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: 18.09.2025

1 Kontaktopplysninger	
1.1 Leverandør (innehaver/søker av markedsføringstillatelse i Norge)	Boehringer Ingelheim International GmbH, Germany
1.2 Navn kontaktperson	Carl Samuelsen Kristie van Lieshout
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1.4 Telefon	Carl Samuelsen: +47 941 80 805 Kristie van Lieshout: +47 486 12 826
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Ekstern representasjon - vedlegg fullmakt	
1.6 Navn/virksomhet	N/A
1.7 Telefon og e-post	N/A

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? *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.*	The expected EMA indications are: - Nerandomilast is indicated for the treatment of adult patients with Idiopathic Pulmonary Fibrosis (IPF). - Nerandomilast is indicated for the treatment of adult patients with Progressive Pulmonary Fibrosis (PPF). Nerandomilast er indisert til: - Behandling av idiopatisk lungefibrose (IPF) hos voksne pasienter. - Behandling av andre kroniske fibroserende interstitielle lungesykdommer (ILD) med en progressiv fenotype hos voksne. Boehringer Ingelheim proposes the following subgroups of patients for both the IPF and PPF indication: 1) Nerandomilast as add-on to standard antifibrotic (AF) treatment, and 2) Nerandomilast as monotherapy for those patients that cannot tolerate standard AF treatment.
2.3 Handelsnavn	None
2.4 Generisk navn/virkestoff	Nerandomilast
2.5 ATC-kode	L04AA61
2.6 Administrasjonsform og styrke *Oppgi også forventet dosering og behandlingslengde* *Skriv kort*	9 mg or 18 mg twice daily, administered orally approximately 12 hours apart. It is expected that both dosages will be approved by EMA.
2.7 Farmakoterapeutisk gruppe og virkningsmekanisme. *Skriv kort*	Selective immunosuppressants (L04AA61). Nerandomilast is a selective inhibitor of phosphodiesterase 4 (PDE4) with at least 9-fold preferential inhibition of the PDE4B isoenzyme over PDE4A, C and D based on in vitro data. PDE4 hydrolyses and inactivates cyclic adenosine monophosphate (cAMP). Nerandomilast exerts both anti-fibrotic and immunomodulatory effects as preferential PDE4B inhibition elevates intracellular cAMP levels and reduces the expression of pro-fibrotic growth factors and inflammatory cytokines, which are overexpressed in fibrotic lung disease.

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: N/A
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: ID2019_136: Nintedanib (Ofev)
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: N/A

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: N/A
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/006405/0000
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): March/2026 Forventet tidspunkt for markedsføringstillatelse (MT) for den aktuelle indikasjonen i Norge (måned/år): June/2026 (EMA approval)

	Hvis metoden har MT: Dato for MT i Norge for den aktuelle indikasjonen: N/A
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: N/A
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»: N/A

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 tilsvarende effekt til den aktuelle indikasjonen?	Ja ☐ Nei ☒ Kommentar: N/A
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: N/A
6.3 Er det eksisterende anbud på terapiområdet som kan være aktuelt for legemiddelet?	Ja ☐ Nei ☒ Kommentar: N/A

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: Different treatment practices.

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: N/A

9 Helseøkonomisk dokumentasjon og forslag til helseøkonomisk analyse	
9.1 Hvilken type helseøkonomisk analyse foreslår leverandøren? *F.eks. kostnad-per-QALY analyse eller kostnadsminimeringsanalyse.* *Begrunn forslaget*	Boehringer Ingelheim suggests a health economic cost-utility analysis (Markov model) as recommended.
9.2 Pasientpopulasjonen som den helseøkonomiske analysen baseres på, herunder eventuelle undergrupper.	Boehringer Ingelheim proposes the following subgroups of patients for both the IPF and PPF indication: 1) Nerandomilast as add-on to standard AF treatment, and 2) Nerandomilast as monotherapy for those patients that cannot tolerate standard AF treatment.
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.*	Double blind, ranodmized, placebo-contolled clinical phase III trials (FIBRONEER-IPF and FIBRONEER-ILD).

