NYE METODER

Anmodning om vurdering av legemiddel i Nye metoder

Skjema for leverandører

En leverandør som ønsker offentlig finansiering av et legemiddel/legemiddelindikasjon i den norske spesialisthelsetjenesten, skal anmode om vurdering i Nye metoder ved å fylle ut dette skjemaet.

Utfylt anmodningsskjema sendes til Nye metoder: nyemetoder@helse-sorost.no

Leverandøren skal på anmodningstidspunktet både ha et forslag til type helseøkonomisk analyse og en plan for når de leverer dokumentasjonen. Merk at dokumentasjon i henhold til oppdraget fra Bestillerforum for nye metoder må leveres inn senest 12 måneder etter anmodningstidspunktet.

Hele anmodningsskjemaet skal fylles ut. Mer informasjon og veiledning finnes i artikkelen For leverandører (nyemetoder.no)

Merk: Skjemaet vil bli publisert i sin helhet på nyemetoder.no.

Innsender er klar over at skjemaet vil bli publisert i sin helhet (må krysses av): ☒

Fyll ut dato for innsending av skjema: 28.04.2026

1 Kontaktopplysninger	
1.1 Leverandør (innehaver/søker av markedsføringstillatelse i Norge)	Alfasigma Spa Company number 03432221202 Via Ragazzi del '99, 5 40133 Bologna Italy
1.2 Navn kontaktperson	Line de Linde Henriksen
1.3 Stilling kontaktperson	Nordic Lead
1.4 Telefon	+4526339168
1.5 E-post	Line.delindehenriksen@alfasigma.com
Ekstern representasjon - vedlegg fullmakt	
1.6 Navn/virksomhet	Klikk eller trykk her for å skrive inn tekst.
1.7 Telefon og e-post	Klikk eller trykk her for å skrive inn tekst.

2 Legemiddelinformasjon og indikasjon	
2.1 Hva gjelder anmodningen? *Kryss av for hva anmodningen gjelder*	Et nytt virkestoff ☐ En indikasjonsutvidelse / ny indikasjon ☒ En ny styrke eller formulering ☐
2.2 Hvilken indikasjon gjelder anmodningen?	**Aksial spondyloartritt**

Indikasjonen skal oppgis på norsk. Hvis prosess for godkjenning pågår, oppgi også indikasjon på engelsk. *Merk: Leverandør skal anmode om vurdering av hele indikasjonen som de har fått godkjent eller søker om godkjenning for. Dersom leverandør foreslår en avgrensning til undergrupper, må dette begrunnes og leverandør må levere dokumentasjonen som trengs for å foreta en vurdering av undergruppen i tillegg til dokumentasjonen for hele indikasjonen.*	**Ikke-radiografisk aksial spondyloartritt (nr-axSpA)** Jyseleca er indisert for behandling av aktiv ikke-radiografisk aksial spondyloartritt hos voksne pasienter med objektive tegn på inflammasjon, dokumentert ved forhøyet C-reaktivt protein (CRP) og/eller magnetisk resonanstomografi (MR), som har hatt utilstrekkelig respons på eller ikke tåler ikke-steroide antiinflammatoriske legemidler (NSAIDs). **Ankyloserende spondylitt (AS, radiografisk aksial spondyloartritt (r-axSpA)** Jyseleca er indisert for behandling av aktiv ankyloserende spondylitt (radiografisk aksial spondyloartritt) hos voksne pasienter som har hatt utilstrekkelig respons på eller ikke tåler konvensjonell behandling. 28th of Jan 2026 Alfasigma SpA submitted a Type II variation to extend the indication of Jyseleca to the treatment of axial spondyloarthitis (nr-axSpA & AS r-xSpA) English: Axial spondyloarthritis Non-radiographic axial spondyloarthritis (nr-axSpA): Jyseleca is indicated for the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). Ankylosing spondylitis (AS, radiographic axial spondyloarthritis (r-axSpA)): Jyseleca is indicated for the treatment of active ankylosing spondylitis (radiographic axial spondyloarthritis) in adult patients who have responded inadequately or are intolerant to conventional therapy.
2.3 Handelsnavn	Jyseleca
2.4 Generisk navn/virkestoff	Filgotinib
2.5 ATC-kode	L04AF04
2.6 Administrasjonsform og styrke *Oppgi også forventet dosering og behandlingslengde* *Skriv kort*	1 stk 100mg eller 1 stk 200mg tablett peroralt en gang daglig til kronisk behandling. Anbefalt dose av filgotinib for voksne pasienter er 200 mg én gang daglig. Hos voksne med økt risiko for venøs tromboembolisme (VTE), alvorlige kardiovaskulære hendelser (MACE) og malignitet, som har oppnådd tilstrekkelig terapeutisk

	effekt under behandling med 200 mg én gang daglig, er anbefalt dose 100 mg én gang daglig og kan økes til 200 mg én gang daglig ved oppbluss. Ved langtidsbehandling skal laveste effektive dose benyttes.
2.7 Farmakoterapeutisk gruppe og virkningsmekanisme. *Skriv kort*	***Selektivt immunsuppressivt middel, JAK-hemmer.*** L04A F04 (Filgotinib)

3 Historikk – virkestoff og indikasjon

3.1 Har Nye metoder behandlet metoder med det aktuelle virkestoffet tidligere? *Hvis ja, oppgi ID-nummer til metoden/metodene i Nye metoder*	Ja ☒ Nei ☐ ID-nummer: ID2020_005 (rheumatoid arthritis) ID2021_014 (ulcerative colitis)
3.2 Er du kjent med om andre legemidler/virkestoff er vurdert i Nye metoder til samme indikasjon? *Hvis ja, oppgi ID-nummer til metoden/metodene i Nye metoder*	Ja ☒ Nei ☐ ID-nummer: ID2015_024 (secukinumab – AS/r-axspa) ID2019_120 (secukinumab – nr-axspa) ID2019_126 (ixekinumab – AS/r-axspa og nr-axspa) ID2020_081 og ID2022_134 (upadacitinib – AS/r-axspa og nr-axspa) ID2021_093 (tofacitinib – AS/r-axspa) ID2022_145 (bimezikumab – AS/r-axspa og nr-axspa)
3.3 Er du kjent med om det er gjennomført en metodevurdering i et annet land som kan være relevant i norsk sammenheng? *Hvis ja, oppgi referanse*	Ja ☐ Nei ☒ Referanse: EMA Type II variation ansøkning sent 28. Jan 2026

