the unmet needs associated with current methods of targeting inflammation and explain how differences in treatment mechanisms of action (MoA) may translate into differences in clinically relevant features.

Learning activities

Check these off as you go!

- ☐ Launch meeting
- ☐ eLearning
- ☐ Quiz
- ☐ Expert webinar
- ☐ Mentorship session

Module hosts

Module hosts are subject to availability and may change

Reflections

Use the space below to think about your learnings from Module 1 and what impact they might have on your clinical practice.

Questions

Use the space below to keep track of any questions that arise throughout this module.

Module 2: Raising the bar in IBD management

Module 2 will be hosted by Professor Stefan Schreiber and Professor Séverine Vermeire who will explore the concept of **holistic disease control** and how best to incorporate this approach within IBD management to result in more ambitious treatment goals. Alongside this, you will discuss treatment goals that should be applied in clinical practice, how these have evolved to become more stringent and how they may differ from the treatment goals that are important to patients.

Learning activities

Check these off as you go!

- ☐ eLearning
- ☐ Quiz
- ☐ Module host webinar
- ☐ Expert webinar
- ☐ Patient case workshop
- ☐ Mentorship session

Module hosts

Module hosts are subject to availability and may change

Reflections

Use the space below to think about your learnings from Module 2 and what impact they might have on your clinical practice.

Questions

Use the space below to keep track of any questions that arise throughout this module.

Module 3: Integrating the patient voice through patient-reported outcomes

Dr Gareth Parkes and Dr Ana Gutiérrez will host Module 3, which focusses on the role of patient-reported outcomes (PROs) in clinical practice to monitor patient-important outcomes, as well as the use of digital health tools and wearables for monitoring PROs. You will identify gaps in current PROs within the concept of holistic disease control, and start to consider how these gaps could be filled.

Learning activities

Check these off as you go!

- ☐ eLearning
- ☐ Quiz
- ☐ Module host webinar
- ☐ Expert webinar
- ☐ Journal club
- ☐ Masterclass

Module hosts

Module hosts are subject to availability and may change

Reflections

Use the space below to think about your learnings from Module 3 and what impact they might have on your clinical practice.

Questions

Use the space below to keep track of any questions that arise throughout this module.

Module 4: Changing practice through research

Module 4, led by Professor Raja Atreya and Professor Séverine Vermeire, will explore the skills and tools needed to collate and interpret real-world evidence, interrogate the literature and conduct systematic literature searches. Learning will focus on best practice in medical writing and identifying the key approaches to statistical analysis and interpretation.

Learning activities

Check these off as you go!

- ☐ eLearning
- ☐ Quiz
- ☐ Module host webinar
- ☐ Expert webinar
- ☐ Journal club
- ☐ Mentorship session

Module hosts

Module hosts are subject to availability and may change

Reflections

Use the space below to think about your learnings from Module 4 and what impact they might have on your clinical practice.

Questions

Use the space below to keep track of any questions that arise throughout this module.

Module 5: From theory to practice: optimising patient care

Professor Mathurin Fumery and Dr Taku Kobayashi will host Module 5, which will focus on the practical application of learnings from Modules 1–4 using patient case studies. Discussions will be based around clinical decision-making, with a focus on how diagnostic and monitoring tools can be applied in practice to optimise the treatment approach towards more personalised care in IBD.

Learning activities

Check these off as you go!

- ☐ eLearning
- ☐ Quiz
- ☐ Module host webinar
- ☐ Expert webinar
- ☐ Masterclass
- ☐ Patient case workshop
- ☐ Mentorship session

Module hosts

Module hosts are subject to availability and may change

Reflections

Use the space below to think about your learnings from Module 5 and what impact they might have on your clinical practice.

Questions

Use the space below to keep track of any questions that arise throughout this module.

Module 6: The art of effective communication

Module 6, hosted by Dr Gareth Parkes and Professor Mathurin Fumery, closes the IBD Training Academy with a focus on effective presentation skills and communication of **scientific data**. The module will cover how to prepare impactful and informative slides, how best to use case studies and tips for keeping your audience engaged. You will also hear about the importance of digital presence and the beneficial use of social media.

Learning activities

Check these off as you go!

- ☐ eLearning
- ☐ Quiz
- ☐ Module host webinar
- ☐ Expert webinar

Module hosts

Module hosts are subject to availability and may change

Reflections

Use the space below to think about your learnings from Module 6 and what impact they might have on your clinical practice.

Questions

Use the space below to keep track of any questions that arise throughout this module.

Notes pages

Notes pages

Notes pages

Notes pages

Notes pages

Prescribing Information

BELIGIAN PRESCRIBING INFORMATION

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 × 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 × 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.

Prescribing Information

GREAT BRITAIN PRESCRIBING INFORMATION

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

JYSELECA® ▼ filgotinib 100 mg or 200 mg film-coated tablets.

Indications:
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.
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).

Dosage: Adults: 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole.
Ulcerative colitis
In patients 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 SmPC). Patients who have not shown any therapeutic benefit after 22 weeks of treatment should discontinue filgotinib.
Laboratory Monitoring: Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption.
Elderly: *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.
Elderly: Rheumatoid Arthritis
A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited.
Renal impairment: No dose adjustment required in patients with estimated 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).
Not recommended in patients with CrCl < 15mL/min.

