

| <p align="center">CLINICAL TRIAL AGREEMENT AMENDMENT NO. 1</p> | <p align="center">DODATOK K ZMLUVE O KLINICKOM SKÚŠANÍ Č. 1</p> |
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| <p>This Clinical Trial Agreement Amendment (“Amendment no.1”) is by and between: ACTICOR BIOTECH with its principal place of business at Inserm U1148-Hôpital Bichat, 46, rue Henri Huchard, 75018 Paris Cedex 18 ,France (“Sponsor”),</p> | <p>Tento Dodatok k Zmluve o klinickom skúšaní („Dodatok č.1“) je uzavretý medzi: ACTICOR BIOTECH so sídlom na adrese Inserm U1148-Hôpital Bichat, 46, rue Henri Huchard, 75018 Paris Cedex 18 , Francúzsko („Zadávateľ“),</p> |
| <p>Fakultná nemocnica Nitra with its registered seat at: Špitálska 6, 950 01 Nitra, Slovak Republic ID No.: 17336007 VAT No.: 2021205197 Represented by: Mgr. Michal Fajin, MBA, LL.M, MPH, Director (“Center”),</p> | <p>Fakultná nemocnica Nitra so sídlom: Špitálska 6, 950 01 Nitra, Slovenská republika IČO: 17336007 DIČ: 2021205197 zastúpena Mgr. Michalom Fajinom, MBA, LL.M, MPH, riaditeľom („Centrum“),</p> |
| and | a |
| <p>MUDr. Gabriel Hajaš, PhD., date of birth September 10, 1967, place of residence: Krivánska 1591/2, 94901 Nitra Slovak Republic (“Principal Investigator”),</p> | <p>MUDr. Gabriel Hajaš, PhD., dátum narodenia 10.09.1967,, miesto trvalého bydliska: Krivánska 1591/2, 94901 Nitra, Slovenská republika („Hlavný skúšajúci“)</p> |
| <p>each a “Party” and collectively “the Parties.”</p> | <p>jednotlivo „zmluvná strana“ a spoločne „zmluvné strany“.</p> |
| <p>Whereas</p> | <p>Pričom</p> |
| <p>A. The Parties have entered into a Clinical Trial Agreement dated July 14, 2022 (“Agreement”) to conduct a medical research study (the “Study”) of GLENZOCIMAB (“Study Drug”) under the Sponsor protocol entitled “A RANDOMIZED, DOUBLE BLIND, MULTICENTER, PLACEBO CONTROLLED, PARALLEL MULTINATIONAL, SINGLE DOSE, GROUP, ADAPTIVE EFFICACY AND SAFETY STUDY OF GLENZOCIMAB USED AS AN ADD-ON THERAPY ON TOP OF</p> | <p>A. Zmluvné strany uzavreli Zmluvu o klinickom skúšaní zo dňa 14. júla 2022 („Zmluva“) na vykonávanie lekárskeho výskumného skúšania („Skúšanie“) lieku GLENZOCIMAB („Skúšaný liek“) na základe protokolu Zadávateľa pod názvom “RANDOMIZOVANÉ, DVOJITO ZASLEPENÉ, MULTICENTRICKÉ, MEDZINÁRODNÉ, PLACEBOM KONTROLOVANÉ ADAPTÍVNE KLINICKÉ SKÚŠANIE BEZPEČNOSTI A</p> |

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| <p>STANDARD OF CARE IN THE 4.5 HOURS FOLLOWING AN ACUTE ISCHEMIC STROKE” ACT-CS-005 (“Protocol”);</p> | <p>ÚČINNOSTI GLENZOCIMABÚ S PARALELNÝMI SKUPINAMI A JEDNOU DÁVKOU, V PRÍDAVNEJ LIEČBE K ŠTANDARDNEJ LIEČBE POČAS 4,5 HODÍN PO AKÚTNEJ ISCHEMICKEJ CIEVNEJ MOZGOVEJ PRÍHODE. ‘ACT-CS-005 ‘ („Protocol“);</p> |
| <p>B. The Parties agree to amend the Agreement as set out in this Amendment no.1; and</p> | <p>B. Zmluvné strany súhlasia so zmenou a doplnením Zmluvy tak, ako je uvedené v tomto Dodatku č.1; a</p> |
| <p>C. Sponsor has authorized Worldwide Clinical Trials Slovakia s.r.o., Cintorínska 7, SK-811 08 Bratislava, Slovak Republic (VAT Reg No: SK2022851039) and its affiliates (“Worldwide”), pursuant to a written agreement to coordinate and/or perform certain activities as the authorized agent of Sponsor, including but not limited to, negotiation and execution of clinical trial agreement amendments.</p> | <p>C. Zadávateľ poveril Worldwide Clinical Trials Slovakia s.r.o., Cintorínska 7, SK-811 08 Bratislava, Slovenská republika (IČ DPH: SK2022851039) a jej pobočky („Worldwide“) na základe písomnej zmluvy, za účelom koordinácie a/alebo realizácie určitých činností v úlohe autorizovaného zástupcu Zadávateľa - okrem iného - rokovania a uzatvárania dodatkov k zmluvám o klinickom skúšaní.</p> |
| <p>1. Definition</p> | <p>1. Definície</p> |
| <p>1.1. Capitalized terms not otherwise defined in this Amendment or any prior written amendment(s) as applicable will have the meanings ascribed to them in the Agreement.</p> | <p>1.1. Pojmy uvedené veľkými písmenami, ktoré nie sú inak definované v tomto Dodatku alebo prípadných iných predchádzajúcich písomných dodatkoch, budú mať rovnaký význam, aký je im priradený v Zmluve.</p> |
| <p>2. Amendments</p> | <p>2. Dodatky</p> |
| <p>2.1. This Amendment no.1 to the Clinical Trial Agreement shall enter into force on the date of signing by the Parties and shall take effect on the day following its publication in the Central Register of Contracts. (“Effective Date”):</p> | <p>2.1. Tento dodatok č.1 k Zmluve o klinickom skúšaní nadobúda platnosť dňom podpísania zmluvných strán a účinnosť dňom nasledujúcim po jeho zverejnení v Centrálnom registry zmlúv („Dátum účinnosti“):</p> |
| <p>2.1.1. The Parties wish to amend the Agreement to update the site overall budget due to Protocol Version 3 and Protocol Version 5.0. Updates in the</p> | <p>2.1.1 Zmluvné strany si želajú zmeniť a doplniť Zmluvu s cieľom aktualizovať celkový rozpočet z dôvodu verzie 3 protokolu a</p> |