4 Status for markedsføringstillatelse (MT) og markedsføring

4.1 Har legemiddelet MT i Norge for en eller flere indikasjoner? *Hvis ja - skriv inn dato for norsk MT for den første indikasjonen*	Ja ☒ Nei ☐ Dato for MT for første indikasjon: 26.10 2020 RA
4.2 Markedsføres legemiddelet i Norge?	Ja ☒ Nei ☐
4.3 Har legemiddelet MT i Norge for anmodet indikasjon? *For alle metoder: Fyll ut prosedyrenummer i EMA (det europeiske legemiddelbyrået)*	MT i Norge: Ja ☐ Nei ☒ Prosedyrenummer i EMA: **EMEA/H/C/005113/II/XXX - C.6.a Type II variation** EMA/VR/0000325892

Hvis metoden ikke har MT i Norge, fyll ut forventet tidspunkt (måned/år) for CHMP opinion i EMA. *Hvis metoden har MT i Norge, fyll ut dato for MT*	
	Hvis metoden ikke har MT: Forventet tidspunkt for CHMP opinion i EMA (måned/år): September 2026 Forventet tidspunkt for markedsføringstillatelse (MT) for den aktuelle indikasjonen i Norge (måned/år): Q4, 2026
	Hvis metoden har MT: Dato for MT i Norge for den aktuelle indikasjonen: Klikk eller trykk for å skrive inn en dato.
4.4 Har legemiddelet en betinget markedsføringstillatelse for anmodet indikasjon? *Hvis ja, fyll ut en beskrivelse av hva som skal leveres til EMA og når.*	Ja ☐ Nei ☒ Beskrivelse: Klikk eller trykk her for å skrive inn tekst.
4.5 Har anmodet indikasjon vært i «accelerated assessment» hos EMA?	Ja ☐ Nei ☒
4.6 Har legemiddelet «orphan drug designation» i EMA? *Hvis ja, fyll ut dato*	Ja ☐ Nei ☒ Dato for «orphan drug designation»: Klikk eller trykk for å skrive inn en dato.

5 Ordning for forenklet vurdering av PD-(L)1-legemidler

5.1 Er legemiddelet registrert i Nye metoders ordning «Forenklet vurdering av PD-(L)1-legemidler"?	Ja ☐ Nei ☒

6 Sammenlignbarhet og anbud

6.1 Finnes det andre legemidler med lignende virkningsmekanisme og /eller	Ja ☒ Nei ☐

tilsvarende effekt til den aktuelle indikasjonen?	Kommentar:
6.2 Vurderer leverandør at legemiddelet i anmodningen er sammenlignbart med et eller flere andre legemidler som Nye metoder har besluttet å innføre til den samme indikasjonen? *Hvis ja, hvilke(t)? Oppgi ID-nummer på metoden/metodene i Nye metoder*	Ja ☒ Nei ☐ Legemiddel og ID-nummer: Alfasigma har foretatt en indirekte sammenligning (ITC) som støtter den sammenlignbare effekt- og sikkerhetsprofilen mellom Jyseleca og de andre legemidler som Nye metoder har besluttet å introdusere till samme indikasjon. Analyser er tilgjengelige for både TNF-naive og erfarne pasienter. See section 3.2.
6.3 Er det eksisterende anbud på terapiområdet som kan være aktuelt for legemiddelet?	Ja ☒ Nei ☐ Kommentar: 2606b TNF BIO

7 Nordisk samarbeid JNHB (Joint Nordic HTA-bodies)

7.1 Er anmodet indikasjon aktuell for utredning i det nordiske HTA-samarbeidet JNHB? *Hvis nei, begrunn kort*	Ja ☐ Nei ☒ Begrunnelse: Jyseleca og andre avanserte behandlinger som er relevante for denne indikasjonen er inkludert i konfidensielle avtaler med SYKEHUSINNKJØP HF.

8 Europeisk samarbeid om vurdering av relativ effekt og sikkerhet (HTAR)

8.1 Er anmodet legemiddel/indikasjon omfattet av regelverket for utredning av relativ effekt og sikkerhet i europeisk prosess (HTAR)? *Hvis ja, fyll ut dato for søknad om MT til EMA*	Ja ☐ Nei ☒ Dato for søknad til EMA: Klikk eller trykk for å skrive inn en dato.

9 Helseøkonomisk dokumentasjon og forslag til helseøkonomisk analyse

9.1 Hvilken type helseøkonomisk analyse foreslår leverandøren?	Det antas at en eventuell innføring av Jyseleca til denne indikasjonen ikke vil påvirke det totale antall pasienter som behandles. Jyseleca vil inngå i anbud og dermed eventuelt erstatte andre etablerte

F.eks. kostnad-per-QALY analyse eller kostnadsminimeringsanalyse. *Begrunn forslaget*	legemidler. Det antas derfor at en eventuell innføring a Jyseleca trolig ikke vil medføre budsjettvirkninger av betydning for spesialisthelsetjenesten. Vi antar derfor at prisnotat (med eller uten en forenklede metodevurdering) er aktuelt for denne indikasjonen.
9.2 Pasientpopulasjonen som den helseøkonomiske analysen baseres på, herunder eventuelle undergrupper.	Ikke relevant.
9.3 Hvilken dokumentasjon skal ligge til grunn? (H2H studie, ITC, konstruert komparatorarm etc.) *Angi det som er relevant med tanke på hvilken type analyse som foreslås.*	Ikke relevant.
9.4 Forventet legemiddelbudsjett i det året med størst budsjettvirkning i de første fem år.	Ikke avklart. Pris er konfidensielle.
9.5 Forventet tidspunkt (måned og år) for levering av dokumentasjon til Direktoratet for medisinske produkter og/eller Sykehusinnkjøp HF. *Tidspunkt må oppgis*	At CHMP (September 2026)