9.4 Forventet legemiddelbudsjett i det året med størst budsjettvirkning i de første fem år.	Expected patient pool is between 400 to 500 patients in year 5 after launch. This results in a budget impact of between 125 to 190 million NOK in year 5.
9.5 Forventet tidspunkt (måned og år) for levering av dokumentasjon til Direktoratet for medisinske produkter og/eller Sykehusinnkjøp HF. *Tidspunkt må oppgis*	March 2026

10 Sykdommen og eksisterende behandling

10.1 Sykdomsbeskrivelse for aktuell indikasjon *Kort beskrivelse av sykdommens patofysiologi og klinisk presentasjon / symptombilde, eventuelt inkl. referanser*	IPF is a specific form of chronic, progressive, fibrosing interstitial pneumonia of unknown cause. It is defined by the presence of a histological and radiological pattern of usual interstitial pneumonia (UIP) detected by imaging (high-resolution computed tomography [HCRT]) in the absence of an alternative interstitial lung disease (ILD) diagnosis. IPF is thought to result from sustained or repetitive injury to the lung epithelium followed by activation of fibroblasts and myofibroblast differentiation. Genetic and environmental factors along with age-related changes trigger damage to epithelial cells, which then secrete cytokines that subsequently promote fibroblast migration and proliferation and also differentiation into myofibroblasts. Myofibroblasts secrete large amounts of extracellular matrix, which leads to deposition and progression of lung fibrosis. Other factors that play a role in disease progression include dysfunction and exhaustion of stem cells, abnormal deposition of extracellular matrix and matrix stiffness. Initial symptoms of IPF include unexplained chronic exertional dyspnoea, dry/unproductive cough, bibasilar inspiratory crackles and/or digital clubbing. Pulmonary function testing (PFT) of patients suspected to have IPF can reveal lung function impairment (decreased forced vital capacity [FVC] and diffusion capacity of the lung for carbon monoxide [DLco]). In addition, severe fatigue is highly prevalent and is associated with depression, dyspnoea, functional activity impairment and a lower quality of life. PPF is a progressive phenotype of fibrosing ILD (F-ILD), and IPF can therefore be considered a prototype of PPF. However, other than IPF, there are many F-ILD

	subtypes that can develop into PPF. PPF and IPF share common pathophysiologic characteristics: alveolar epithelial cell injury and subsequent dysregulated repair, characterised by excessive deposition of extracellular matrix and loss of normal parenchymal architecture and lung function. In PPF, fibroblasts are recruited from resident fibroblasts, circulating fibroblasts in addition to epithelial cells and fibrocytes undergoing epithelial-mesenchymal transition. Growth factors are released by the damaged epithelium and endothelium, and leukocytes are recruited. In addition, ononuclear cells and T-cells are also recruited to the injury site and release pro-fibrotic mediators. Activated fibroblasts transition to myofibroblasts, which release excessive amounts of extracellular matrix, resulting in increased tissue stiffness, which drives self-sustaining and progressive fibrosis. Chronic inflammation is thought to be an important mediator of pulmonary fibrosis in diseases such as systemic sclerosis (SSc), hypersensitivity pneumonitis (HP), sarcoidosis and rheumatoid arthritis (RA). Common symptoms reported by patients include dyspnoea, cough and fatigue.
10.2 Fagområde *Angi hvilket fagområde som best beskriver metoden*	Velg fagområde fra menyen: Lunge- og luftveissykdommer
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*	Currently, no treatment alternatives exist for patients that do not respond well enough on AF treatment or that do not tolerate AF treatment. Patients are treated with palliative care or lung transplantation.
10.5 Prognose *Beskriv prognosen med nåværende behandlingstilbud, inkl. referanse*	IPF is a progressive and irreversible ILD characterized by progressive fibrosis (scaring of the lungs), worsening lung function, and dyspnea (shortness of breath). Disease progression is associated with worsening symptoms and health-related quality of life (HRQoL) as well as decline in lung function measured

