AMENDMENT # 2TO CLINICAL TRIAL AGREEMENT	DODATOK Č. 2, K ZMLUVE O KLINICKOM SKÚŠANÍ
Protocol # THR-149-002	**Protokol č. THR-149-002**
This Amendment # 2 ("Amendment"), is made out pursuant to the in § 269. 2 of Law no. 513/1991 Coll. Commercial Code, as amended (the "Commercial Code"), to the § 29 to § 44 of Act no. 362/2011 Coll. on medicines and medical devices (the "Medicines Act") and the relevant provisions of the Act no. 576/2004 Coll. (the" Healthcare Act"),	Tento dodatok č. 2 (ďalej len „dodatok") uzatvorený v súlade s § 269 ods. 2 zákona č. 513/1991 Zb. Obchodného zákonníka v znení neskorších predpisov (ďalej len „Obchodný zákonník"), s § 29 až § 44 zákona č. 362/2011 Z. z. o liekoch a zdravotníckych pomôckach a o doplnení niektorých zákonov v znení neskorších predpisov (ďalej len „zákon o liekoch") a príslušných ustanovení zákona č. 576/2004 Z. z. (ďalej len „zákon o zdravotnej starostlivosti") medzi
Syneos Health UK Limited, with principal offices located in the United Kingdom at Farnborough Business Park, 1 Pinehurst Road, Farnborough, Hampshire, GU14 7BF, United Kingdom, including its affiliates, subsidiaries, and specifically its parent company Syneos Health, LLC ("CRO")	spoločnosť **Syneos Health UK Limited,** s hlavným sídlom v Spojenom kráľovstve na adrese Farnborough Business Park, 1 Pinehurst Road, Farnborough, Hampshire, GU14 7BF, Spojené kráľovstvo, vrátane jej pobočiek, dcérskych spoločností a predovšetkým jej materskej spoločnosti Syneos Health LLC (ďalej len „CRO")
and	a
Fakultná nemocnica Trenčín with a place of business at Legionárska 28, 911 71 Trenčín, Slovak Republic ID: 00610470, VAT: 2021254631 EU VAT: SK 2021254631 Represeted by the director: Ing. Tomáš Janík, MBA ("Institution")	**Fakultná nemocnica Trenčín**], so sídlom podnikania na adrese Legionárska 28911 71 Trenčín, Slovenská republika IČO: 00610470, DIČ: 2021254631 IČ DPH: SK 2021254631 Zastúpená riaditeľom: Ing. Tomáš Janík, MBA (ďalej len „zdravotnícke zariadenie")
and	a
MUDr. Marek Káčerik, PhD., , Slovak Republic ("Principal Investigator").	**MUDr. Marek Káčerik, PhD.,** Slovenská republika (ďalej len „hlavný skúšajúci").
WHEREAS, the Parties desire to modify the Clinical Trial Agreement with an effective date of 8.July 2020 as amended on 10.November 2020 ("Agreement") for the clinical trial with Sponsor Drug THR-149, encoded THR-149-002 entitled " A Phase 2, randomised, multicentre study to assess the dose level of multiple THR-149 injections and to evaluate the efficacy and safety of THR-149 versus aflibercept for the treatment of diabetic macular oedema (DME)" ("Protocol") to be conducted at Institution ("Trial") to involve patients participating in the Trial ("Trial Subjects").	KEĎŽE zmluvné strany si želajú upraviť zmluvu o klinickom skúšaní s dátumom nadobudnutia platnosti od 8.júla 2020, tak, ako bola zmenená a doplnená dňa10.Novembra 2020 (ďalej len „zmluva") pre klinické skúšanie so skúšaným liekom zadávateľa THR-149, s kódovým označením THR-149-002 pod názvom „Randomizované, klinické multicentrické skúšanie fázy 2 na vyhodnotenie úrovne dávky pri viacnásobných injekciách THR-149 a na vyhodnotenie účinnosti a bezpečnosti THR-149 v porovnaní s aflibercepton pri liečbe diabetického makulárneho edému (DME)" (ďalej