10 Sykdommen og eksisterende behandling

10.1 Sykdomsbeskrivelse for aktuell indikasjon *Kort beskrivelse av sykdommens patofysiologi og klinisk presentasjon / symptombilde, eventuelt inkl. referanser*	Sykdomsbeskrivelse og pasientgrunnlag Ankyloserende spondylitt (tidligere kalt Bekhterevs sykdom) er en kronisk antiinflammatorisk sykdom som hovedsakelig angriper bekkenet, ryggen, nakken og brystkassen, men også perifere ledd kan rammes. Betennelse i et av leddene nederst i ryggen med strukturforandringer påvist ved røntgen er et av diagnosekriteriene. Sykdommen kjennetegnes først og fremst ved morgenstivhet i ryggen og i mindre grad av smerter. Typisk er at smerter og stivhet bedres ved aktivitet, men ikke ved hvile. Sykdommen er hyppigst hos individer med genetisk disposisjon og debuterer vanligvis før 40 års alder. Tilstanden innebærer økt tilbøyelighet til inflammasjon på steder der sener,

	ligamenter eller leddkapsler fester til ben (entesitt). (3) Tilstanden er hyppigere hos menn enn hos kvinner. Prevalensen i europeisk befolkning er mellom 0,15 og 0,5% Aksial spondylartritt (axSpA) er en, kronisk, inflammatorisk artrittsykdom i vertebralcolumna (spondylitt) og iliosakralledd (sakroiliitt). Den debuterer oftest før 45 år alder og gir plager med kroniske ryggsmerter samt stivhet i rygg som lindres ved aktivitet. Andre muskel- og skjelettmanifestasjoner er artritt, entesitt og daktylitt. Fremre uveitt, inflammatorisk tarmlidelse og psoriasis kan opptre som ekstraartikulære manifestasjoner. Sykdomsgruppen er assosiert med HLA-B27 og pasienter med aktiv sykdom har ofte forhøyet akuttfaserespons. Sykdomsårsaken er ukjent. AxSpA omfatter gruppen av pasienter hvor symptomer fra bekken/rygg/nakke dominerer, mens ved Perifer Spondyloartritt (pSpA) dominerer symptomer fra perifere ledd (artritt, entesitt, daktylitt). 4
10.2 Fagområde *Angi hvilket fagområde som best beskriver metoden*	Velg fagområde fra menyen: Immunologi
10.3 Kreftområde *Hvis metoden gjelder fagområdet Kreftsykdommer, angi hvilket kreftområde som er aktuelt*	Velg kreftområde fra menyen: Velg et element.
10.4 Dagens behandling *Nåværende standardbehandling i Norge, inkl. referanse*	Current standard of care include options from the TNF inhibitors class (adalimumab, etanercept, certolizumab, golimumab), the IL-17 class (secukinumab, bimezikumab), and the JAK-inhibitor class (tofacitinib in radiographic axSpA only). It is worth noting that ixekizumab (IL-17) and upadacitinib (JAKi) have not been recommended in Norway. The recommendation of filgotinib would therefore offer a second option in radiographic axSpA and be the first option from the JAKi class to be available in non-radiographic axSpA. In current norwegian guidelines, tofacitinib (JAKi) is ranked before IL-17s. TNF BIO - Sykehusinnkjøp HF
10.5 Prognose	Despite the availability of advanced therapies (TNFi, IL-17i, JAKi), many patients fail to achieve sustained disease control:

Beskriv prognosen med nåværende behandlingstilbud, inkl. referanse	• **Suboptimal response rates:** Only around 30–60% of patients reach ASAS40[1-4], ASAS20[4-10], or BASDAI50[11-12] responses within 3–24 months, and just 18–24% achieve ASDAS <1.3 remission, within this window[13]. • **High discontinuation rates:** Approximately 33–50% of patients with axSpA discontinue advanced therapies within 2 to 4 years[14-17]. • **High switching rates:** Treatment switching is also common, with around 7–27% of patients switching to another biologic often due to lack of efficacy or tolerability[14], and the time to first switch is often short, occurring within just 5 to 8 months of initiating bDMARD therapy[16]. • bDMARDs use is limited by: • Immunogenicity, leading to secondary loss of efficacy[18]. • Parenteral administration burdens and injection-site reactions, which may not be preferred by some patients[19-21]. • Limited suitability for certain EMMs, which complicates treatment selection and sequencing in clinical practice and often necessitate therapy changes even when axial symptoms are controlled[22-23]. Additional effective treatment options are needed to manage the diverse clinical features of axSpA and to accommodate patients' individual preferences regarding route of administration and achievement of specific treatment targets. 1. Van Der Heijde, D., et al. Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomised controlled trials. Annals of the rheumatic diseases **2023**, 82, 515-526. **2.** van der Heijde, D., et al. Efficacy and safety of upadacitinib in patients with active ankylosing spondylitis (SELECT-AXIS 1): a multicentre, randomised, double-blind, placebo-controlled, phase 2/3 trial. Lancet **2019**, 394, 2108-2117 <https://doi.org/10.1016/s0140-6736(19)32534-6>. **3.** Deodhar, A., et al. Upadacitinib for the treatment of active non-radiographic axial spondyloarthritis (SELECT-AXIS 2): a randomised, double-blind, placebo-controlled, phase 3 trial. The Lancet **2022**, 400, 369-379. **4.** Ørnbjerg, L.M., et al. Treatment response and drug retention rates in 24 195 biologic-naïve patients with axial spondyloarthritis initiating TNFi treatment: routine care data from 12 registries in the EuroSpA collaboration. Ann Rheum Dis **2019**, 78, 1536-1544 <https://doi.org/10.1136/annrheumdis-2019-215427>. 5. van der Heijde, D., et al. Efficacy and safety of adalimumab in patients with ankylosing spondylitis: results of a multicenter, randomized, double-blind, placebo-controlled trial. Arthritis Rheum **2006**, 54, 2136-46 <https://doi.org/10.1002/art.21913>. **6.** Deodhar, A., et al. Tofacitinib for the treatment of ankylosing spondylitis: a phase III, randomised, double-blind, placebo-controlled study. Ann Rheum Dis **2021**, 80, 1004-1013 <https://doi.org/10.1136/annrheumdis-2020-219601>. **7.** Baeten, D., et al. Secukinumab, an Interleukin-17A Inhibitor, in Ankylosing Spondylitis. N Engl J Med **2015**, 373, 2534-48 <https://doi.org/10.1056/NEJMoa1505066>. **8.** Kivitz, A., et al., *SECUKINUMAB REDUCES SIGNS AND SYMPTOMS OF ACTIVE ANKYLOSING SPONDYLITIS: RESULTS FROM A 16-WEEK, RANDOMIZED PLACEBO-CONTROLLED PHASE 3 TRIAL*, in *JCR-JOURNAL OF CLINICAL RHEUMATOLOGY*. 2016. LIPPINCOTT WILLIAMS & WILKINS TWO COMMERCE SQ, 2001 MARKET ST, PHILADELPHIA …. **9.** 16-week Efficacy and 3-year Safety, Tolerability and Efficacy of Secukinumab in Active Ankylosing Spondylitis Patients (MEASURE 3). Identifier: NCT02008916. 2015. ClinicalTrials.gov. Available online: https://clinicaltrials.gov/study/NCT04626297 (accessed on 13 Aug 2025). **10.** Landewé, R., et al. Efficacy of certolizumab pegol on signs and symptoms of axial spondyloarthritis including ankylosing spondylitis: 24-week results of a double-blind randomised placebo-controlled Phase 3 study. Ann Rheum Dis **2014**, 73, 39-47 <https://doi.org/10.1136/annrheumdis-2013-204231>. **11.** Navarro-Compán, V., et al. Switching biological disease-modifying antirheumatic drugs in patients with axial spondyloarthritis: results from a systematic literature review. RMD Open **2017**, 3, e000524 <https://doi.org/10.1136/rmdopen-2017-000524>. **12**. Glintborg, B., et al. Ankylosing Spondylitis versus Nonradiographic Axial Spondyloarthritis: Comparison of Tumor Necrosis Factor Inhibitor Effectiveness and Effect of HLA-B27 Status. An Observational Cohort Study