budget regarding Protocol Version 5.0 dated March 14, 2023 will be effective as per the date of implementation at Study Site

- 2.1.2 The Parties wish to amend the Section 2.1 and 2.2 within Exhibit B to the Agreement, which is hereby deleted in its entirety and replaced with the following:

2.1 Worldwide will make payments on behalf of Sponsor through its corporate affiliate, **International Grants Administration, Inc. (IGA)** with address in 401 North Maple Drive, Beverly Hills, CA 90210, USA (Tax Identification Number: 26-4445619) a wholly owned Worldwide company that performs administrative accounting services for Worldwide. Payments made to Payee may come through a third-party vendor.

2.2 All billing invoices shall be issued in the name of the Sponsor, including VAT, if Payee and Sponsor are located in the same country. Otherwise, all invoices shall be issued in the name of: International Grants Administration, Inc. 401 North Maple Drive, Beverly Hills, CA 90210, USA, and sent electronically to:

payments@worldwide.com
(preferred method)

verzie 5.0 protokolu. Aktualizácie v rozpočte týkajúce sa verzie protokolu 5.0 zo 14. marca 2023 budú účinné od dátumu implementácie na mieste štúdie

- 2.1.2. Zmluvné strany si želajú zmeniť článok 2.1 a 2.2 v rámci prílohy B k zmluve, ktorý sa týmto v celom rozsahu vypúšťa a nahrádza sa týmto textom:


2.1 Spoločnosť Worldwide bude uskutočňovať platby v mene zadávateľa prostredníctvom svojej dcérskej spoločnosti **International Grants Administration, Inc. (IGA)** s adresou 401 North Maple Drive, Beverly Hills, CA 90210, USA (daňové identifikačné číslo: 26-4445619) ktorá je v úplnom vlastníctve spoločnosti Worldwide, a ktorá poskytuje administratívne účtovnícke služby pre spoločnosť Worldwide. Platby uskutočnené v prospech príjemcu platby môžu prichádzať prostredníctvom dodávateľa tretej strany.

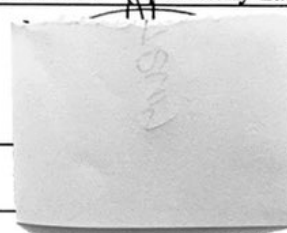
2.2 Všetky vyúčtovacie faktúry sa vystavujú na meno Zadávateľa vrátane DPH, ak sa príjemca a Zadávateľ nachádzajú v tej istej krajine. V opačnom prípade sa všetky faktúry vystavujú na meno: International Grants Administration, Inc. 401 North Maple Drive, Beverly Hills, CA 90210, USA, a zasielajú sa elektronicky na adresu:


payments@worldwide.com
(preferovaná metóda)

| | |
|---|---|
| <p>3. Conflict</p> <p>3.1. In the case of a conflict between the terms of the Agreement (including any prior written amendment(s) as applicable) and this Amendment, the terms of this Amendment shall prevail.</p> | <p>3. Rozpor</p> <p>3.1. V prípade rozporu medzi pojmami Zmluvy (vrátane všetkých prípadných iných predchádzajúcich písomných dodatkov) a tohto Dodatku budú mať presnosť pojmy tohto Dodatku.</p> |
| <p>4. No Other Change</p> <p>4.1. Except as otherwise provided in this Amendment or any prior written amendment(s) as applicable, the other terms and conditions of the Agreement shall remain unchanged and in full force and effect.</p> | <p>4. Žiadna iná zmena</p> <p>4.1. Okrem toho, čo je výslovne uvedené v tomto Dodatku alebo prípadných iných predchádzajúcich písomných dodatkoch, ostatné pojmy a podmienky Zmluvy zostávajú nezmenené a v plnom rozsahu platné a účinné.</p> |
| <p>5. General Provisions</p> <p>5.1. This Amendment, and any subsequent amendment(s), is executed in 3 counterparts and the counterparts, together, shall constitute a single agreement.</p> | <p>5. Všeobecné ustanovenia</p> <p>5.1. Tento Dodatok a všetky jeho následné úpravy a doplnenia sú vyhotovené vo 3 rovnopisoch a takéto rovnopisy spoločne predstavujú jeden dokument.</p> |
| <p>5.2. The Parties agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The Parties agree they will have no rights to challenge the use or authenticity of this document based solely on the absence of an original signature.</p> | <p>5.2. Zmluvné strany sa dohodli, že kópia originálneho podpisu (vrátane elektronickej kópie) sa môže použiť na akékoľvek účely, na aké by sa mohol použiť originálny podpis. Zmluvné strany súhlasia, že nebudú mať nijaké práva namietať proti použitiu alebo pravosti tohto dokumentu výlučne na základe absencie originálneho podpisu.</p> |
| <p>5.3. This Amendment may be executed in two languages. In case of discrepancies between the Slovak version and the English version of this Amendment, the Slovak version shall prevail.</p> | <p>5.3. Tento Dodatok je možné vyhotoviť v dvoch jazykoch. V prípade rozporov medzi slovenskou verziou a anglickou verziou tohto Dodatku má prednosť slovenská verzia.</p> |
| <p>5.4. Except as expressly amended by this Amendment, the Agreement shall be unchanged and shall remain in full force and effect in accordance with its terms.</p> | <p>5.4. Okrem toho, čo je výslovne zmenené týmto Dodatkom, zostáva Zmluva nezmenená a bude naďalej platná a účinná v plnom rozsahu v súlade s podmienkami v nej uvedenými.</p> |