	len „protokol"), ktoré sa má vykonať v zdravotníckom zariadení (ďalej len „skúšanie") s účasťou pacientov zaradených do skúšania (ďalej len „účastníci skúšania").
WHEREAS, in accordance with Section 25 (Entire Agreement) of the Agreement, the Parties desire to modify the specific language and hence agree to the following modifications to the Agreement:	VZHĽADOM NA TO, že v súlade s článkom 25 (Celá zmluva) zmluvy si zmluvné strany želajú upraviť jej špecifické znenie, preto súhlasia s nasledujúcimi úpravami v zmluve:
1. The Attachment B (Financial Arrangements Worksheet) to the Agreement is deleted in its entirety and replaced with Attachment B (Financial Arrangements Worksheet) as attached to this Amendment to reflect the new budget costs due to alignment with the latest industry benchmark.	1. Príloha B (Hárok s finančnými podmienkami) tejto zmluvy sa v celom rozsahu odstráni a nahradí prílohou B (Hárok s finančnými podmienkami) pripojenou k tomuto dodatku, čím sa v rozpočte zohľadnia nové náklady spojené so zosúladením s najnovším štandardom v odvetví.
2. Defined terms used in this Amendment and not defined herein will have the same meanings assigned such terms in the Agreement. To the extent the Agreement cross references Attachment B, those cross references are hereby amended to refer to the revised Attachment B attached hereto.	2. Vymedzené pojmy, ktoré sú použité v tomto dodatku a nie sú v ňom vymedzené, budú mať rovnaký význam ako v zmluve. Pokiaľ zmluva odkazuje na prílohu B, tieto odkazy sa týmto upravujú tak, že odkazujú na revidovanú prílohu B pripojenú k tejto zmluve.
3. All other provisions of the Agreement shall remain unaltered and given full force and effect.	3. Všetky ostatné ustanovenia zmluvy zostávajú nezmenené a plne platné a účinné.
[SIGNATURE PAGE FOLLOWS]	[NASLEDUJE STRANA S PODPISMI]

This Amendment is executed in English and Slovak language, the Contracting Parties considering both language versions to be equivalent, but in case of inconsistencies between various versions, the Contranting Parties agree that Slovak version of the Amendment will prevail. This Amendment and all its Attachments constitute the entire Agreement of Contracting Parties with respect to the subject metter hereof. This Amendment is made in Three (3) copies with the validity of the original and shall enter into force on the day following the day of its publication in the Central Register of Contracts managed by the Office of the Government of the Slovak Republic.	Tento dodatok je vyhotovený v slovenskom a v anglickom jazyku, pričom Zmluvné strany považujú obe jazykové verzie za rovnocenné, avšak pre prípad výkladových nezrovnalostí medzi jednotlivými verziami sa Zmluvné strany dohodli, že prednosť má slovenská verzia dodatku. Tento dodatok a všetky jeho prílohy predstavujú úplnú dohodu Zmluvných strán o predmete tohto dodatku. Tento dodatok je vyhotovený v troch (3) rovnopisoch s platnosťou originálu a nadobúda účinnosť dňom nasledujúcim po dni jej zverejnenia v Centrálnom registri zmlúv vedenom Úradom vlády Slovenskej republiky.
Agreed to and accepted:	**Súhlasím a prijímam:**