	from the Nationwide DANBIO Registry. J Rheumatol **2017**, 44, 59-69 <https://doi.org/10.3899/jrheum.160958>. **13.** Doumeth, S.A., O. Pamuk, and M.N. Magrey, *Achieving ASDAS Inactive Disease Status in Axial Spondyloarthritis: A Systematic Review and Meta-analysis*, in *ARTHRITIS & RHEUMATOLOGY*. 2023. WILEY 111 RIVER ST, HOBOKEN 07030-5774, NJ USA. **14.** Perrone, V., et al. Treatment Pattern Analysis and Health-care Resource Consumption on Patients with Psoriatic Arthritis or Ankylosing Spondylitis Treated with Biological Drugs in a Northern Italian Region. Ther Clin Risk Manag **2020**, 16, 509-521 <https://doi.org/10.2147/tcrm.S248390>. **15.** Pons, M., et al. Four-year secukinumab treatment outcomes in European real-world patients with axial spondyloarthritis and psoriatic arthritis. Joint Bone Spine **2025**, 92, 105824. **16.** Perrone, V., et al. Analysis of the prevalence of ankylosing spondylitis and treatment patterns and drug utilization among affected patients: an Italian real-world study. Expert Rev Pharmacoecon Outcomes Res **2022**, 22, 327-333 <https://doi.org/10.1080/14737167.2022.2032663>. **17.** Pinto, A.S., et al. Effectiveness and safety of original and biosimilar etanercept (Enbrel® vs Benepali®) in bDMARD-naïve patients in a real-world cohort of Portugal. ARP Rheumatol **2022**, 1, 109-116. **18.** Hiltunen, J., et al. Immunogenicity of subcutaneous TNF inhibitors and its clinical significance in real-life setting in patients with spondyloarthritis. Rheumatol Int **2022**, 42, 1015-1025 <https://doi.org/10.1007/s00296-021-04955-8>. **19.** Feng, H., et al. Adverse events of tumor necrosis factor alpha inhibitors for the treatment of ankylosing spondylitis: a meta-analysis of randomized, placebo-controlled trials. Frontiers in Pharmacology **2023**, 14, 1084614. **20.** National Institute for Health and Care Excellence (NICE). Upadacitinib for treating active ankylosing spondylitis. **30 September 2022**. Accessed: 30 June 2025. Available at: https://www.nice.org.uk/guidance/ta829 **21.** National Institute for Health and Care Excellence (NICE). Tofacitinib for treating active ankylosing spondylitis. **8 October 2023**. Accessed: 30 June 2025. Available at: https://www.nice.org.uk/guidance/ta920 **22.** Ramiro, S., et al. ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis **2023**, 82, 19-34 <https://doi.org/10.1136/ard-2022-223296>. **23.** Zhao, S.S., et al. The 2025 British Society for Rheumatology guideline for the treatment of axial spondyloarthritis with biologic and targeted synthetic DMARDs. Rheumatology **2025**, keaf089.
10.6 Det nye legemiddelets innplassering i behandlingsalgoritmen	Treatment algorithms are influenced by the existing ranking and confidential rebates provided in the context of the TNF BIO tenders. We expect to have a similar ranking as Xeljanz (tofacitinib), i.e. after TNF-inhibitors and before IL17s.
10.7 Pasientgrunnlag *Beskrivelse, insidens og prevalens av pasienter omfattet av aktuell indikasjon* i Norge, inkl. referanse.*	www.metodebok.no Data on axSpA prevalence is limited, with no data identified for the overall axSpA or nr-axSpA prevalence in the EU5. The prevalence of r-axSpA in EU5 ranged from 8.8 to 37 per 10,000 people[1-5]. Data specific to Norway range from 13.1 to 53.0 patients for 10,000 people[3,6-7].