Hepatic impairment: Mild/moderate hepatic impairment: No dose adjustment required. Severe hepatic impairment not recommended.

Children (<18 years) Safety and efficacy not yet been established.

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

Warnings/Precautions: See SmPC for full information.
Immunosuppression: Combination use, with immunosuppressants e.g., ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded.
Infections: Infections, including serious infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be applied prior to initiating in patients with infection risk factors (see SmPC). Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. Treatment should be interrupted if the patient is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population.
Tuberculosis: Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB.
Viral reactivation: Cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster, filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed.

Malignancy: Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC).

Fertility: In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown.
Haematological abnormalities: Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) <1 × 10^9 cells/L, ALC <0.5 × 10^9 cells/L or haemoglobin <8 g/dL Temporarily stop therapy if these values are observed during routine patient management.
Vaccinations: Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended.
Lipids: Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC).
Cardiovascular risk: Rheumatoid arthritis and ulcerative colitis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care.
Venous thromboembolism: Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged immobilisation.
Lactose content: Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucosegalactose malabsorption should not take filgotinib.
Pregnancy/Lactation: Filgotinib is contraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing potential must use effective contraception during and for at least 1 week after cessation of treatment.
Driving/Using machinery: No or negligible influence, however dizziness has been reported, during treatment with Jyseleca (SmPC for full information)

Side effects: See SmPC for full information.
Common (≥1/100 to <1/10): nausea, upper respiratory tract infection, urinary tract infection and dizziness.
Uncommon (≥1/1000 to <1/100): herpes zoster, pneumonia, neutropenia hypercholesterolaemia, blood creatine phosphokinase increase
Serious side effects: See SmPC for full information
Legal category: POM

Pack: 30 film-coated tablets/ bottle

Price: UK Basic NHS cost: £863.10

Marketing authorisation number(s):

Jyseleca 100mg film-coated tablets PLGB 42147/0001
Jyseleca 200mg film-coated tablets PLGB 42147/0002

Further information:
Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UB8 1QS, United Kingdom
00800 7878 1345
medicalinfo@glpg.com.
Jyseleca® is a trademark.

Date of Preparation: January 2022

UK-FIL-202112-00003

▼Additional monitoring required

Adverse events should be reported.
For Great Britain, reporting forms and information can be found at yellowcard.mhra.gov.uk or via the Yellow Card app (download from the Apple App Store or Google Play Store).
Adverse events should also be reported to Galapagos via email to DrugSafety.UK.Ireland@glpg.com or 00800 7878 1345

Prescribing Information

IRELAND PRESCRIBING INFORMATION

PRESCRIBING INFORMATION
Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

JYSELECA® ▼ filgotinib 100 mg or 200 mg film-coated tablets.

Indications:
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.
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).

Dosage: Adults: 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole.
Ulcerative colitis
In patients 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 SmPC). Patients who have not shown any therapeutic benefit after 22 weeks of treatment should discontinue filgotinib.
Laboratory Monitoring: Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption.
Elderly: *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.
Elderly: Rheumatoid Arthritis
A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited.
Renal impairment: No dose adjustment required in patients with estimated 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).
Not recommended in patients with CrCl < 15mL/min.

Hepatic impairment: Mild/moderate hepatic impairment: No dose adjustment required. Severe hepatic impairment not recommended.

Children (<18 years) Safety and efficacy not yet been established.

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

Warnings/Precautions: See SmPC for full information.
Immunosuppression: Combination use, with immunosuppressants e.g., ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded.
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Serious side effects: See SmPC for full information
Legal category: POM

Pack: 30 film-coated tablets/ bottle

Price: UK Basic NHS cost: £863.10 Ireland POA

Marketing authorisation number(s):

Jyseleca 100mg film-coated tablets
EU/1/20/1480/001
EU/1/20/1480/002

Jyseleca 200mg film-coated tablets
EU/1/20/1480/003
EU/1/20/1480/004

Further information:
Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UB8 1QS, United Kingdom
00800 7878 1345
medicalinfo@glpg.com.
Jyseleca® is a trademark.

Date of Preparation: January 2022

IE-FIL-202112-00001

▼Additional monitoring required

Adverse events should be reported.
For Northern Ireland, reporting forms and information can be found at yellowcard.mhra.gov.uk or via the Yellow Card app (download from the Apple App Store or Google Play Store).
Adverse events should also be reported to Galapagos via email to DrugSafety.UK.Ireland@glpg.com or 00800 7878 1345

Adverse events should be reported.
For Ireland, reporting forms and information can be found at www.hpra.ie and can be reported to HPRA on +353 1 6764971.
Adverse events should also be reported to Galapagos via email to DrugSafety.UK.Ireland@glpg.com or 00800 7878 1345

IBD Training Academy

We look forward to meeting you soon!

This programme is organised and funded by Galapagos.

For more information or if you have any questions, please contact your local MSL or email us at **IBDTrainingAcademy@glpg.com**.

March 2022 | GL-IBD-NA-202202-00008

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Pioneering for patients