	as Forced Vital Capacity (FVC) and high mortality (Cox et al. 2020, Martinez et al. 2017, Raghu et al. 2022). The median post-diagnosis survival in patients with IPF has been reported to be around 2.5–7 years in a mixed population of IPF patients receiving antifibrotic treatment and not receiving antifibrotic treatment (Doubková et al. 2018, Hyldgaard et al. 2014, Kärkkäinen et al. 2018, Lassenius et al. 2020, Lee et al. 2023a, Yoon et al. 2024, Zaman et al. 2020). In one study that compared patients receiving and not receiving antifibrotics, median survival was around 3.0–3.75 years for those patients who had received antifibrotics and 2.5 years in those who were untreated (Noor et al. 2020). PPF is a progressive phenotype of fibrosing ILD (F-ILD), and IPF can therefore be considered a prototype of PPF. However, other than IPF, there are many F-ILD subtypes that can develop into PPF. PPF other than IPF has a clinical course like IPF, irrespective of underlying ILD diagnosis or the fibrotic pattern on imaging (HRCT). This includes declining lung function, worsening symptoms, functional impairment and HRQoL as well as early mortality (Brown et al. 2022, Brown et al. 2020, Simpson et al. 2021). Despite the availability of AF therapies, disease progression in patients with IPF and PPF remains a significant clinical challenge with continued decline in lung function. A recent study shows that even small declines in FVC % of predicted were associated with increased risk of subsequent death or lung transplantation in patients with IPF (Oldham et al. 2025). Currently, no treatment alternatives exist for patients beyond AF treatment or patients that do not tolerate AF treatment. Patients are then treated with palliative care or lung transplantation.
10.6 Det nye legemiddelets innplassering i behandlingsalgoritmen	Boehringer Ingelheim proposes nerandomilast as 1) add-on to standard AF treatment (either nintedanib or pirfenidone), and 2) as monotherapy for those patients that cannot tolerate standard AF treatment.

10.7 Pasientgrunnlag *Beskrivelse, insidens og prevalens av pasienter omfattet av aktuell indikasjon* i Norge, inkl. referanse.* *Antall norske pasienter antatt aktuelle for behandling med legemiddelet til denne indikasjonen.* ** Hele pasientgruppen som omfattes av aktuell indikasjon skal beskrives*	**IPF:** IPF is a rare disease. The prevalence of IPF is estimated at not more than 3 in 10,000 in the Community (EPAR Ofev). We are not aware of any (reliable) Norwegian estimates. **PPF:** In a previous HTA (Ofev HTA), BI estimated a yearly incidence of 64 new PPF patients and a prevalence of 429 PPF patients in Norway. This was considered to be reasonable by DMP. We are not aware of updated/more reliable Norwegian estimates. **IPF and PPF combined:** Combined data for IPF and PPF from Legemiddelregisteret shows there were 774 and 927 Norwegian patients who filled a prescription for pirfenidone and nintedanib in 2023 and 2024, respectively. If we take into account treatment switches because of adverse events (meaning double counting of patients in the Legemiddelregisteret) and the fact that some patients experience enough control on their current treatment, we expect there to be 400-500 patients eligible for nerandomilast in year 5.

11 Studiekarakteristika for relevante kliniske studier

	Studie 1	Studie 2	Studie 3
11.1 Studie-ID *Studienavn, NCT-nummer, hyperlenke*	A Study to Find Out Whether BI 1015550 Improves Lung Function in People With Idiopathic Pulmonary Fibrosis (IPF) (NCT05321069)	A Study to Find Out Whether BI 1015550 Improves Lung Function in People With Progressive Fibrosing Interstitial Lung Diseases (PF-ILDs) (NCT05321082)	N/A
11.2 Studietype og -design	A double-blind, randomized, placebo-controlled trial conducted at 332 sites in 36 countries.	A double-blind, randomized, placebo-controlled trial conducted at 403 sites in 44 countries.	N/A

11.3 Formål	To investigate the efficacy and safety of nerandomilast at a dose of 9 mg twice daily or 18 mg twice daily, as monotherapy or with background AF therapy, in patients with IPF.	To investigate the efficacy and safety of nerandomilast at a dose of 18 mg twice daily or 9 mg twice daily, as monotherapy or with background AF therapy, in patients with PPF.	N/A
11.4 Populasjon *Viktige inklusjons- og eksklusjonskriterier*	Eligible patients were 40 years of age or older and had IPF, a FVC of at least 45% of the predicted value, and a DLCO of at least 25% of the predicted value. IPF was diagnosed by the investigator according to guidelines, on the basis of an HRCT scan obtained no more than 12 months before screening. A UIP or probable UIP pattern on HRCT was confirmed by central review. Patients with an indeterminate pattern on HRCT or a pattern suggesting an alternative diagnosis could participate if IPF was confirmed locally on the basis of historical surgical lung biopsy or cryobiopsy. Patients who were receiving nintedanib or pirfenidone needed to have taken a stable dose for at least 12 weeks before potentially receiving add-on of nerandomilast to AF treatment.	Eligible patients were 18 years or older with a diagnosis of ILD other than IPF and a fibrotic lung disease extent of more than 10% on the basis of an HRCT scan obtained no more than 12 months before screening and confirmed by central review. Patients had an FVC of least 45% of the predicted value and a DLCO of at least 25% of the predicted value. Patients also met at least one of the following criteria no more than 24 months before screening: a relative decline of at least 10% in the percentage of the predicted FVC; a relative decline of at least 5% but less than 10% in the percentage of the predicted FVC with worsened respiratory symptoms, an increased extent of fibrotic changes on imaging, or both; or worsened respiratory symptoms and an increased extent of fibrotic changes on imaging.	N/A

