AMENDMENT #1 TO CLINICAL STUDY AGREEMENT

This Amendment (the "**Amendment**") to the Clinical Study Agreement, dated 21 December 2020 (the "**Agreement**"), for the clinical study (the "**Study**"), conducted in accordance with the protocol ITM-LET-01 "A prospective, randomised, **C**ontrolled, **O**pen-label, **M**ulticentre phase III study to evaluate efficacy and safety of **Pe**ptide Receptor Radionuclide **T**herapy (PRRT) with 177Lu-Edotreotide compared to targeted molecular therapy with **E**verolimus in patients with inoperable, progressive, somatostatin receptor-positive (SSTR+), neuroendocrine tumours of gastroenteric or pancreatic origin (GEP-NET)" and any amendments thereto (the "**Protocol**"), is made by and between:

Fakultní nemocnice Olomouc,

I. P. Pavlova 185/6, 779 00, Olomouc - Nová Ulice, Czech Republic, ID: 00098892, TIN: CZ00098892, represented by: [redacted] state-allowance organization established by a decision of the Ministry of Healthcare (the "**Institution**")

and

[redacted]

affiliated with Fakultní nemocnice Olomouc located at I. P. Pavlova 185/6, 779 00, Olomouc – Nová Ulice, Czech Republic (the "**Investigator**")

and

ITM Solucin GmbH,

Lichtenbergstrasse 1, D-85748 Garching, Germany ("**Sponsor**")

PREAMBLE:

WHEREAS, the parties wish to revise the Attachment 2 to the Agreement (the "**Attachment 2**") in order to:

DODATEK #1 KE SMLOUVĚ O KLINICKÉM HODNOCENÍ

Tento Dodatek (dále jen „**Dodatek**") ke Smlouvě o klinickém hodnocení s datem 21. prosince 2020 (dále jen „**Smlouva**") ke klinické studii (dále jen „**Studie**") prováděné v souladu s Protokolem ITM-LET-01 s názvem: „Prospektivní multicentrická randomizovaná kontrolovaná otevřená klinická studie fáze III hodnotící účinnost a bezpečnost peptidové receptorové radionuklidové terapie (PRRT) 177Lu-Edotreotidem ve srovnání s cílenou molekulární terapií Everolimem u pacientů s neoperovatelnými progresivními neuroendokrinními tumory gastroenterického nebo pankreatického původu (GEP-NET) pozitivními na somatostatinový receptor (SSTR+)" a všemi jeho dodatky (dále jen „**Protokol**") se uzavírá mezi:

Fakultní nemocnicí Olomouc

adresa: I. P. Pavlova 185/6, 779 00, Olomouc - Nová Ulice, Česká republika, IČO: 00098892, DIČ: CZ00098892, zastoupenou [redacted] státní příspěvkovou organizací zřízenou z rozhodnutí Ministerstva zdravotnictví (dále jen „**Zdravotnické zařízení**")

a

[redacted]

s pracovištěm na adrese: Fakultní nemocnice Olomouc, I. P. Pavlova 185/6, 779 00, Olomouc – Nová Ulice, Česká republika (dále jen „**Hlavní zkoušející**")

a

ITM Solucin GmbH,

Lichtenbergstrasse 1, D-85748 Garching, Německo (dále jen „**Zadavatel**")

PREAMBULE:

VZHLEDEM K TOMU, ŽE si strany přejí revidovat Přílohu 2 ke Smlouvě (dále jen „**Příloha 2**") za účelem;

- reflect the changes intruduced by the Protocol Amendment V6.2 Am07 – extention of the Study;
- make updates by adding 5 Year Survival Follow Up and ratio for reimbursement of screen failures.

WHEREAS, the parties agree that for the purposes of efficient payment administration they will completely replace the contents of the Attachment 2 with the relevant updated contents;

WHEREAS, in order to so replace the contents of the Attachment 2, the parties have agreed to enter into this Amendment.

NOW, THEREFORE, in consideration of the terms and conditions set forth herein, the parties agree as follows:

1. The Attachment 2 shall be replaced in its entirety by the revised Attachment 2 as attached to this Amendment.

2. Capitalized terms used but not re-defined in this Amendment shall have the same meaning as they have in the Agreement.

3. This Amendment shall be made part of the Agreement and attached thereto. Except as provided herein, all other terms of the Agreement shall remain in full force and effect.

[SIGNATURE PAGE TO FOLLOW]

- reflektování změn, které zavádí Dodatek k Protokolu V6.2 Am07 – prodloužení Studie;
- vytvoření aktualizace přidáním pětiletého následného sledování přežití.

VZHLEDEM K TOMU, ŽE strany souhlasí s tím, aby obsah Přílohy 2 byl zcela nahrazen relevantním aktualizovaným obsahem za účelem efektivní úhrady plateb;

VZHLEDEM K TOMU, ŽE strany souhlasí s uzavřením tohoto Dodatku za účelem nahrazení obsahu Přílohy 2;

SE NYNÍ PROTO strany při zvážení podmínek stanovených tímto Dodatkem dohodly následovně:

1. Příloha 2 byla zcela nahrazena revidovanou Přílohou 2 připojenou k tomuto Dodatku.

2. Výrazy s velkým počátečním písmenem použité v tomto Dodatku, které však nejsou redefinovány, mají stejný význam jako ve Smlouvě.

3. Tento Dodatek je součástí Smlouvy jako její příloha. S výjimkou ustanovení tohoto Dodatku zůstávají v plné platnosti veškeré podmínky stanovené Smlouvou.

[NÁSLEDUJE PODPISOVÁ STRANA]

By signing below, each party hereby accepts and agrees to the above terms and conditions.

Svým podpisem níže každá ze stran přijímá výše uvedené podmínky a zavazuje se k jejich dodržování.

The Institution/Zdravotnické zařízení: Fakultní nemocnice Olomouc

_____

Name/Jméno: [redacted]
Title/pozice: [redacted]

Dated/Datum: _____

The Investigator/Hlavní zkoušející:

_____

Name/Jméno: [redacted]

Dated/Datum: _____

The Sponsor: ITM Solucin GmbH

(Signed by PSI CRO Czech Republic s.r.o. in the name of ITM Solucin GmbH, based on Power of Attorney))/(Podepsala PSI CRO Czech Republic, s.r.o. jménem ITM Solucin GmbH na základě plné moci)

_____

Name: [redacted]
Title/Pozice: based on Power of Attorney/na základě plné moci

Dated/Datum:_____

_____

Name/Jméno: [redacted]
Title/Pozice: by Power of Attorney/na základě plné moci

Dated/Datum: _____

Attachment 2

[redacted]

Příloha 2

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]		[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]						
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted]

[redacted]