CRO

Signature / Podpis

Printed Name / Meno tlačeným písmom

Title / Funkcia

Date / Dátum

INSTITUTION / ZDRAVOTNÍCKE ZARIADENIE

Signature / Podpis

Ing.Tomáš Janík, MBA
Printed Name / Meno tlačeným písmom

Director/ Riaditeľ
Title / Funkcia

Date / Dátum

PRINCIPAL INVESTIGATOR / HLAVNÝ SKÚŠAJÚCI

Signature / Podpis

MUDr. Marek Káčerik, PhD.
Printed Name / Meno tlačeným písmom

Principal Investigator / Zodpovedný skúšajúci
Title / Funkcia

Date / Dátum

ATTACHMENT B **FINANCIAL ARRANGEMENTS WORKSHEET** FINANCE SUMMARY BOX	**DODATOK B** **HÁROK S FINANČNÝMI PODMIENKAMI** RÁMČEK S FINANČNÝM ZHRNUTÍM
Invoice Currency :EUR Payment Base : Procedure-based OR Visit-based Effective Date:This Agreement will become effective upon signature of each contracting party and legally binding on the day following its publication in the Central Register of agreement, managed by the Office of the Government. CRO Contracting Entity :Syneos Health UK Limited	Mena faktúry :EUR Platobný základ Podľa počtu návštev alebo procedúr, ak je to aplikovateľné Dátum účinnosti: Táto Zmluva nadobúda platnosť dňom jej podpisu stranami Zmluvy a účinnosť dňom nasledujúcim po dni jej zverejnenia v Centrálnom registri zmlúv vedenom Úradom vlády SR Zmluvný subjekt CRO *:* Syneos Health UK Limited

Trial Sponsor:	Oxurion NV
Trial Protocol:	THR-149-002
Title of the Trial:	A Phase 2, randomised, multicentre study to assess the dose level of multiple THR-149 injections and to evaluate the efficacy and safety of THR-149 versus aflibercept for the treatment of diabetic macular oedema (DME)
Protocol Version:	Version 5.0 (Amendment 3): 10 November 2021
Project:	7004550
Country:	Slovakia
Currency:	EUR
Trial Site:	Fakultna nemocnica Trencin
Principal Investigator:	MUDr. Marek Kacerik

Institution / Príjemca platby 1 - Inštitúcia
INSTITUTION BUDGET- ROZPOČET INŠTITÚCIE

Procedure Costs:											
Informed Consent	€ 14.10	1								€ 14.10	
Demographics, medical and ocular history	€ 33.90	1								€ 33.90	
Review Concomitant Medications, treatments and interventions	€ 7.20	1	1	1	1	1	1	1	1	€ 57.60	1
Blood pressure measurement	€ 7.80	1	1							€ 15.60	
BCVA (ETDRS) both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits	€ 10.50	2	1	1	1	1	1	1	1	€ 94.50	1
Full Ophthalmological Exam both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits	€ 86.70	2	1	1	1	1	1	1	1	€ 780.30	1
SD-OCT both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits	€ 34.20	2	1	1	1	1	1	1	1	€ 307.80	1
Color fundus photography both eyes at Visit 1 study eye only, Visits 5 and 8	€ 21.90	2				1			1	€ 87.60	
Fluorescein angiography both eyes at Visit 1 study eye only at Visit 8	€ 56.10	2							1	€ 168.30	
Blood sampling for HbA1c (includes collection, prep, ship)	€ 9.60	1				1			1	€ 28.80	
Blood sampling for THR-149 immunogenicity (includes collection, prep, ship)	€ 15.00		1			1				€ 30.00	

IMP and kit number allocation	€ 5.40		1	1	1	1				€ 21.60	
Assess list of withdrawal criteria from repeat injection	€ 5.40			1	1	1				€ 16.20	
IMP Administration (study eye)	€ 118.20		1	1	1	1				€ 472.80	
Study eye post-injection assessment	€ 5.40		1	1	1	1				€ 21.60	
AE and SAE monitoring and reporting	€ 6.30	1	1	1	1	1	1	1	1	€ 50.40	1
Total Procedure Fees:		**€ 497.70**	**€ 296.70**	**€ 279.30**	**€ 279.30**	**€ 325.80**	**€ 144.90**	**€ 144.90**	**€ 232.50**	**€ 2,201.10**	**€ 144.90**
Non-Procedure Costs:											
Study Coordinator/Nurse Fee	€ 26.10	1	1	1	1	1	1	1	1	€ 208.80	1
Principal Investigator Fee	€ 54.60	1	1	1	1	1	1	1	1	€ 436.80	1
Total Non-Procedure Fees:		**€ 80.70**	**€ 80.70**	**€ 80.70**	**€ 80.70**	**€ 80.70**	**€ 80.70**	**€ 80.70**	**€ 80.70**	**€ 645.60**	**€ 80.70**
Total Procedure and Non-Procedure Fees:		**€ 578.40**	**€ 377.40**	**€ 360.00**	**€ 360.00**	**€ 406.50**	**€ 225.60**	**€ 225.60**	**€ 313.20**	**€ 2,846.70**	**€ 225.60**
Overhead:	15%	€ 86.76	€ 56.61	€ 54.00	€ 54.00	€ 60.98	€ 33.84	€ 33.84	€ 46.98	€ 427.01	€ 33.84
Total Per Visit Costs[1]:		**€ 665.16**	**€ 434.01**	**€ 414.00**	**€ 414.00**	**€ 467.48**	**€ 259.44**	**€ 259.44**	**€ 360.18**	**€ 3,273.71**	**€ 259.44**