	Patients who had not received AF therapy for at least 8 weeks were eligible to participate; these patients could initiate nintedanib or pirfenidone in the event of IPF progression, acute exacerbation, or both after 12 weeks of the trial. Prednisone at a dose of more than 15 mg per day or equivalent for respiratory reasons, not permitted at enrollment, could be prescribed during the trial for suspected acute exacerbation.	Patients who were receiving nintedanib at screening needed to have taken a stable dose for at least 12 weeks before potentially receiving add-on of nerandomilast to AF treatment. Patients who had not received nintedanib therapy for at least 8 weeks were eligible to participate; these patients could initiate nintedanib in the event of ILD progression or acute exacerbation after week 12 of the trial. Immunosuppressant therapy that had been received at a stable dose for at least 12 weeks was permitted at enrollment, with the following exceptions: cyclophosphamide, tocilizumab, mycophenolate (mycophenolate mofetil or mycophenolate sodium), and rituximab were not permitted at enrollment but could be prescribed after 6 months to manage worsening of systemic disease, and prednisone at a dose of more than 15 mg per day or equivalent was not permitted at enrollment but could be prescribed for acute exacerbation of ILD. Other changes in immunosuppressant therapy were not permitted during the first 6 months of the	

		trial. Pirfenidone was not permitted.	
11.5 Intervensjon (n) *Dosering, doseringsintervall, behandlingsvarighet*	Nerandomilast: 9 mg or 18 mg twice daily over a period of 52 weeks.	Nerandomilast: 9 mg or 18 mg twice daily over a period of 52 weeks.	N/A
11.6 Komparator (n) *Dosering, doseringsintervall, behandlingsvarighet*	Placebo over a period of 52 weeks.	Placebo over a period of 52 weeks.	N/A
11.7 Endepunkter *Primære, sekundære og eksplorative endepunkter, herunder definisjon, målemetode og ev. tidspunkt for måling*	Primary: Absolute change from baseline in FVC (mL) [Time Frame: at baseline, at week 52]. Key secondary: Time to the first occurrence of any of the components of the composite endpoint: time to first acute IPF exacerbation, first hospitalization for respiratory cause, or death (whichever occurs first) over the duration of the trial [Time Frame: up to 30 months]. Other secondary [Time Frame: up to 30 months]: Time to first acute IPF exacerbation or death; Time to hospitalization for respiratory cause or death; Time to absolute decline in FVC % predicted of >10% from	Primary: Absolute change from baseline in FVC (mL) [Time Frame: at baseline, at week 52]. Key secondary: Time to the first occurrence of any of the components of the composite endpoint: time to first acute ILD exacerbation, first hospitalization for respiratory cause, or death (whichever occurs first) [Time Frame: up to 31 months]. Other secondary [Time Frame: up to 31 months]: Time to first acute Interstitial Lung Disease (ILD) exacerbation or death; Time to hospitalization for respiratory cause or death; Time to absolute decline in FVC % predicted of >10% from	N/A

	baseline or death; Time to absolute decline in DLCO % predicted of >15% from baseline or death; Time to death. Other secondary [Time Frame: at baseline, at week 52]: Absolute change from baseline in Living with Pulmonary Fibrosis (L-PF) Symptoms Dyspnea domain score; Absolute change from baseline in L-PF Symptoms Cough domain score; Absolute change from baseline in L-PF Symptoms Fatigue domain score; Absolute change from baseline in FVC %; Absolute change from baseline in DLCO %.	baseline or death; Time to absolute decline in DLCO % predicted of >15% from baseline or death; Time to death. Other secondary [Time Frame: at baseline, at week 52]: Absolute change from baseline in L-PF Symptoms Dyspnea domain score; Absolute change from baseline in L-PF Symptoms Cough domain score; Absolute change from baseline in L-PF Symptoms Fatigue domain score; Absolute change from baseline in FVC %; Absolute change from baseline in DLCO %.	
11.8 Relevante subgruppeanalyser *Beskrivelse av ev. subgruppeanalyser*	Use of background AF therapy (nintedanib/ pirfenidone/none).	Use of background AF therapy (nintedanib/ none.	N/A
11.9 Oppfølgingstid *Hvis pågående studie, angi oppfølgingstid for data som forventes å være tilgjengelige for*	52 weeks.	52 weeks.	N/A

