# Horizon Scanning

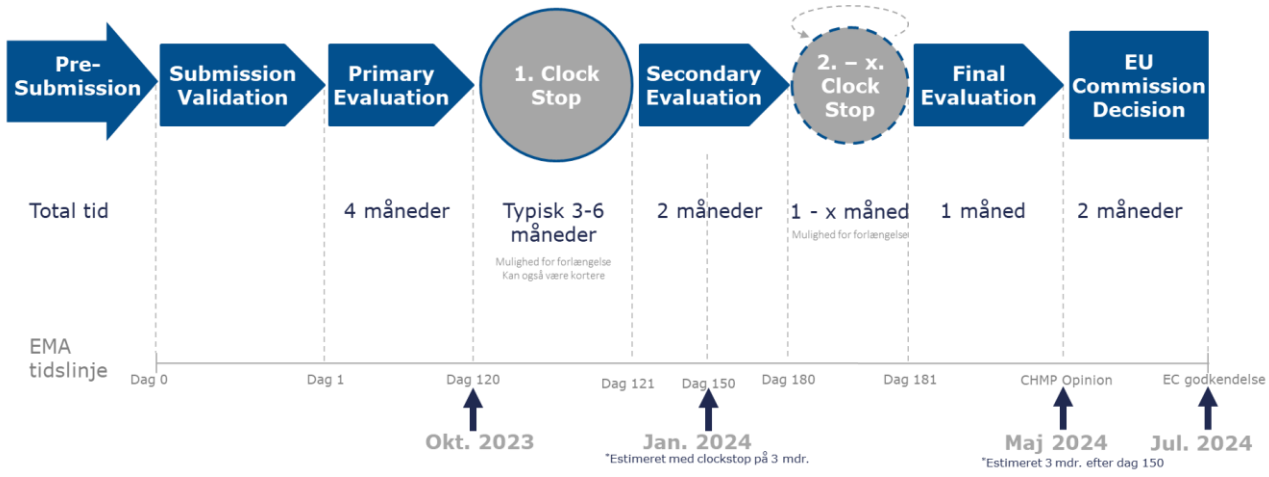
# Orientering om nyt lægemiddel: Fruquintinib

**Lægemiddelstof**: Fruquintinib
**Produkt navn:** NA
**ATC-kode**: (L01XE)
**Dispenseringsform:** (Oral)
**Anvendelsesområde:** Treatment of metastatic colorectal cancer[1]
**Virksomhed:** (Takeda)
**Sektor:** Formodentlig sekundær sektor

Udarbejdet: 11. juli 2023
*Dokumentet opdateres ikke.*

## Status for godkendelse[1]

Estimeret tidsperspektiv for markedsføringstilladelse i Danmark:
*(Godkendes via proces for nye lægemidler. Procedurenummer EMEA/H/C/005979)*




## Beskrivelse af nyt lægemiddel[2,3]

An orally available, small molecule inhibitor of vascular endothelial growth factor receptors (VEGFRs), with potential anti-angiogenic and antineoplastic activities. Upon oral administration, fruquintinib inhibits VEGF-induced phosphorylation of VEGFRs 1, 2, and 3 which may result in the inhibition of migration, proliferation and survival of endothelial cells, microvessel formation, the inhibition of tumor cell proliferation, and tumor cell death. Expression of VEGFRs may be upregulated in a variety of tumor cell types.

Fruquintinib is a highly selective and potent oral inhibitor of VEGFR -1, -2 and -3. VEGFR inhibitors play a pivotal role in blocking tumor angiogenesis. Fruquintinib was designed to improve kinase selectivity with the intention of minimizing off-target toxicities, improving tolerability and providing more consistent target coverage. Fruquintinib has been generally well tolerated in patients to date and is being investigated in combinations with other anti-cancer therapies.

## Sygdomsbeskrivelse og patientgrundlag[4]

Kræft i tyk- og endetarm (KRC) er en af de hyppigste kræftsygdomme i Danmark. I 2019 blev i alt 4296 diagnosticeret med KRC, heraf størstedelen med tyktarmskræft. Hyppigheden stiger med alderen og ses sjældent før 40-årsalderen, og de fleste tilfælde ses først efter 60-årsalderen. Femårsoverlevelsen for endetarmskræft er hhv. 66 og 69 % for mænd og kvinder, mens den for tyktarmskræft er hhv. 63 og 65 %. Årsagen til sygdommen er ofte ukendt.