[SIGNATURES TO FOLLOW]
[NASLEDUJÚ PODPISY]

| SPONSOR / ZADÁVATEL | |
|--|---|
| Name Surname/ Meno Priezvisko | Adeline Meilhoc |
| Title/ Titul | Head of Global Clinical Development |
| Date/ Dátum DD-MMM-YYYY/ DD-MMM-RRR | Nov 22nd 2023 |
| Signature/ Podpis |  |

| CENTER (authorized signatory)/ CENTRUM (oprávnený zástupca) | |
|--|--|
| Name Surname/ Meno Priezvisko |  A, LL.M, MPH |
| Title/ Titul | titel' |
| Date/ Dátum DD-MMM-YYYY/ DD-MMM-RRR | 29/11/2023 |
| Signature/ Podpis | |

| PRINCIPAL INVESTIGATOR/ HLAVNÝ SKÚŠAJÚCI | |
|--|--|
| Name Surname/ Meno Priezvisko | MUDr. Gabriel Hajaš |
| Title/ Titul | principal investigator/hlavný skúšajúci |
| Date/ Dátum <small>DD-MMM-YYYY/ DD-MMM-RRR</small> | 29/nov/2023 |
| Signature/ Podpis |  |

**LIST OF APPENDIXES/ ZOZNAM
PRÍLOH**
Appendix 1/ Príloha č. 1

Financial Terms / Finančné podmienky

Príloha č. 1: Finančné podmienky / Appendix 1 : Financial Terms

BUDGET / ROZPOČET

CENTER/ CENTRUM

| PI: Hajas Site: SL02 | | SLOVAKIA | | | | | | | | Visit 4 | Visit 5 |
|--|-----------------|-----------------------------------|-----------------------------|--------------------------|-----------------------|---------------|--------------|------------------------|------------------------|--------------|--------------|
| ITEM COST (EURO) | Visit 1 | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | Item Total | Day 30 Telemedicine | Day 60 Telemedicine | | |
| | Day 1 | Day 2 | Day 7 or on discharge | Day 30 At Hospital | Day 60 at Hospital | Day 90 EOS | | | | | |
| | Baseline | Infusion (6 hr IV infusion) | 24 hours ± 3 hrs | ± 3 days | ± 3 days | ± 7 days | | | | ± 7 days | |
| Procedures & Assessments | | | | | | | | | | | |
| Informed Consent | 20 | 20 | | | | | 20 | | | | |
| Eligibility criteria | 20 | 20 | | | | | 20 | | | | |
| Medical History with Demographics | 28 | 28 | | | | | 28 | | | | |
| Clinical evaluation (at Screening) | 38 | 38 | | | | | 38 | | | | |
| Clinical evaluation (all other visits) | 20 | | | | | | | | | | |
| Concomitant Medication | 7 | | 20 | 20 | 20 | 20 | 101 | | | | |
| IV Line insertion | 29 | 7 | 7 | 7 | 7 | 7 | 45 | 7 | 7 | | |
| IP/Placebo IV administration | 40 | | 40 | | | | 40 | | | | |
| NIHSS | 7 | 7 | 7 | | | | 21 | | | | |
| mRS | 7 | | | | | | | | | | |
| Blood draw for Central lab analysis (ADA) | 13 | | | | 7 | 7 | 21 | 7 | 7 | | |
| Lab handling/shipping of blood samples for ADA to Central lab | 9 | 13 | | | | | 25 | | | | |
| EQ-5D-5L | 6 | | | | | | 18 | | | | |
| 12-lead ECG: Includes tracing, interpretation and report | 29 | 29 | | | | | 6 | | | | |
| Blood Pressure and Heart Rate | 7 | | | | | | 57 | | | | |
| Blood draw for Local labs (Hematology, Coagulation, Biochemistry, Biological | 6 | 82 | 54 | 7 | | | 156 | | | | |
| Hematology, Complete Blood Count (CBC), Platelets (local lab) | 7 | | 6 | 6 | | | 26 | | | | |
| Coagulation: PT, aPTT, INR (local lab) | 16 | | 7 | 7 | | | 28 | | | | |
| Biochemistry: Serum creatinine (local lab) | 6 | 16 | 16 | | | | 33 | | | | |
| Biochemistry: GFR (local lab) | 6 | 6 | 6 | 6 | | | 25 | | | | |
| Biochemistry: Serum glucose (local lab) | 5 | 5 | 5 | 5 | | | 25 | | | | |
| Biochemistry: Urea (at Baseline and Day 7 Urea will be only evaluated), ASAT, ALAT (local lab) | 12 | 4 | 12 | 1 | | | 16 | | | | |
| Biochemistry: LDH (local lab) | 4 | | 4 | | | | 28 | | | | |
| Biochemistry: Triglycerides (local lab) | 3 | | 3 | | | | 8 | | | | |
| Biochemistry: Total Cholesterol (local lab) | 5 | | 5 | | | | 6 | | | | |
| Biological markers: D-dimers with/without Fibrin degradation products (FDP) (l | 7 | 7 | 7 | 7 | | | 10 | | | | |
| Biological markers: Fibrinogen (local lab) | 8 | 8 | 8 | 8 | | | 27 | | | | |
| Adverse Event / SAE | 10 | 10 | 10 | 10 | 10 | 10 | 30 | | | | |
| Study Coordinator Fee (includes I&RS (randomization & supply kit allocation), Post-stroke management information) | 27 | 27 | 27 | 27 | 27 | 27 | 57 | 10 | 10 | | |
| Data Entry Fee | 10 | 10 | 10 | 10 | 10 | 10 | 159 | 7 | 7 | | |
| Principal Investigator Fee | 48 | 48 | 48 | 48 | 48 | 48 | 61 | 3 | 3 | | |
| Pharmacy Fee - Preparation/Dispensation of IP/Placebo | 19 | | 19 | | | | 191 | | | | |
| Subtotal: | | 337 | 176 | 298 | 170 | 81 | 81 | 233 | 1,376 | 33 | 33 |
| Overhead | 17% | 57.96 | 29.86 | 50.64 | 28.93 | 13.73 | 13.73 | 39.66 | 233.89 | 5.62 | 5.62 |
| | | 394.76 | 205.48 | 348.51 | 199.09 | 94.47 | 94.47 | 272.93 | 1,609.70 | 38.69 | 38.69 |
| | Payment at 90% | 355.28 | 184.93 | 313.66 | 179.18 | 85.02 | 85.02 | 245.63 | 1,448.73 | 34.82 | 34.82 |
| | 10% Withholding | 39.48 | 20.55 | 34.85 | 19.91 | 9.45 | 9.45 | 27.29 | 160.97 | 3.87 | 3.87 |