Antall norske pasienter antatt aktuelle for behandling med legemiddelet til denne indikasjonen. ** Hele pasientgruppen som omfattes av aktuell indikasjon skal beskrives*	- Bohn, 2018[3]: 1986–1987, axSpA in Norway, prevalence of 53,0 per 10.000 people - Bohn, 2018[3]: 1960–1993, r-axSpA in Norway: prevalence of 26,0 per 10.000 people - Kerola, 2023[6]: 2017, axSpA in Norway: prevalence of 41.4 per 10.000 people - Kerola, 2023[6]: 2017, r-axSpA in Norway: prevalence of 28.3 per 10.000 people: - Kerola, 2023[6]: 2017, nr-axSpA in Norway: prevalence of 13.1 per 10.000 people: - Dean, 2013[7] : r-axSpA in Norway: prevalence of 26,3 per 10.000 people Data on the incidence of axSpA are sparse. Most of the identified data are outdated and limited to r-axSpA only[2-3,8]. Only one study reported r-axSpA incidence in EU-4 or the UK, showing 0.54 per 10,000 person-year (PY) in the UK-based Clinical Practice Research Datalink database (1988–2017) among people with rheumatic and musculoskeletal diseases[2]. One systematic literature review (SLR) reported crude incidence rates of AS (also known as r-axSpA) recorded in Norway between 1960 and 1993 (0.73 per 10,000 PYs), in Albania between 1995 and 2010 (0.60 per 10,000 PYs), and annual incidence in Iceland between 1947 and 2005 (ranging from 0.04 to 0.55 per 10,000 persons)[3]. In Denmark, an increasing trend in the number of r-axSpA cases over time was reported with 476 incident cases between 2000 and 2004 and 660 cases between 2010 and 2013[8]. **1.** Perrone, V., et al. Analysis of the prevalence of ankylosing spondylitis and treatment patterns and drug utilization among affected patients: an Italian real-world study. Expert Rev Pharmacoecon Outcomes Res **2022**, 22, 327-333 <https://doi.org/10.1080/14737167.2022.2032663>. **2.** Crossfield, S.S.R., et al. Changes in ankylosing spondylitis incidence, prevalence and time to diagnosis over two decades. RMD Open **2021**, 7, <https://doi.org/10.1136/rmdopen-2021-001888>. **3.** Bohn, R., et al. Incidence and prevalence of axial spondyloarthritis: methodologic challenges and gaps in the literature. Clin Exp Rheumatol **2018**, 36, 263-274. **4.** Dean, L.E., et al. Global prevalence of ankylosing spondylitis. Rheumatology (Oxford) **2014**, 53, 650-7 <https://doi.org/10.1093/rheumatology/ket387>. **5.** Quilis, N., et al. Prevalence of ankylosing spondylitis in Spain: EPISER2016 Study. Scandinavian Journal of Rheumatology **2020**, 49, 210-213. **6.** Kerola, A., et al. Psoriatic arthritis, axial spondyloarthritis and rheumatoid arthritis in Norway: nationwide prevalence and use of biologic agents. Scandinavian Journal of Rheumatology **2023**, 52, 42-50. **7.** Dean, L.E., et al. Global prevalence of ankylosing spondylitis. Rheumatology **2014**, 53, 650-657. **8.** Nygaard, A., et al. Incidence of ankylosing spondylitis and spondyloarthritis in 2000–2013: a nationwide Danish cohort study. Scandinavian journal of rheumatology **2020**, 49, 21-27.

11 Studiekarakteristika for relevante kliniske studier

	Studie 1	Studie 2	Studie 3
11.1 Studie-ID *Studienavn, NCT-nummer, hyperlenke*	TORTUGA (NCT03117270) **Study Details | NCT03117270 | A Study to Assess Efficacy and Safety of Filgotinib in Ankylosing Spondylitis | ClinicalTrials.gov**	OLINGUITO Study A (NCT05785611) Study Details | NCT05785611 | A Study Evaluating the Effect of Filgotinib in Participants With Active Axial	OLINGUITO Study B (NCT05785611) Study Details | NCT05785611 | A Study Evaluating the Effect of Filgotinib in Participants With Active Axial

		Spondyloarthritis | ClinicalTrials.gov	Spondyloarthritis | ClinicalTrials.gov
11.2 Studietype og -design	Multicenter, Phase 2, double-blind, placebo-controlled study in subjects with active Ankylosing Spondylitis (AS – radiographic AxSpA)	Multicenter, Phase 3, double-blind, placebo-controlled study in subjects with active Ankylosing Spondylitis (AS – radiographic AxSpA)	Multicenter, Phase 3, double-blind, placebo-controlled study in subjects with active non-radiographic AxSpA.
11.3 Formål	Evaluate the efficacy and safety of filgotinib in radiographic axSpA.	Evaluate the efficacy and safety of filgotinib in radiographic axSpA.	Evaluate the efficacy and safety of filgotinib in non-radiographic axSpA.

11.4 Populasjon
 	
Viktige inklusjons- og eksklusjonskriterier
	Key Inclusion Criteria:
	- Male or female subjects who are ≥18 years of age on the day of signing informed consent.
	- Diagnosis of moderate to severe ankylosing spondylitis with documented evidence of fulfilling the Modified New York (NY) criteria
	- Have active ankylosing spondylitis with a BASDAI ≥4 (numeric rating scale [NRS] 0-10) and spinal pain ≥4 (0-10 NRS) (based on BASDAI question 2, see protocol) at screening and baseline.
	- Have had a documented inadequate response to NSAIDs including cyclooxygenase-2 (COX-2) inhibitors.
	- If using cDMARD therapy, stable dose for at lead 4 weeks prior to Baseline.
	- If using non-drug therapies (including physical therapies), these should be kept stable during screening.
	- Male and female subjects of childbearing potential who engage in heterosexual intercourse must agree to use highly effective methods of contraception as described in the protocol.
	Key Exclusion Criteria:
	- Use of JAK inhibitors, investigational or approved, at any time, including filgotinib;
	- Prior use of more than one TNF inhibitor, at any time.
	- Use of oral steroids at a dose >10
		Key Inclusion Criteria:
		- Have an established diagnosis of axSpA by a rheumatologist (or other specialist with expertise in diagnosing axSpA).
		- Study A (r-axSpA): Meet Assessment of SpondyloArthritis International Society (ASAS) classification criteria with radiographic sacroiliitis on X-ray as follows:
		  - History of back pain >=12 weeks and age at onset of back pain <45 years, AND
		  - Have radiographic bilateral grade 2-4 sacroiliitis or unilateral grade 3-4 sacroiliitis, based on New York grading system, confirmed by central reading, AND,
		  - >=1 spondyloarthritis (SpA) feature.
		- Have active axSpA at screening and Day 1 defined by:
		  - Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) >=4 (numeric rating scale [NRS] 0-10), AND
		  - Spinal pain score >=4 (0-10 NRS) (based on BASDAI question 2),
		- Have a history of inadequate response to >=2 NSAIDs at the maximum dose of NSAIDs used in axSpA for >=2 weeks each (a total duration of NSAID trial >=4 weeks) or intolerance to >=2 NSAIDs for the treatment of
			Key Inclusion Criteria:
			- Have an established diagnosis of axSpA by a rheumatologist (or other specialist with expertise in diagnosing axSpA).
			- Study A (r-axSpA): Meet Assessment of SpondyloArthritis International Society (ASAS) classification criteria with radiographic sacroiliitis on X-ray as
			- Study B (nr- axSpA): Meet ASAS classification criteria without radiographic sacroiliitis on X-ray as follows:
			  - History of back pain >= 12 weeks and age at onset of back pain <45 years, AND
			  - No radiographic bilateral grade 2-4 sacroiliitis or unilateral grade 3-4 sacroiliitis, AND,
			  - Presence of sacroiliitis on MRI (based on central reading) and at least 1 SpA feature or when positive for human leukocyte antigen (HLA)-B27: having at least 2 SpA features, AND
			  - Have objective signs of inflammation, by sacroiliitis on MRI or elevated CRP.
			- Have active axSpA at screening and Day 1 defined by:
			  - Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) >=4 (numeric rating scale