Additional Treatment Related Costs (inclusive of applicable overhead)[2]	
Urine collection test (pregnancy test, each) - Visits 1, 2, 3, 4, 5 and 8 (dipstick will be provided)	€ 5.18
Anterior chamber aqueous humour sampling[3] of the study eye at Visits 2 and 5 (includes consent, collection, prep, ship) - only for Trial Subjects who consent to procedure	€ 101.78
OCT angiography both eyes at Visit 1 and study eye only at Visits 5 and 8 - only for subjects at sites that have the required type of OCTA equipment	€ 47.96
Re-Consent (due to Protocol amendment)	€ 16.22
Unscheduled Visit[4]	INVOICE
Screen Failure[5]	INVOICE
Additional Study Related Costs (inclusive of applicable overhead)[6]	
Site Start-up Costs (includes administrative, document preparation, staff training and Protocol review)	€ 1,500.00
Additional study management costs (for each additional patient that has received at least 1 injection with IMP starting from the 4th patient enrolled)[9]	€ 97.50

[1] Cost inclusive of, but is not limited to, the following: staff time with the Trial Subject during procedures, CRF/eCRF completion, meeting attendance, audits, and monitoring visits.

[2] If applicable, will be reimbursed after CRF data is entered by Institution.

[3]Only at sites that perform aqueous humour sampling, in Trial Subjects who consent to the procedure.

[4] To be paid based on actual procedures performed, plus applicable additional services and overhead.

[5] Pursuant to section A-3 (Screen Failures) of Attachment A (Payment Terms), reimbursement will be made based on actual procedures performed

[6] Will be reimbursed after receipt of invoice reflecting actual costs.

[9]To the extent permissible under Applicable Law and if desired by the site, the site will be reimbursed at the amount listed above for each eligible treated Trial Subject exceeding three eligible treated Trial Subjects per site to compensate for the increase in necessary administrative activities by the study coordinator and the principal investigator.

"INVOICE" = invoiced items will be reimbursed by Sponsor under terms in Attachment A (Payment Terms).

Payments will be prorated based on number of visits completed; visit payments will be based upon CRFs completed. If a visit is not completed in full, reimbursement will be made for actual procedures performed.

All costs above include applicable overhead (operating costs).

Payee 2 – Principal Investigator / Príjemca platby 2 – Zodpovedný skúšajúci

PRINCIPAL INVESTIGATOR BUDGET- ROZPOČET ZODPOVEDNÉHO SKÚŠAJÚCEHO

Trial Procedure	Unit Cost	V1	V2	V3	V4	V5	V6	V7	V8 / End of Study	TOTAL	Unscheduled Visit
		Screening	Day 1	Month 1 (Day 29) ±4d	Month 2 (Day 57) ±4d	Month 3 (Day 85) ±4d	Month 4 (Day 113) ±4d	Month 5 (Day 141) ±4d	Month 6 (Day 169) ±4d		Any time during the study
Procedure Costs:											
Informed Consent		1									
Demographics, medical and ocular history		1									
Review Concomitant Medications, treatments and interventions		1	1	1	1	1	1	1	1		1
Blood pressure measurement		1	1								
BCVA (ETDRS) both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
Full Ophthalmological Exam both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
SD-OCT both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1