| INVOICEABLE ITEMS | COST | FREQUENCY |
|--|---------|---------------------------|
| IRB/EC Fees | Invoice | As Needed |
| Study Start-Up Fee | 1,500 | 1x, at completion of STV |
| Document Storage / Record Retention | 1,500 | 1x, at COV |
| Blood draw for Local labs (Hematology; Coagulation; Biochemistry; Biological markers) | 7.49 | As Needed; per protocol |
| Hematology: Complete Blood Count (CBC), Platelets (local lab) | 8.08 | As Needed; per protocol |
| Coagulation: PT, aPTT, INR (local lab) | 19.27 | As Needed; per protocol |
| Biochemistry: Serum creatinine (local lab) | 7.46 | As Needed; per protocol |
| Biochemistry: GFR (local lab) | 7.46 | As Needed; per protocol |
| Biochemistry: Serum glucose (local lab) | 6.22 | As Needed; per protocol |
| Biochemistry: Urea, ASAT, ALAT (local lab) | 13.57 | As Needed; per protocol |
| Biochemistry: LDH (local lab) | 4.68 | As Needed; per protocol |
| Biochemistry: Triglycerides (local lab) | 3.74 | As Needed; per protocol |
| Biochemistry: Total Cholesterol (local lab) | 6.08 | As Needed; per protocol |
| Biological markers: D-dimers with/without Fibrin degradation products (FDP) (local lab) | 7.96 | As Needed; per protocol |
| Biological markers: Fibrinogen (local lab) | 8.89 | As Needed; per protocol |
| Biological markers: Fibrin monomers (optional) | 37.44 | As Needed; per protocol |
| Urine collection for Local labs (Urinalysis) (optional) | 8.19 | As Needed; per protocol |
| Urinalysis (local lab) (optional) | 10.53 | As Needed; per protocol |
| Unscheduled Procedures/Visits (for safety, abnormal test results, and/or additional procedures/visits per Protocol will be paid per procedure(s) performed plus staff fees, overhead, and subject reimbursement) | Invoice | As Needed |
| Treatment failure after randomization | 197.38 | for any treatment failure |