	mg/day of prednisone or prednisone equivalent or at a dose that hasn't been stable for at least 4 weeks prior to baseline;
	- Any therapy by intra-articular injections (e.g. corticosteroid, hyaluronate) within 4 weeks prior to screening;
	- Use of more than 1 NSAID or COX-2 inhibitor.
	- Contraindication to MRI.
	- History of known or suspected complete ankylosis of the spine.
	- Presence of very poor functional status or unable to perform self-care.
	- Have undergone surgical treatment for ankylosing spondylitis within the last 12 weeks prior to screening.
	- Administration of a live or attenuated vaccine within 12 weeks prior to baseline.
		axSpA.
		- Participants who are biologic disease-modifying antirheumatic drug (BDMARD)(s) experienced; defined as below.
		  - Participants designated as bDMARD(s)-inadequate responder(IR) must have received not more than 2 bDMARD(s), that was/were administered in accordance with its/their labeling and discontinued due to:
		  - Participants designated as bDMARD(s) non-IR have previously received bDMARD(s) and have discontinued these due to other reasons than non-response or intolerance (e.g. economic reasons, treatment as part of a clinical study, other, or unknown).
		- If continuing conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) during the study, participants are permitted to use only a maximum of 2 csDMARDs and must have been on this treatment for >=12 weeks prior to screening, with a stable dose and route of administration (defined as no change in prescription) for >4 weeks prior to Day 1.
		- For participants aged 65 years or above on the date of signing the informed consent form (ICF), the investigator should carefully consider if participation is in the best interest of the participant.
		Key Exclusion Criteria:
		- Prior exposure to a Janus kinase inhibitor, investigational or approved, at any time, including filgotinib.
		- Use of any opioid analgesic at average daily doses >30 mg/day of morphine (or equivalent) or use of unstable doses of any opioid analgesic <=2 weeks prior to Day 1.
		- Use of any of the following systemic immunomodulating therapies <= 4 weeks prior to Day 1, including, but not limited to: 6-mercaptopurine, azathioprine, cyclosporine or other calcineurin inhibitors (e.g. sirolimus, tacrolimus), methotrexate if being discontinued, mycophenolate, antimalarials (e.g. hydroxychloroquine, chloroquine) if being discontinued, or sulfasalazine if being discontinued.
		- Complete spinal ankylosis defined as the presence of consecutive bridging syndesmophytes in >=5 segments on the lateral radiograph (assessed by the central reader).
		- Have undergone surgical treatments for peripheral manifestation of axSpA, including synovectomy or arthroplasty, or
			[NRS] 0-10), AND
			  - Spinal pain score >=4 (0-10 NRS) (based on BASDAI question 2),
			- Have a history of inadequate response to >=2 NSAIDs at the maximum dose of NSAIDs used in axSpA for >=2 weeks each (a total duration of NSAID trial >=4 weeks) or intolerance to >=2 NSAIDs for the treatment of axSpA.
			- Participants who are biologic disease-modifying antirheumatic drug (BDMARD)(s) experienced; defined as below.
			  - Participants designated as bDMARD(s)-inadequate responder(IR) must have received not more than 2 bDMARD(s), that was/were administered in accordance with its/their labeling and discontinued due to:
			  - Participants designated as bDMARD(s) non-IR have previously received bDMARD(s) and have discontinued these due to other reasons than non-response or intolerance (e.g. economic reasons, treatment as part of a clinical study, other, or unknown).
			- If continuing conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) during the study, participants are permitted to use only a maximum of 2 csDMARDs and must have been on this treatment for >=12 weeks prior to screening, with a stable dose and route of administration (defined as no change in prescription) for >4 weeks prior to Day 1.
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			- Use of any of the following systemic immunomodulating therapies <= 4 weeks prior to Day 1, including, but not limited to: 6-mercaptopurine, azathioprine, cyclosporine or other calcineurin inhibitors (e.g. sirolimus, tacrolimus), methotrexate if being discontinued, mycophenolate, antimalarials (e.g. hydroxychloroquine, chloroquine) if being discontinued, or sulfasalazine if