Color fundus photography both eyes at Visit 1 study eye only, Visits 5 and 8		2				1			1		
Fluorescein angiography both eyes at Visit 1 study eye only at Visit 8		2							1		
Blood sampling for HbA1c (includes collection, prep, ship)		1				1			1		
Blood sampling for THR-149 immunogenicity (includes collection, prep, ship)			1			1					
IMP and kit number allocation			1	1	1	1					
Assess list of withdrawal criteria from repeat injection				1	1	1					
IMP Administration (study eye)			1	1	1	1					
Study eye post-injection assessment			1	1	1	1					
AE and SAE monitoring and reporting		1	1	1	1	1	1	1	1		1
Total Procedure Fees:											
Non-Procedure Costs:											
Study Coordinator/Nurse Fee		1	1	1	1	1	1	1	1		1
Principal Investigator Fee		1	1	1	1	1	1	1	1		1
Total Non-Procedure Fees:											
Total Procedure and Non-Procedure Fees:											
Overhead:											
Total Per Visit Costs[1]:											

Additional Treatment Related Costs (inclusive of applicable overhead)[2]	
Urine collection test (pregnancy test, each) - Visits 1, 2, 3, 4, 5 and 8 (dipstick will be provided)	
Anterior chamber aqueous humour sampling[3] of the study eye at Visits 2 and 5 (includes consent, collection, prep, ship) - only for Trial Subjects who consent to procedure	
OCT angiography both eyes at Visit 1 and study eye only at Visits 5 and 8 - only for subjects at sites that have the required type of OCTA equipment	
Re-Consent (due to Protocol amendment)	
Unscheduled Visit[4]	INVOICE
Screen Failure[5]	INVOICE

Additional Study Related Costs (inclusive of applicable overhead)[6]	
Trial Subject Travel Reimbursement, if applicable[7]	
Pre-screening/Database Review Fee [8]/ Predskríning/ Poplatok za preskúmanie databáz [8]	
Additional study management costs (for each additional patient that has received at least 1 injection with IMP starting from the 4th patient enrolled)[9]	

[1] Cost inclusive of, but is not limited to, the following: staff time with the Trial Subject during procedures, CRF/eCRF completion, meeting attendance, audits, and monitoring visits.

[2] If applicable, will be reimbursed after CRF data is entered by Institution.

[3] Only at sites that perform aqueous humour sampling, in Trial Subjects who consent to the procedure.

[4] To be paid based on actual procedures performed, plus applicable additional services and overhead.

[5] Pursuant to section A-3 (Screen Failures) of Attachment A (Payment Terms), reimbursement will be made based on actual procedures performed

[6] Will be reimbursed after receipt of invoice reflecting actual costs.

[8] A One time fee of € 1,000.00 will be paid to principal Investigator upon receipt of invoice and completion of Principal Investigator's efforts to pre-screen at least 100 patients from Institution's database, which need to be listed in the "Database pre-screen log" documenting the primary reason not being eligible. Out of those 100 patients, at least 10 potential Trial Subjects need to be entered into the pre-screening "Medical History check" tool, for evaluation of possible eligibility. The database

pre-screen log and the pre-screening tool need both be provided to the CRO clinical team. /
Jednorazový poplatok vo výške 1 000 EUR sa uhradí Zodpovednému skúšajúcemu po prijatí faktúry a dokončení snáh Zodpovedného vyšetrujúceho, o predbežnú kontrolu najmenej 100 pacientov z databázy inštitúcie, ktorí musia byť uvedení v dokumentácii „Protokol predbežnej kontroly databázy" dokumentujúci ako primárny dôvod, že nie je spôsobilý. Z týchto 100 pacientov musí byť do predbežného skríningu „kontrola anamnézy" vložených najmenej 10 potenciálnych subjektov, aby sa vyhodnotila možná spôsobilosť. Protokol predbežného skríningu databázy a nástroj predbežného skríningu sa musia byť poskytné klinickému tímu spoločnosti CRO.