PRINCIPAL INVESTIGATOR/HLAVNÝ SKÚŠAJÚCI

| PT: Hajas SRe: SL02 | SLOVAKIA | | | | | | | | | | Rem Total | Visit 4 Day 30 Telemedicine | Visit 5 Day 60 Telemedicine | | |
|--|------------------------|---------------|-----------------------------------|------------------------|---------------------------|-------------------------|-------------------------|---------------|---------------|--------------|-----------|-----------------------------------|-----------------------------------|--|--|
| | ITEM COST (EURO) | Visit 1 | | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | | | | | | | |
| | | Day 1 | | Day 2 | Day 7 or on dischar | Day 30 At Hospita | Day 60 at Hospita | Day 90 EOS | | | | | | | |
| | | Baseline | Infusion (6 hr IV infusion) | 24 hours ± 3 hrs | ± 3 days | ± 3 days | ± 7 days | ± 7 days | | | | | | | |
| Procedures & Assessments | | | | | | | | | | | | | | | |
| Informed Consent | 8 | | | | | | | | | | | | | | |
| Eligibility criteria | 8 | | | | | | | | | | | | | | |
| Medical History with Demographics | 10 | | | | | | | | | | | | | | |
| Clinical evaluation (at Screening) | 14 | | | | | | | | | | | | | | |
| Clinical evaluation (all other visits) | 8 | | | 8 | 8 | 8 | 8 | 8 | 8 | | | | | | |
| Concomitant Medication | 3 | | | 3 | 3 | 3 | 3 | 3 | 3 | | | | | | |
| IV Line insertion | 11 | | 11 | | | | | | | | | | | | |
| IP/Placebo IV administration | 15 | | 15 | | | | | | | | | | | | |
| IMPSS | 3 | | 3 | 3 | | | | | | | | | | | |
| mRS | 3 | | | | | | | | | | | | | | |
| Blood draw for Central lab analysis (ADA) | 5 | | | | | | | | | | | | | | |
| Lab handling/shipping of blood samples for ADA to Central lab | 3 | | | | | | | | | | | | | | |
| EG-RD-SL | 2 | | | | | | | | | | | | | | |
| 12-lead ECG: Includes tracing, interpretation and report | 11 | | | 11 | | | | | | | | | | | |
| Blood Pressure and Heart Rate | 3 | | | | | | | | | | | | | | |
| Blood draw for Local labs (Hematology, Coagulation, Biochemistry) | 2 | | 31 | 20 | 3 | | | | | | | | | | |
| Hematology, Complete Blood Count (CBC), Platelets (local lab) | 3 | | | 2 | 2 | | | | | | | | | | |
| Coagulation: PT, aPTT, INR (local lab) | 6 | | | 3 | 3 | | | | | | | | | | |
| Biochemistry: Serum creatinine (local lab) | 2 | | | 2 | 2 | | | | | | | | | | |
| Biochemistry: GFR (local lab) | 2 | | | 2 | 2 | | | | | | | | | | |
| Biochemistry: Serum glucose (local lab) | 2 | | | 2 | 2 | | | | | | | | | | |
| Biochemistry: Urea (at Baseline and Day 7 Urea will be only evaluated), ASAT, ALAT (local lab) | 14 | | | 4 | 0 | | | | | | | | | | |
| Biochemistry: LDH (local lab) | 2 | | | 2 | | | | | | | | | | | |
| Biochemistry: Triglycerides (local lab) | 1 | | | 1 | | | | | | | | | | | |
| Biochemistry: Total Cholesterol (local lab) | 2 | | | 2 | | | | | | | | | | | |
| Biological markers: D-dimers with/without Fibrin degradation products (FDP) | 3 | | | 3 | 3 | | | | | | | | | | |
| Biological markers: Fibrinogen (local lab) | 3 | | | 3 | 3 | | | | | | | | | | |
| Adverse Event / SAE | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | | | | | | |
| Study Coordinator Fee (includes mRS (randomization & supply kit allocation), Post-stroke management information) | 10 | | | 10 | 10 | 10 | 10 | 10 | 10 | | | | | | |
| Data Entry Fee | 4 | | | 4 | 4 | 4 | 4 | 4 | 4 | | | | | | |
| Principal Investigator Fee | 18 | | | 18 | 18 | | | | | | | | | | |
| Pharmacy Fee - Preparation/Dispensation of IP/Placebo | 7 | | | 7 | | | | | | | | | | | |
| Subtotal: | 127 | 66 | 112 | 64 | 30 | 30 | 87 | 516 | | | | | | | |
| Overhead | 17% | 21.51 | 11.20 | 11.11 | 11.11 | 5.15 | 5.15 | 14.87 | 87.71 | | | | | | |
| | | 148.03 | 77.05 | 130.11 | 74.66 | 35.43 | 35.43 | 102.35 | 603.64 | | | | | | |
| Payment at 90% 10% Withholding | | 133.23 | 69.35 | 117.02 | 67.19 | 31.88 | 31.88 | 92.11 | 543.27 | | | | | | |
| | | 14.80 | 7.71 | 13.07 | 7.47 | 3.54 | 3.54 | 10.23 | 60.38 | | | | | | |
| | | | | | | | | | | 12 | | 12 | | | |
| | | | | | | | | | | 2.11 | | 2.11 | | | |
| | | | | | | | | | | 14.51 | | 14.51 | | | |
| | | | | | | | | | | 13.06 | | 13.06 | | | |
| | | | | | | | | | | 1.45 | | 1.45 | | | |

ACTICOR BIOTECH-ACT-CS-005-from-Worldwide-Master-Am-1 0-20Apr2020
SL-SL02-Hajas-CTA Am 1-FINAL-21Nov2023-PA3 and PA5

| INVOICEABLE ITEMS | COST | FREQUENCY |
|--|---------|---------------------------|
| Unscheduled Procedures/Visits (for safety, abnormal test results, and/or additional procedures/visits per Protocol will be paid per procedure(s) performed plus staff fees, overhead, and subject reimbursement) | Invoice | As Needed |
| Treatment failure after randomization | 74.02 | for any treatment failure |