		major surgery (requiring regional block or general anesthesia) <=12 weeks prior to Day 1 or planned major surgery during the study. - Have a diagnosis of any generalized musculoskeletal disorder, e.g. generalized osteoarthritis, or systemic inflammatory condition other than axSpA. - Have active Crohn's disease (CD) or active ulcerative colitis (UC). Note: participants may be enrolled if they have had a history of inflammatory bowel disease (IBD), including CD and UC, but have had no exacerbation within 6 months prior to Day 1, and, if currently on treatment, must be on stable treatment for >=6 months prior to Day 1 and this treatment should be allowed per protocol. - Active autoimmune disease that would interfere with assessment of study parameters or increase risk to the participant by participating in the study (e.g. uncontrolled uveitis, uncontrolled thyroiditis, transverse myelitis, current peptic ulcer disease or prior history of severe diverticulitis [i.e. requiring hospitalization] or previous gastrointestinal perforation), per judgment of investigator, - History of opportunistic infection, or immunodeficiency syndrome, which would put the participant at risk, as per investigator judgment, - Active infection that is clinically significant, as per judgment of the investigator, or history of a serious infection (requiring hospitalization or systemic antibiotics) within 12 weeks prior to screening. - Participant has a history of malignancy or myelo- or lymphoproliferative disorder, including non-melanoma skin cancer (NMSC), excised and curatively treated non-metastatic basal cell carcinoma, squamous cell carcinoma of the skin, or in situ uterine cervical carcinoma within the past 5 years prior to screening. - Participant has any other condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (e.g. compromise the well-being) or that could prevent, limit, or confound the protocol-specified assessments. For participants at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past (>10 pack-years) and those at increased risk of cancer, the investigator should carefully consider if participation is in the best interest of the participant.	being discontinued. - Complete spinal ankylosis defined as the presence of consecutive bridging syndesmophytes in >=5 segments on the lateral radiograph (assessed by the central reader). - Have undergone surgical treatments for peripheral manifestation of axSpA, including synovectomy or arthroplasty, or major surgery (requiring regional block or general anesthesia) <=12 weeks prior to Day 1 or planned major surgery during the study. - Have a diagnosis of any generalized musculoskeletal disorder, e.g. generalized osteoarthritis, or systemic inflammatory condition other than axSpA. - Have active Crohn's disease (CD) or active ulcerative colitis (UC). Note: participants may be enrolled if they have had a history of inflammatory bowel disease (IBD), including CD and UC, but have had no exacerbation within 6 months prior to Day 1, and, if currently on treatment, must be on stable treatment for >=6 months prior to Day 1 and this treatment should be allowed per protocol. - Active autoimmune disease that would interfere with assessment of study parameters or increase risk to the participant by participating in the study (e.g. uncontrolled uveitis, uncontrolled thyroiditis, transverse myelitis, current peptic ulcer disease or prior history of severe diverticulitis [i.e. requiring hospitalization] or previous gastrointestinal perforation), per judgment of investigator, - History of opportunistic infection, or immunodeficiency syndrome, which would put the participant at risk, as per investigator judgment, - Active infection that is clinically significant, as per judgment of the investigator, or history of a serious infection (requiring hospitalization or systemic antibiotics) within 12 weeks prior to screening. - Participant has a history of malignancy or myelo- or lymphoproliferative disorder, including non-melanoma skin cancer (NMSC), excised and curatively treated non-metastatic basal cell carcinoma, squamous cell carcinoma of the skin, or in situ uterine cervical carcinoma within the past 5 years prior to screening. - Participant has any other condition for which, in the opinion of the investigator, participation would not be in the best interest of the participant (e.g. compromise the well-being) or that could prevent, limit, or confound the protocol-specified

		- Contraindication to magnetic resonance imaging (MRI).	assessments. For participants at increased risk of major cardiovascular problems (such as heart attack or stroke), those who smoke or have done so for a long time in the past (>10 pack-years) and those at increased risk of cancer, the investigator should carefully consider if participation is in the best interest of the participant. - Contraindication to magnetic resonance imaging (MRI).
11.5 Intervensjon (n) *Dosering, doseringsintervall, behandlingsvarighet*	Filgotinib 200mg daily vs placebo (double-blind) for 12 weeks.	Filgotinib 200mg daily or placebo (double-blind) until week 16, then open-label filgotinib 200mg or 100mg until week 234	Filgotinib 200mg daily or placebo (double-blind) until week 16, then open-label filgotinib 200mg or 100mg until week 234
11.6 Komparator (n) *Dosering, doseringsintervall, behandlingsvarighet*	Placebo for 12 weeks	Placebo for 16 weeks	Placebo for 16 weeks
11.7 Endepunkter *Primære, sekundære og eksplorative endepunkter, herunder definisjon, målemetode og ev. tidspunkt for måling*	Primary endpoint - Change from Baseline (CFB) in ASDAS-CRP at week 12 Secondary endpoints (all at week 12) - ASAS response - CFB in severity of peripheral arthritis by TJC44 and SJC44 in subjects with at least one affected joint at baseline - CFB in BASDAI - CFB in BASFI - CFB in BASMI (linear score) - CFB in SPARCC MRI score of sacroiliac joints - CFB in MASES - CFB in FACIT-Fatigue - CFB in SF-36 score - CFB in ASQoL - Frequency and severity of TEAEs	Primary endpoint - Achieving ASAS40 response at week 16 Secondary endpoints (at week 16) - Change from Baseline (CFB) in ASDAS-CRP - CFB in SPARCC MRI score of sacroiliac joints - CFB in BASFI - CFB in ASQoL - CFB in BASMI (linear score) - Other efficacy endpoints - Achieving ASAS20 response - Achieving ASDASCRP <2.1 - Achieving Inactive disease (ASDAS-CRP <1.3) - Achieving BASDAI50 response - CFB in ASDAS-CRPΔ - CFB in BASDAI - CFB in morning stiffness - CFB in SPARCC MRI score of spine - CFB in chest expansion - CFB in MASES - CFB in ASAS-HI - CFB in SF-36 score - CFB in FACIT-Fatigue - CFB in MOS-Sleep	Primary endpoint - Achieving ASAS40 response at week 16 Secondary endpoints (at week 16) - Change from Baseline (CFB) in ASDAS-CRP - CFB in SPARCC MRI score of sacroiliac joints - CFB in BASFI - CFB in ASQoL - CFB in BASMI (linear score) - Other efficacy endpoints - Achieving ASAS20 response - Achieving ASDASCRP <2.1 - Achieving Inactive disease (ASDAS-CRP <1.3) - Achieving BASDAI50 response - CFB in ASDAS-CRPΔ - CFB in BASDAI - CFB in morning stiffness - CFB in SPARCC MRI score of spine - CFB in chest expansion - CFB in MASES - CFB in ASAS-HI - CFB in SF-36 score - CFB in FACIT-Fatigue - CFB in MOS-Sleep