[9]To the extent permissible under Applicable Law and if desired by the site, the site will be reimbursed at the amount listed above for each eligible treated Trial Subject exceeding three eligible treated Trial Subjects per site to compensate for the increase in necessary administrative activities by the study coordinator and the principal investigator.

"INVOICE" = invoiced items will be reimbursed by Sponsor under terms in Attachment A (Payment Terms).

Payments will be prorated based on number of visits completed; visit payments will be based upon CRFs completed. If a visit is not completed in full,
reimbursement will be made for actual procedures performed.

All costs above include applicable overhead (operating costs).

Payee 3 – Sub-Investigator #1 / Príjemca platby 3 – Pomocný skúšajúci #1

MUDr. MUDr. JAMSHED ANWARZAI SUB-INVESTIGATOR BUDGET- MUDr. JAMSHED ANWARZAI ROZPOČET POMOCNÉHO SKÚŠAJÚCEHO

Trial Procedure	Unit Cost	V1	V2	V3	V4	V5	V6	V7	V8 / End of Study	TOTAL	Unscheduled Visit
		Screening	Day 1	Month 1 (Day 29) ±4d	Month 2 (Day 57) ±4d	Month 3 (Day 85) ±4d	Month 4 (Day 113) ±4d	Month 5 (Day 141) ±4d	Month 6 (Day 169) ±4d		Any time during the study
Procedure Costs:											
Informed Consent		1									
Demographics, medical and ocular history		1									
Review Concomitant Medications, treatments and interventions		1	1	1	1	1	1	1	1		1
Blood pressure measurement		1	1								
BCVA (ETDRS) both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
Full Ophthalmological Exam both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
SD-OCT both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1

Color fundus photography both eyes at Visit 1 study eye only, Visits 5 and 8		2				1			1		
Fluorescein angiography both eyes at Visit 1 study eye only at Visit 8		2							1		
Blood sampling for HbA1c (includes collection, prep, ship)		1				1			1		
Blood sampling for THR-149 immunogenicity (includes collection, prep, ship)			1			1					
IMP and kit number allocation			1	1	1	1					
Assess list of withdrawal criteria from repeat injection				1	1	1					
IMP Administration (study eye)			1	1	1	1					
Study eye post-injection assessment			1	1	1	1					
AE and SAE monitoring and reporting		1	1	1	1	1	1	1	1		1
Total Procedure Fees:											
Non-Procedure Costs:											
Study Coordinator/Nurse Fee		1	1	1	1	1	1	1	1		1
Principal Investigator Fee		1	1	1	1	1	1	1	1		1
Total Non-Procedure Fees:											
Total Procedure and Non-Procedure Fees:											
Overhead:											
Total Per Visit Costs[1]:											

Additional Treatment Related Costs (inclusive of applicable overhead)[2]	
Unscheduled Visit[4]	INVOICE
Screen Failure[5]	INVOICE

[4] To be paid based on actual procedures performed, plus applicable additional services and overhead.

[5] Pursuant to section A-3 (Screen Failures) of Attachment A (Payment Terms), reimbursement will be made based on actual procedures performed –

"INVOICE" = invoiced items will be reimbursed by Sponsor under terms in Attachment A (Payment Terms).

Payments will be prorated based on number of visits completed; visit payments will be based upon CRFs completed. If a visit is not completed in full,
reimbursement will be made for actual procedures performed.
All costs above include applicable overhead (operating costs).