SUB-INVESTIGATOR/ SPOLUZKÚŠAJUCÍ

| PI: Hajas Site: SL02 | SLOVAKIA | | | | | | | | | | Visit 4 | Visit 5 | |
|---|---------------------|----------|-----------------------------------|---------------------|-----------------------------|--------------------------|-----------------------|---------------|------------|------------------------|---------|---------|------------------------|
| | ITEM COST (EURO) | Visit 1 | | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | Item Total | Day 30 Telemedicine | | | Day 60 Telemedicine |
| | | Day 1 | | Day 2 | Day 7 or on discharge | Day 30 At Hospital | Day 60 at Hospital | Day 90 EOS | | | | | |
| | | Baseline | Infusion (6 hr IV infusion) | 24 hours ± 3 hrs | ± 3 days | ± 3 days | ± 7 days | ± 7 days | | | | | |
| Procedures & Assessments | | | | | | | | | | | | | |
| Informed Consent | 18 | 18 | | | | | | | 18 | | | | |
| Eligibility criteria | 18 | 18 | | | | | | | 18 | | | | |
| Medical History with Demographics | 24 | 24 | | | | | | | 24 | | | | |
| Clinical evaluation (at Screening) | 33 | 33 | | | | | | | 33 | | | | |
| Clinical evaluation (all other visits) | 18 | | | | | | | | | | | | |
| Concomitant Medication | 7 | | 18 | 18 | 18 | 18 | 18 | 18 | 88 | | | | |
| IV Line insertion | 25 | 7 | | 7 | 7 | 7 | 7 | 7 | 39 | 7 | 7 | | |
| IP/Placebo IV administration | 35 | | 25 | | | | | | 25 | | | | |
| NIHSS | 6 | 6 | 35 | | | | | | 35 | | | | |
| mRS | 6 | 6 | 6 | | | | | | 18 | | | | |
| Blood draw for Central lab analysis (ADA) | 11 | 11 | | | 6 | 6 | 6 | 6 | 18 | 6 | 6 | | |
| Lab handling/shipping of blood samples for ADA to Central lab | 8 | 8 | | | | | | 11 | 22 | | | | |
| EQ-SD-SI | 6 | 6 | | | | | | 8 | 16 | | | | |
| 12-lead ECG: Includes tracing, interpretation and report | 25 | 25 | | | | | | 6 | 6 | | | | |
| Blood Pressure and Heart Rate | 6 | 6 | 25 | 25 | | | | | 50 | | | | |
| Blood draw for Local labs (Hematology, Coagulation, Biochemistry, Biological) | 6 | 6 | 71 | 48 | 6 | | | 6 | 137 | | | | |
| Hematology, Complete Blood Count (CBC), Platelets (local lab) | 6 | 6 | 6 | 6 | 6 | | | 6 | 22 | | | | |
| Coagulation: PT, aPTT, INR (local lab) | 14 | 14 | 6 | 6 | | | | 6 | 24 | | | | |
| Biochemistry: Serum creatinine (local lab) | 6 | 6 | 14 | 14 | | | | | 29 | | | | |
| Biochemistry: GFR (local lab) | 6 | 6 | 6 | 6 | | | | 6 | 22 | | | | |
| Biochemistry: Serum glucose (local lab) | 6 | 6 | 6 | 6 | | | | 6 | 22 | | | | |
| Biochemistry: Urea (at Baseline and Day 7 Urea will be only evaluated), ASAT, ALAT (local lab) | 5 | 5 | 5 | 5 | | | | 5 | 14 | | | | |
| Biochemistry: LDE (local lab) | 10 | 3 | 10 | 1 | | | | 10 | 25 | | | | |
| Biochemistry: Triglycerides (local lab) | 4 | 4 | 4 | | | | | 4 | 7 | | | | |
| Biochemistry: Total Cholesterol (local lab) | 3 | 3 | 3 | | | | | 3 | 6 | | | | |
| Biological markers: D-dimers with/without Fibrin degradation products (FDP) (local lab) | 5 | 5 | 5 | | | | | 5 | 9 | | | | |
| Biological markers: Fibrinogen (local lab) | 6 | 6 | 6 | 6 | | | | 6 | 24 | | | | |
| Adverse Event / SAE | 7 | 7 | 7 | 7 | | | | 7 | 27 | | | | |
| Study Coordinator Fee [includes IxRS (randomization & supply kit allocation), Post-stroke management information] | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 8 | 50 | 8 | 8 | | |
| Data Entry Fee | 23 | 23 | 23 | 23 | 23 | 23 | 23 | 23 | 139 | 6 | 6 | | |
| Principal Investigator Fee | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 53 | 2 | 2 | | |
| Pharmacy Fee - Preparation/Dispensation of IP/Placebo | 42 | 42 | 42 | 42 | 42 | 42 | 42 | 42 | 167 | | | | |
| Subtotal: | 16 | 16 | 16 | 16 | 16 | 16 | 16 | 16 | 16 | | | | |
| Overhead | | 296 | 164 | 261 | 149 | 71 | 71 | 204 | 1,204 | 29 | 29 | | |
| | 17% | 50.19 | 26.12 | 44.31 | 25.31 | 12.01 | 12.01 | 34.70 | 204.65 | 4.92 | 4.92 | | |
| | | 345.41 | 179.79 | 304.94 | 174.20 | 82.66 | 82.66 | 238.81 | 1,408.48 | 33.85 | 33.85 | | |
| | Payment at 90% | 310.87 | 161.81 | 274.45 | 156.78 | 74.39 | 74.39 | 214.93 | 1,267.64 | 30.47 | 30.47 | | |
| | 10% Withholding | 34.54 | 17.98 | 30.49 | 17.42 | 8.27 | 8.27 | 23.88 | 140.85 | 3.39 | 3.39 | | |

| INVOICEABLE ITEMS | COST | FREQUENCY |
|--|-------------|---------------------------|
| Reconsent Fee | 22.23 | As Needed |
| Unscheduled Procedures/Visits (for safety, abnormal test results, and/or additional procedures/visits per Protocol will be paid per procedure(s) performed plus staff fees, overhead, and subject reimbursement) | Invoice | As Needed |
| Treatment failure after randomization | 172.71 | for any treatment failure |

STUDY NURSE/ ŠTUDIJNÁ SESTRA
(Ferencziová Petronela)