vurderingen hos Direktoratet for medisinske produkter samt den forventede/planlagte samlede oppfølgingstid for studien			
11.10 Tidsperspektiv resultater *Pågående eller avsluttet studie? Tilgjengelige og fremtidige datakutt*	Completed study.	Completed study.	N/A
11.11 Publikasjoner *Tittel, forfatter, tidsskrift og årstall. Ev. forventet tidspunkt for publikasjon*	Richeldi L et al. Nerandomilast in Patients with Idiopathic Pulmonary Fibrosis. N Engl J Med. 2025 Jun 12;392(22):2193-2202. doi: 10.1056/NEJMoa2414108. Epub 2025 May 18. PMID: 40387033.	Maher TM et al. Nerandomilast in Patients with Progressive Pulmonary Fibrosis. N Engl J Med. 2025 Jun 12;392(22):2203-2214. doi: 10.1056/NEJMoa2503643. Epub 2025 May 19. PMID: 40388329.	N/A

12 Igangsatte og planlagte studier

12.1 Er det pågående eller planlagte studier for legemiddelet innenfor samme indikasjon som kan gi ytterligere informasjon i fremtiden? *Hvis ja, oppgi forventet tidspunkt*	Ja ☒ Nei ☐ The long-term efficacy and safety of nerandomilast in adult patients with IPF or PPF are investigated in the ongoing FIBRONEER-ON open label extension of the phase III clinical trials (NCT06238622):: A Follow-up Study to Test Long-term Treatment With Nerandomilast in People With Pulmonary Fibrosis Who Took Part in a Previous Study With Nerandomilast (FIBRONEER™-ON). The results are expected to be available in April 2027.

	The efficacy and safety of nerandomilast in adult patients treated with immunosuppressant treatment will be investigated in the double-blinded, randomized controlled phase III clinical trial (NCT06806592): A Study to Test Whether Nerandomilast Helps People With Lungfibrosis Related to Rheumatic Diseases. The study is expected to be completed in July 2027. The efficacy and safety of nerandomilast in patients with interstitial lung disease secondary to systemic sclerosis will be investigated in the double-blinded, randomized placebo-contolled, phase IIb clinical trial (NCT06195072): Platform Clinical Study for Conquering Scleroderma (CONQUEST). The study is expected to be completed in November 2026.
12.2 Er det pågående eller planlagte studier for legemiddelet for andre indikasjoner?	Ja ☐ Nei ☒ N/A

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	N/A

14 Andre relevante opplysninger

14.1 Har dere vært i kontakt med fagpersoner (for eksempel klinikere) ved	Ja ☒ Nei ☐

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)*	For IPF: Michael Durheim, OUS Phuong Phuong Diep, OUS Ragnhild Gagama, Ahus Tomas Mikal Lind Eagan, HUS Marit Wilskow, Bodø Merethe Selnes Hansen, UNN Kamilla Flaatten Federici, Sørlandet Sykehus For PPF: Ragnhild Gagama, Ahus Phuonh Phuong Diep, OUS Tomas Mikal Lind Eagan, HUS Merethe Selnes Hansen, UNN Jens Vikse, SUS
14.2 Anser leverandør at det kan være spesielle forhold ved dette legemiddelet som gjør at en innkjøpsavtale ikke kan 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	Ja ☐ Nei ☒ N/A
14.3 Andre relevante opplysninger?	Boehringer Ingelheim expects to request a pre-meeting with the Norwegian Medical Products Agency (NOMA). At the meeting, we suggest discussing the following topics: 1) The chosen PICO and the most relevant clinical trial data for the Norwegian clinical practice. 2) The relevance of a systematic literature review (SLR). 3) Whether to submit 1 HTA dossier (combined for IPF and PPF) or 2 separate dossiers. A more detailed meeting agenda will be send with the request.

Informasjon om Nye metoder finnes på nettsiden nyemetoder.no