

**Subject:** VS: Norgine on behalf of the OPTION study - Application for shelf life extension of clinical trial medication Angusta tablets 25 µg used in OPTION study (EudraCT no.: 2020-000233-41).

**Date:** Friday, 23 September 2022 at 13:09:00 Central European Summer Time

**From:** Mogens Gisselbaek

**To:** Mogens Gisselbaek

**Attachments:** image001.jpg, image003.png, image005.png, image007.png, image009.jpg, Shelf life extension of ANGUSTA justification\_Redacted.pdf, ANGUSTA Stability\_Redacted.pdf, ANGUSTA Stability1\_Redacted.pdf, Acceptance to apply on behalf of the OPTION study.pdf

**Mogens Gisselbaek MD**  
**Nordic Medical Director**  
[Norgine](#)

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**Fra:**

**Sendt:** 9. september 2022 16:07

**Til:** [registrator@lakemedelsverket.se](mailto:registrator@lakemedelsverket.se)

**Cc:**

**Emne:** Norgine on behalf of the OPTION study - Application for shelf life extension of clinical trial medication Angusta tablets 25 µg used in OPTION study (EudraCT no.: 2020-000233-41).

**Norgine on behalf of the OPTION study - Application for shelf life extension of clinical trial medication Angusta tablets 25 µg used in OPTION study (EudraCT no.: 2020-000233-41).**

Dear MPA,

We are pleased to submit our application for shelf life extension of clinical trial medication Angusta tablets 25 µg used in the OPTION study.

Please find enclosed justification document and supporting data provided by Norgine as well as statement on agreement for Norgine to apply for the extension on behalf of the OPTION study signed by Verena Sengpiel, Coordinating Principal Investigator.

Please do not hesitate to contact me if you require any further information.

Kind regards,



*Because patients inspire us*