| PI: Hajas Site: SL02 | | SLOVAKIA | | | | | | | | Visit 4 | Visit 5 |
|---|-----------------------------------|-----------------------------------|---------------------|-----------------------------|--------------------------|-----------------------|---------------|------------|-----------------------------------|-----------------------------------|---------|
| ITEM COST (EURO) | Visit 1 | | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | Item Total | Visit 4 Day 30 Telemedicine | Visit 5 Day 60 Telemedicine | |
| | Day 1 | | Day 2 | Day 7 or on discharge | Day 30 At Hospital | Day 60 at Hospital | Day 90 EOS | | | | |
| | Baseline | Infusion (6 hr IV infusion) | 24 hours ± 3 hrs | ± 3 days | ± 3 days | ± 7 days | ± 7 days | | | | |
| Procedures & Assessments | | | | | | | | | | | |
| Informed Consent | 3 | 3 | | | | | | 3 | | | |
| Eligibility criteria | 3 | 3 | | | | | | 3 | | | |
| Medical History with Demographics | 3 | 3 | | | | | | 3 | | | |
| Clinical evaluation (at Screening) | 5 | 5 | | | | | | 5 | | | |
| Clinical evaluation (all other visits) | 3 | | 3 | 3 | 3 | 3 | 3 | 13 | | | |
| Concomitant Medication | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 6 | 1 | 1 | |
| IV Line insertion | 4 | | 4 | | | | | 4 | | | |
| IP/Placebo IV administration | 5 | | 5 | | | | | 5 | | | |
| NIHSS | 1 | 1 | 1 | | | | | 3 | | | |
| mRS | 1 | | | | 1 | 1 | 1 | 3 | 1 | 1 | |
| Blood draw for Central lab analysis (ADA) | 2 | 2 | | | | | 2 | 3 | | | |
| Lab handling/shipping of blood samples for ADA to Central lab | 1 | 1 | | | | | 1 | 2 | | | |
| EQ-SD-SI | 1 | | | | | | 1 | 1 | | | |
| 12-lead ECG: Includes tracing, interpretation and report | 4 | 4 | 4 | | | | | 7 | | | |
| Blood Pressure and Heart Rate | 1 | 1 | 10 | 7 | 1 | | 1 | 20 | | | |
| Blood draw for Local labs (Hematology, Coagulation, Biochemistry, Biological) | 1 | 1 | | 1 | 1 | | 1 | 3 | | | |
| Hematology, Complete Blood Count (CBC), Platelets (local lab) | 1 | 1 | | 1 | 1 | | 1 | 3 | | | |
| Coagulation: PT, aPTT, INR (local lab) | 2 | 2 | | 2 | | | | 4 | | | |
| Biochemistry: Serum creatinine (local lab) | 1 | 1 | | 1 | 1 | | 1 | 3 | | | |
| Biochemistry: GFR (local lab) | 1 | 1 | | 1 | 1 | | 1 | 3 | | | |
| Biochemistry: Serum glucose (local lab) | 1 | 1 | | 1 | | | 1 | 2 | | | |
| Biochemistry: Urea (at Baseline and Day 7 Urea will be only evaluated), ASAT, ALAT (local lab) | 1 | 0.5 | | 1 | 0.2 | | 1 | 4 | | | |
| Biochemistry: LDE (local lab) | 1 | | | 1 | | | 1 | 1 | | | |
| Biochemistry: Triglycerides (local lab) | 0 | | | 0.4 | | | 0 | 1 | | | |
| Biochemistry: Total Cholesterol (local lab) | 1 | | | 1 | | | 1 | 1 | | | |
| Biological markers: D-dimers with/without Fibrin degradation products (FDP) (l | 1 | 1 | | 1 | 1 | | 1 | 3 | | | |
| Biological markers: Fibrinogen (local lab) | 1 | 1 | | 1 | 1 | | 1 | 4 | | | |
| Adverse Event / SAE | 1 | 1 | | 1 | 1 | 1 | 1 | 7 | 1 | 1 | |
| Study Coordinator Fee (includes InRS (randomization & supply kit allocation), Post-stroke management information) | 3 | 3 | | 3 | 3 | 3 | 3 | 20 | 1 | 1 | |
| Data Entry Fee | 1 | 1 | | 1 | 1 | 1 | 1 | 8 | 0 | 0 | |
| Principal Investigator Fee | 6 | 6 | | 6 | 6 | | 6 | 24 | | | |
| Pharmacy Fee - Preparation/Dispensation of IP/Placebo | 2 | | 2 | | | | | 2 | | | |
| Subtotal: | | 42 | 22 | 37 | 21 | 10 | 10 | 29 | 172 | 4 | 4 |
| Overhead | 17% | 7.17 | 3.73 | 6.33 | 3.62 | 1.72 | 1.72 | 4.96 | 29.24 | 0.70 | 0.70 |
| | | 49.34 | 25.68 | 43.56 | 24.89 | 11.81 | 11.81 | 34.12 | 201.21 | 4.94 | 4.94 |
| | | 44.41 | 23.12 | 39.21 | 22.40 | 10.63 | 10.63 | 30.70 | 181.09 | 4.35 | 4.35 |
| | Payment at 90% 10% Withholding | 4.93 | 2.57 | 4.36 | 2.49 | 1.18 | 1.18 | 3.41 | 20.12 | 0.48 | 0.48 |

| INVOICEABLE ITEMS | COST | FREQUENCY |
|--|-------------|-------------------------|
| Serum Pregnancy Test | 31.59 | As Needed; per protocol |
| Urine Pregnancy Test | 19.89 | As Needed; per protocol |
| Blood Pressure and Heart Rate | 19.89 | As Needed; per protocol |
| Unscheduled Procedures/Visits (for safety, abnormal test results, and/or additional procedures/visits per Protocol will be paid per procedure(s) performed plus staff fees, overhead, and subject reimbursement) | Invoice | As Needed |