## Standardbehandling/ andre behandlingsmuligheder til indikationen[5]

Ved progression under eller efter endt 1. linjebehandling tilbydes patienterne videre behandling i form af 2. og evt. 3. linjebehandling. Medicinrådets vejledning indeholder cetuximab (Erbitux) og panitumumab (Vectibix):
https://medicinraadet.dk/anbefalinger-og-vejledninger/behandlingsvejledninger/tyk-og-endetarmskræft

## Status for dokumentation[4]

### Studier:

| Land, Population, Studienr. | Intervention | Komparator | Primær outcome | Sekundær outcome | Afsluttet |
|---|---|---|---|---|---|
| Kina,<br>Fase III,<br>N = 416,<br>NCT02314819[a] | Active Comparator: treatment arm<br>treatment arm- subjects will receive Fruquintinib 5mg orally, QD, plus BSC for 3 wks on/ 1 wk off. Patients will receive a cycles of 4 weeks of study treatment (1 cycle of study treatment includes 3 weeks of treatment and 1 week of drug discontinuation) or until the occurrence of progressive disease (PD), death, unacceptable toxicity, withdrawal of consent or other conditions that meet the end of treatment criteria. | Placebo Comparator: control arm<br>control arm- subjects will receive Fruquintinib placebo 5mg orally, QD, plus BSC for 3 wks on/ 1 wk off. Patients will receive a cycles of 4 weeks of study treatment (1 cycle of study treatment includes 3 weeks of treatment and 1 week of drug discontinuation) or until the occurrence of progressive disease (PD), death, unacceptable toxicity, withdrawal of consent or other conditions that meet the end of treatment criteria. | overall survival | progression free survival | Januar 2017 |
| Flere lande,<br>Fase III,<br>N = 691,<br>NCT04322539[b] | Experimental: fruquintinib plus best supportive care<br>In this arm, subjects will receive active study drug plus best supportive care | Placebo Comparator: placebo plus best supportive care<br>In this arm, subjects will receive placebo plus best supportive care | Overall Survival | | Juli 2022 |

[a]A Randomized, Double-blind and Placebo-controlled Phase III Trial Comparing Fruquintinib Efficacy and Safety vs Best Support Care (BSC) in Advanced Colorectal Cancer Patients Who Have Failed At least Second Lines of Chemotherapies (FRESCO)
Sponsor: Hutchison Medipharma Limited

[b]A Global Multicenter Randomized Placebo-Controlled Phase 3 Trial To Compare The Efficacy And Safety Of Fruquintinib Plus Best Supportive Care To Placebo Plus Best Supportive Care In Patients With Refractory Metastatic Colorectal Cancer (FRESCO-2)
Sponsor: Hutchison Medipharma Limited

## Opmærksomhedspunkter identificeret af Horizon Scanning

Ansøger om 3. linje behandling

Pressemeddelelse fra Takeda:
European Medicines Agency (EMA) has validated and accepted for regulatory review the marketing authorization application (MAA) for fruquintinib, a highly selective and potent inhibitor of vascular endothelial growth factor receptors (VEGFR) -1, -2 and -3 for the treatment of adult patients with previously treated metastatic colorectal cancer (CRC). If approved, fruquintinib will be the first and only highly selective inhibitor of all three VEGF receptors approved in the European Union (EU) for previously treated metastatic CRC.
https://www.takeda.com/takeda-and-hutchmed-announce-marketing-authorization-application-of-fruquintinib/

Følgende VEGF inhibitorer er allerede godkendt:

Cetuximab (Erbitux)

Panitumumab (Vectibix)

## Hovedkilder til orienteringen


1. /agenda-chmp-meeting-19-22-june-2023
2. https://www.cancer.gov/publications/dictionaries/cancer-drug/def/fruquintinib
3. https://www.takeda.com/newsroom/
4. https://medicinraadet.dk/
5. /protokol-for-medicinrådets-grundlag-for-klinisk-ligestilling-vedr-tillægsbeh-med-egfr-hæmmer-til-mkrc
6. https://classic.clinicaltrials.gov/


Teksten i dokumentet er kopieret fra de angivne kilder, derfor fremstår teksten på både dansk og engelsk.


**Ansvarlig:** Senior analytiker Anne-Mette Ørkild Mud, Amgros