Payee 4 – Sub-Investigator #2 / Príjemca platby 4 – Pomocný skúšajúci #2

MUDr. DANIEL KLÁNEK SUB-INVESTIGATOR BUDGET- MUDr. DANIEL KLÁNEK ROZPOČET POMOCNÉHO SKÚŠAJÚCEHO

Trial Procedure	Unit Cost	V1	V2	V3	V4	V5	V6	V7	V8 / End of Study	TOTAL	Unscheduled Visit
		Screening	Day 1	Month 1 (Day 29) ±4d	Month 2 (Day 57) ±4d	Month 3 (Day 85) ±4d	Month 4 (Day 113) ±4d	Month 5 (Day 141) ±4d	Month 6 (Day 169) ±4d		Any time during the study
Procedure Costs:											
Informed Consent		1									
Demographics, medical and ocular history		1									
Review Concomitant Medications, treatments and interventions		1	1	1	1	1	1	1	1		1
Blood pressure measurement		1	1								
BCVA (ETDRS) both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
Full Ophthalmological Exam both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
SD-OCT both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1

Color fundus photography both eyes at Visit 1 study eye only, Visits 5 and 8		2				1			1		
Fluorescein angiography both eyes at Visit 1 study eye only at Visit 8		2							1		
Blood sampling for HbA1c (includes collection, prep, ship)		1				1			1		
Blood sampling for THR-149 immunogenicity (includes collection, prep, ship)			1			1					
IMP and kit number allocation			1	1	1	1					
Assess list of withdrawal criteria from repeat injection				1	1	1					
IMP Administration (study eye)			1	1	1	1					
Study eye post-injection assessment			1	1	1	1					
AE and SAE monitoring and reporting		1	1	1	1	1	1	1	1		1
Total Procedure Fees:											
Non-Procedure Costs:											
Study Coordinator/Nurse Fee		1	1	1	1	1	1	1	1		1
Principal Investigator Fee		1	1	1	1	1	1	1	1		1
Total Non-Procedure Fees:											
Total Procedure and Non-Procedure Fees:											
Overhead:											
Total Per Visit Costs[1]:											

Additional Treatment Related Costs (inclusive of applicable overhead)[2]	
Unscheduled Visit[4]	INVOICE
Screen Failure[5]	INVOICE

[4] To be paid based on actual procedures performed, plus applicable additional services and overhead.

[5] Pursuant to section A-3 (Screen Failures) of Attachment A (Payment Terms), reimbursement will be made based on actual procedures performed –

"INVOICE" = invoiced items will be reimbursed by Sponsor under terms in Attachment A (Payment Terms).

Payments will be prorated based on number of visits completed; visit payments will be based upon CRFs completed. If a visit is not completed in full,
reimbursement will be made for actual procedures performed.
All costs above include applicable overhead (operating costs).

Payee 5 – Sub-Investigator #3 / Príjemca platby 5 – Pomocný skúšajúci #3

MUDr. ZUZANA ŠULAVÍKOVÁ SUB-INVESTIGATOR BUDGET- MUDr. ZUZANA ŠULAVÍKOVÁ ROZPOČET POMOCNÉHO SKÚŠAJÚCEHO

Trial Procedure	Unit Cost	V1	V2	V3	V4	V5	V6	V7	V8 / End of Study	TOTAL	Unscheduled Visit
		Screening	Day 1	Month 1 (Day 29) ±4d	Month 2 (Day 57) ±4d	Month 3 (Day 85) ±4d	Month 4 (Day 113) ±4d	Month 5 (Day 141) ±4d	Month 6 (Day 169) ±4d		Any time during the study
Procedure Costs:											
Informed Consent		1									
Demographics, medical and ocular history		1									
Review Concomitant Medications, treatments and interventions		1	1	1	1	1	1	1	1		1
Blood pressure measurement		1	1								
BCVA (ETDRS) both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
Full Ophthalmological Exam both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
SD-OCT both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1

Color fundus photography both eyes at Visit 1 study eye only, Visits 5 and 8		2				1			1		
Fluorescein angiography both eyes at Visit 1 study eye only at Visit 8		2							1		
Blood sampling for HbA1c (includes collection, prep, ship)		1				1			1		
Blood sampling for THR-149 immunogenicity (includes collection, prep, ship)			1			1					
IMP and kit number allocation			1	1	1	1					
Assess list of withdrawal criteria from repeat injection				1	1	1					
IMP Administration (study eye)			1	1	1	1					
Study eye post-injection assessment			1	1	1	1					
AE and SAE monitoring and reporting		1	1	1	1	1	1	1	1		1
Total Procedure Fees:											
Non-Procedure Costs:											
Study Coordinator/Nurse Fee		1	1	1	1	1	1	1	1		1
Principal Investigator Fee		1	1	1	1	1	1	1	1		1
Total Non-Procedure Fees:											
Total Procedure and Non-Procedure Fees:											
Overhead:											
Total Per Visit Costs[1]:											