STUDY NURSE/ ŠTUDIJNÁ SESTRA
(Zalúbelová Silvia)

| PI: Hajas Site: SL02 | SLOVAKIA | | | | | | | | Item Total | Visit 4 | Visit 5 | | |
|---|-----------------------------------|----------|-----------------------------------|---------------------|-----------------------------|--------------------------|-----------------------|---------------|------------|---------|---------|------------------------|------------------------|
| | ITEM COST (EURO) | Visit 1 | | Visit 2 | Visit 3 | Visit 4 | Visit 5 | Visit 6 | | | | Day 30 Telemedicine | Day 60 Telemedicine |
| | | Day 1 | | Day 2 | Day 7 or on discharge | Day 30 At Hospital | Day 60 at Hospital | Day 90 EOS | | | | | |
| | | Baseline | Infusion (6 hr IV infusion) | 24 hours ± 3 hrs | ± 3 days | ± 3 days | ± 7 days | ± 7 days | | | | | |
| Procedures & Assessments | | | | | | | | | | | | | |
| Informed Consent | 3 | 3 | | | | | | | | | | | |
| Eligibility criteria | 3 | 3 | | | | | | | | | | | |
| Medical History with Demographics | 3 | 3 | | | | | | | | | | | |
| Clinical evaluation (at Screening) | 5 | 5 | | | | | | | | | | | |
| Clinical evaluation (all other visits) | 3 | | 3 | 3 | 3 | 3 | 3 | 3 | 13 | | | | |
| Concomitant Medication | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 6 | 1 | | | |
| IV Line insertion | 4 | | 4 | | | | | | 4 | | | | |
| IP/Placebo IV administration | 5 | | 5 | | | | | | 5 | | | | |
| NIHSS | 1 | 1 | 1 | 1 | | | | | 3 | 1 | | | |
| mRS | 1 | | | | | 1 | 1 | 1 | 3 | 1 | | | |
| Blood draw for Central lab analysis (ADA) | 2 | 2 | | | | | | 2 | 3 | | | | |
| Lab handling/shipping of blood samples for ADA to Central lab | 1 | 1 | | | | | | 1 | 2 | | | | |
| EQ-5D-5L | 1 | | | | | | | | 1 | | | | |
| 12-lead ECG: Includes tracing, interpretation and report | 4 | 4 | | 4 | | | | | 7 | | | | |
| Blood Pressure and Heart Rate | 1 | 1 | 10 | 7 | 1 | | | 1 | 20 | | | | |
| Blood draw for Local labs (Hematology, Coagulation, Biochemistry, Biological | 1 | 1 | | 1 | 1 | | | 1 | 3 | | | | |
| Hematology, Complete Blood Count (CBC), Platelets (local lab) | 1 | 1 | | 1 | 1 | | | 1 | 3 | | | | |
| Coagulation: PT, aPTT, INR (local lab) | 2 | 2 | | 2 | | | | | 4 | | | | |
| Biochemistry: Serum creatinine (local lab) | 1 | 1 | | 1 | 1 | | | 1 | 3 | | | | |
| Biochemistry: GFR (local lab) | 1 | 1 | | 1 | 1 | | | 1 | 3 | | | | |
| Biochemistry: Serum glucose (local lab) | 1 | 1 | | 1 | 1 | | | 1 | 2 | | | | |
| Biochemistry: Urea (at Baseline and Day 7 Urea will be only evaluated), | 1 | 0.5 | | 1 | 0.2 | | | 1 | 4 | | | | |
| ASAT, ALAT (local lab) | 1 | | | 1 | | | | 1 | 1 | | | | |
| Biochemistry: LDH (local lab) | 1 | | | 1 | | | | 0 | 1 | | | | |
| Biochemistry: Triglycerides (local lab) | 0 | | | 0.4 | | | | 0 | 1 | | | | |
| Biochemistry: Total Cholesterol (local lab) | 1 | | | 1 | | | | 1 | 1 | | | | |
| Biochemistry: Total Cholesterol (local lab) | 1 | 1 | | 1 | 1 | | | 1 | 3 | | | | |
| Biological markers: D-dimers with/without Fibrin degradation products (FDP) (| 1 | 1 | | 1 | 1 | | | 1 | 4 | | | | |
| Biological markers: Fibrinogen (local lab) | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 7 | 1 | | | |
| Adverse Event / SAE | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 7 | 1 | | | |
| Study Coordinator Fee [includes IxRS (randomization & supply kit allocation); | 3 | 3 | | 3 | 3 | 3 | 3 | 3 | 20 | 1 | | | |
| Post-stroke management information] | 1 | 1 | | 1 | 1 | 1 | 1 | 1 | 8 | 0 | | | |
| Data Entry Fee | 6 | 6 | | 6 | 6 | | | 6 | 24 | | | | |
| Principal Investigator Fee | 2 | 2 | | 2 | | | | 2 | 2 | | | | |
| Pharmacy Fee - Preparation/Dispensation of IP/Placebo | | | 2 | | | | | | 2 | | | | |
| Subtotal: | | 42 | 22 | 37 | 21 | 10 | 10 | 29 | 172 | 4 | | | |
| Overhead | 17% | 7.17 | 3.73 | 6.33 | 3.62 | 1.72 | 1.72 | 4.96 | 29.24 | 0.70 | | | |
| | | 49.34 | 25.68 | 43.56 | 24.89 | 11.81 | 11.81 | 34.12 | 201.21 | 4.84 | | | |
| | | 44.41 | 23.12 | 39.21 | 22.40 | 10.63 | 10.63 | 30.70 | 181.09 | 4.35 | | | |
| | Payment at 90% 10% Withholding | 4.93 | 2.57 | 4.36 | 2.49 | 1.18 | 1.18 | 3.41 | 20.12 | 0.48 | | | |

| INVOICABLE ITEMS | COST | FREQUENCY |
|--|---------|-------------------------|
| Serum Pregnancy Test | 31.59 | As Needed, per protocol |
| Urine Pregnancy Test | 19.89 | As Needed, per protocol |
| Blood Pressure and Heart Rate | 19.89 | As Needed, per protocol |
| Unscheduled Procedures/Visits (for safety, abnormal test results, and/or additional procedures/visits per Protocol will be paid per procedure(s) performed plus staff fees, overhead, and subject reimbursement) | Invoice | As Needed |