

**Amendment No. 1 to the Clinical Trial Agreement Related to Protocol I6T-MC-AMAM, "A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active- Controlled, Treat-Through Study to Evaluate the Efficacy and Safety of Mirikizumab in Patients with Moderately to Severely Active Crohn's Disease (VIVID-1)" (hereinafter referred to as "Study")**

This letter (hereinafter referred to as "Amendment no. 1"), amends the change of the clinical trial agreement (hereinafter referred to as "Agreement") related to the above-referenced Study, which was concluded between:

Oblastní nemocnice Náchod a.s.

With its Registered Office in: Purkyňova 446, 547 01 Náchod, Czech Republic

Represented by: [REDACTED]  
Identification number: 26000202

(hereinafter referred to as "Institution")

and

MUDr. [REDACTED]  
With a residence at: [REDACTED]  
Date of birth: [REDACTED]

(hereinafter referred to as "Investigator")

And

**Eli Lilly Cork Limited,**  
Address: Island House, Eastgate Road, Eastgate Business Park, Little Island, Cork, Ireland

IČO: 615384,  
DIČ: IE3508310BH

(hereinafter referred to as "Lilly")

dated [REDACTED]

**The parties wish to make the following amendments to the Agreement:**

1) All charts in **Exhibit 1** "Budget" of the Agreement are replaced with new charts in Exhibit 1 of this Amendment no. 1.

**Dodatek č. 1 ke smlouvě o provedení klinického hodnocení dle protokolu I6T-MC-AMAM „Multicentrické, randomizované, dvojitě zaslepené, placebem a aktivním komparátorem kontrolované, „treat through“ klinické hodnocení fáze 3 hodnotící účinnost a bezpečnost Mirikizumabu u pacientů se středně těžkou až těžkou aktivní Crohnovou chorobou (VIVID-1)“ (dále jen jako „Studie“)**

*Tento dodatek (dále jen jako "Dodatek č. 1") upravuje změnu smlouvy o provedení klinického hodnocení (dále jen jako "smlouvu") uvedeného výše, která byla uzavřena mezi:*

Oblastní nemocnice Náchod a.s.

se sídlem: Purkyňova 446, 547 01 Náchod, Česká republika

zastoupená [REDACTED]  
IČ: 26000202

(dále jen „zdravotnické zařízení“)

a

[REDACTED]  
Trvalým bydlištěm: [REDACTED]  
Datum nar.: [REDACTED]

(dále jen jako „zkoušející“)

A

**Eli Lilly Cork Limited,**  
Adresa: Island House, Eastgate Road, Eastgate Business Park, Little Island, Cork, Irsko,

IČO: 615384,  
DIČ: IE3508310BH

(dále jen jako „Lilly“)

podepsána dne [REDACTED]

**Smluvní strany si přejí ve smlouvě provést tyto změny:**

1) *Veškeré tabulky v **Příloze 1** „Rozpočet“ Smlouvy se ruší a nahrazují se tabulkami v příloze novými tabulkami v Příloze 1 tohoto dodatku.*

2) This Amendment is made part of the Agreement and is an integral part of it at the date of its signature by all contracting parts.

2) *Tento Dodatek mění smlouvu a představuje její nedílnou součást ke dni podpisu tohoto Dodatku všemi smluvními stranami.*

3) As hereby amended, the Agreement remains in full force and effect.

3) *Mimo změn Dodatkem provedených zůstává smlouva v plné účinnosti a beze změn.*

**Eli Lilly Cork Limited**

\_\_\_\_\_

Date / Datum: \_\_\_\_\_

**AGREED AND ACCEPTED/SOUHLASÍ A PŘIJÍMÁ:**

**Institution/Zdravotnické zařízení:**

\_\_\_\_\_

Date / Datum: \_\_\_\_\_

**Investigator/Zkoušející:**

\_\_\_\_\_

Date / Datum: \_\_\_\_\_

**Exhibit 1A: Budget**

**Příloha 1: Rozpočet**

The below Budget Template is completed where there are MULTIPLE PAYEES listed in the contract

STUDY BUDGET NOTES:

The start of the clinical trial is planned for [redacted]. Patient recruitment is expected to be completed in [redacted]. The study has competitive enrolment. A minimum of [redacted] randomised patients and up to [redacted] randomised patients are planned for this site. The pro-rata payment will be made per evaluable patient. All payments will be made in currency Czech Crowns (CZK) excl. VAT. Should any of the services performed by the Investigator and/or Institution in connection with this Agreement be subjected to VAT, then the Investigator and/or Institution is entitled to charge VAT at the legally applicable rate.

Please confirm the Trial Alias: I6T-MC-AMAM
Please confirm the site number: [redacted]
Eli Lilly Contracting Entity Eli Lilly Cork Limited

PAYEE DETAILS (for Payee #1)

Payee Name: [redacted]
Supplier Information Form completed and signed? Yes
Payee Type (select from the list) Institution
Email Address for ALL payments/finance correspondence [redacted]
Note: All payments will be made according to local fiscal requirements.

PAYEE DETAILS (for Payee #2)

Payee Name: [redacted]
Supplier Information Form completed and signed? Yes
Payee Type (select from the list) Principal Investigator
Email Address for ALL payments/finance correspondence [redacted]
Note: All payments will be made according to local fiscal requirements.

PAYEE DETAILS (for Payee #3)

Payee Name: [redacted]
Supplier Information Form completed and signed? Yes
Payee Type (select from the list) Sub Investigator
Email Address for ALL payments/finance correspondence [redacted]
Note: All payments will be made according to local fiscal requirements.

PAYEE DETAILS (for Payee #4)

Payee Name: [redacted]
Supplier Information Form completed and signed? Yes
Payee Type (select from the list) Study Nurse
Email Address for ALL payments/finance correspondence [redacted]
Note: All payments will be made according to local fiscal requirements.

PAYEE DETAILS (for Payee #5)

Payee Name: [redacted]
Supplier Information Form completed and signed? Yes
Payee Type (select from the list) Study Nurse
Email Address for ALL payments/finance correspondence [redacted]
Note: All payments will be made according to local fiscal requirements.

Please select appropriate box:

Naive Site

Worked with Lilly

Payment Split Details:

"The amount of the remuneration due to the Institution shall equal [redacted] of the total remuneration for the performance of this Trial, while remuneration due to the Investigator shall equal the remaining [redacted] of the total remuneration. Investigator shall confirm the split between Payee #2 - Payee #5."

NOTE: If there are other payees please confirm their percentage split also

If there is no payment split and Payee #1 receives 100% remuneration please tick here:

If payment split is not confirmed in the contract (& investigator will confirm the split prior to payment) please tick here:

Table with 10 columns and 10 rows, containing budget data for various categories. Many cells are redacted with black boxes.

Table with 10 columns and 3 rows, containing budget data for various categories. Many cells are redacted with black boxes.