Additional Treatment Related Costs (inclusive of applicable overhead)[2]	
Unscheduled Visit[4]	INVOICE
Screen Failure[5]	INVOICE

[4] To be paid based on actual procedures performed, plus applicable additional services and overhead.

[5] Pursuant to section A-3 (Screen Failures) of Attachment A (Payment Terms), reimbursement will be made based on actual procedures performed .
"INVOICE" = invoiced items will be reimbursed by Sponsor under terms in Attachment A (Payment Terms).

Payments will be prorated based on number of visits completed; visit payments will be based upon CRFs completed. If a visit is not completed in full,
reimbursement will be made for actual procedures performed.
All costs above include applicable overhead (operating costs).

Payee 6 – Sub-Investigator #4 / Príjemca platby 6 – Pomocný skúšajúci #4

MUDr. ALEXANDRA RAČEKOVÁ SUB-INVESTIGATOR BUDGET- MUDr. ALEXANDRA RAČEKOVÁ ROZPOČET POMOCNÉHO SKÚŠAJÚCEHO

Trial Procedure	Unit Cost	V1	V2	V3	V4	V5	V6	V7	V8 / End of Study	TOTAL	Unscheduled Visit
		Screening	Day 1	Month 1 (Day 29) ±4d	Month 2 (Day 57) ±4d	Month 3 (Day 85) ±4d	Month 4 (Day 113) ±4d	Month 5 (Day 141) ±4d	Month 6 (Day 169) ±4d		Any time during the study
Procedure Costs:											
Informed Consent		1									
Demographics, medical and ocular history		1									
Review Concomitant Medications, treatments and interventions		1	1	1	1	1	1	1	1		1
Blood pressure measurement		1	1								
BCVA (ETDRS) both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
Full Ophthalmological Exam both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1
SD-OCT both eyes at Visit 1 study eye only, Visits 2- 8 and Unscheduled Visits		2	1	1	1	1	1	1	1		1

Color fundus photography both eyes at Visit 1 study eye only, Visits 5 and 8		2				1			1		
Fluorescein angiography both eyes at Visit 1 study eye only at Visit 8		2							1		
Blood sampling for HbA1c (includes collection, prep, ship)		1				1			1		
Blood sampling for THR-149 immunogenicity (includes collection, prep, ship)			1			1					
IMP and kit number allocation			1	1	1	1					
Assess list of withdrawal criteria from repeat injection				1	1	1					
IMP Administration (study eye)			1	1	1	1					
Study eye post-injection assessment			1	1	1	1					
AE and SAE monitoring and reporting		1	1	1	1	1	1	1	1		1
Total Procedure Fees:											
Non-Procedure Costs:											
Study Coordinator/Nurse Fee		1	1	1	1	1	1	1	1		1
Principal Investigator Fee		1	1	1	1	1	1	1	1		1
Total Non-Procedure Fees:											
Total Procedure and Non-Procedure Fees:											
Overhead:											
Total Per Visit Costs[1]:											

Additional Treatment Related Costs (inclusive of applicable overhead)[2]	
Unscheduled Visit[4]	INVOICE
Screen Failure[5]	INVOICE

[4] To be paid based on actual procedures performed, plus applicable additional services and overhead.

[5] Pursuant to section A-3 (Screen Failures) of Attachment A (Payment Terms), reimbursement will be made based on actual procedures performed .
"INVOICE" = invoiced items will be reimbursed by Sponsor under terms in Attachment A (Payment Terms).

Payments will be prorated based on number of visits completed; visit payments will be based upon CRFs completed. If a visit is not completed in full,
reimbursement will be made for actual procedures performed.
All costs above include applicable overhead (operating costs).