		- CFB in WPAI-axSpA - CFB in PGA of Disease - CFB in severity of peripheral arthritis by TJC44 and SJC44 in subjects with at least one affected joint at baseline - CFB in CANDEN MRI Score (spine) - CFB in mSASSS - Pharmacokinetics - Pharmacodynamic Safety endpoints - Frequency and severity of TEAEs - Frequency and severity of treatment-emergent SAEs - Frequency and severity of TEAEs leading to treatment discontinuation	- CFB in WPAI-axSpA - CFB in PGA of Disease - CFB in severity of peripheral arthritis by TJC44 and SJC44 in subjects with at least one affected joint at baseline - CFB in CANDEN MRI Score (spine) - CFB in mSASSS - Pharmacokinetics - Pharmacodynamic Safety endpoints - Frequency and severity of TEAEs - Frequency and severity of treatment-emergent SAEs - Frequency and severity of TEAEs leading to treatment discontinuation
11.8 Relevante subgruppeanalyser *Beskrivelse av ev. subgruppeanalyser*	None	Per sex (male/female), age, risk factor, race, region, BMI, duration of disease since first symptoms, disease activity (ASDASCRP level at baseline), hs-CRP level at screening, use of prior bDMARD(s), us of prior csDMARD(s).	Per sex (male/female), age, risk factor, race, region, BMI, duration of disease since first symptoms, disease activity (ASDASCRP level at baseline), hs-CRP level at screening, use of prior bDMARD(s), us of prior csDMARD(s), disease phenotype (MRI, HLA-B27), inflammation based on SIJ/CRP.
11.9 Oppfølgingstid *Hvis pågående studie, angi oppfølgingstid for data som forventes å være tilgjengelige for vurderingen hos Direktoratet for medisinske produkter samt den forventede/planlagte samlede oppfølgingstid for studien*	12 weeks data	Open-label filgotinib 200mg or 100mg until week 234. Data at 52 weeks already available and to be submitted to the DMP.	Open-label filgotinib 200mg or 100mg until week 234. Data at 52 weeks already available and to be submitted to the DMP.
11.10 Tidsperspektiv resultater *Pågående eller avsluttet studie? Tilgjengelige og fremtidige datakutt*	Study concluded.	Ongoing study. 52 weeks data cut-off available. Future data cut-off planned at 104 weeks.	Ongoing study. 52 weeks data cut-off available. Future data cut-off planned at 104 weeks.

11.11 Publikasjoner *Tittel, forfatter, tidsskrift og årstall. Ev. forventet tidspunkt for publikasjon*	Efficacy and safety of filgotinib, a selective Janus kinase 1 inhibitor, in patients with active ankylosing spondylitis (TORTUGA): results from a randomised, placebo-controlled, phase 2 trial. Van Der Heijde D. et al. Lancet. 2018 **Impact of filgotinib on sacroiliac joint magnetic resonance imaging structural lesions at 12 weeks in patients with active ankylosing spondylitis (TORTUGA trial). Maksymowych WP et al. Rheumatology (Oxford). 2022** **Filgotinib decreases both vertebral body and posterolateral spine inflammation in ankylosing spondylitis: results from the TORTUGA trial. Maksymowych WP et al. Rheumatology (Oxford). 2022**	Primary manuscript in development. 52 weeks data publication expected Q3 2026. 104 week data publication expected 2027.	Primary manuscript in development. 52 weeks data publication expected Q3 2026. 104 week data publication expected 2027.

12 Igangsatte og planlagte studier	
12.1 Er det pågående eller planlagte studier for legemiddelet innenfor samme indikasjon	Ja ☒ Nei ☐

som kan gi ytterligere informasjon i fremtiden? *Hvis ja, oppgi forventet tidspunkt*	A phase 4 study is in the design stage. Expected 2027.
12.2 Er det pågående eller planlagte studier for legemiddelet for andre indikasjoner?	Ja ☐ Nei ☒ Klikk eller trykk her for å skrive inn tekst.

13 Diagnostikk

13.1 Vil bruk av legemiddelet til anmodet indikasjon kreve diagnostisk test for analyse av biomarkør? *Hvis ja, fyll ut de neste spørsmålene*	Ja ☐ Nei ☒
13.2 Er testen etablert i klinisk praksis? *Hvis ja, testes pasientene rutinemessig i dag?*	Ja ☐ Nei ☐ Hvis ja, testes pasientene rutinemessig i dag? Ja ☐ Nei ☐
13.3 Hvis det er behov for en test som ikke er etablert i klinisk praksis, beskriv behovet inkludert antatte kostnader/ressursbruk	Klikk eller trykk her for å skrive inn tekst.

14 Andre relevante opplysninger

14.1 Har dere vært i kontakt med fagpersoner (for eksempel klinikere) ved norske helseforetak om dette legemiddelet/indikasjonen? *Hvis ja, hvem har dere vært i kontakt med og hva har de bidratt med?* *(Relevant informasjon i forbindelse med rekruttering av fageksperter i Nye metoder)*	Ja ☐ Nei ☒ Klikk eller trykk her for å skrive inn tekst.
14.2 Anser leverandør at det kan være spesielle forhold ved dette legemiddelet som gjør at en innkjøpsavtale ikke kan	Ja ☐ Nei ☒ Klikk eller trykk her for å skrive inn tekst.

basere seg på flat rabatt for at legemiddelet skal kunne oppfylle prioriteringskriteriene? *Hvis ja, begrunn kort.* *Hvis ja, skal eget skjema fylles ut og sendes til Sykehusinnkjøp HF samtidig med at dokumentasjon til metodevurdering sendes til Direktoratet for medisinske produkter.* *Nærmere informasjon og skjema:* Informasjon og opplæring - Sykehusinnkjøp HF	
14.3 Andre relevante opplysninger?	1) 1. Jyseleca, Preparatomtale.Oppdatert 29.04.2020. Hentet fra https://www.ema.europa.eu/en/medicines/human/EPAR/jyseleca 3) Ankyloserende spondylitt. Norsk elektronisk legehåndbok. Hentet 20.08.2020 fra https://legehandboka.no/handboken/kliniskekapitler/revmatologi/tilstander-og-sykdommer/artritter/ankyloserende-spo 4) Metodebok

Informasjon om Nye metoder finnes på nettsiden nyemetoder.no