



AZIENDA SANITARIA LOCALE DI PESCARA
Via Renato Paolini, 47 – 65124 Pescara (PE)

**DELIBERAZIONE DEL DIRETTORE GENERALE
AZIENDA SANITARIA LOCALE DI PESCARA**

ANNO: 2026

N. 1720

Data 23/10/2026

**OGGETTO: DETERMINAZIONI: APPROVAZIONE EMENDAMENTO ALLA
CONVENZIONE STUDIO "TAK-339-3001" E MODIFICA E INTEGRAZIONE DELLA
DELIBERA N. 198 DEL 19.02.2026. SPERIMENTATORE PRINCIPALE DELLA ASL DI
PESCARA, DOTT. CARMINE LIBERATORE**

IL DIRETTORE GENERALE

OGGETTO: Determinazioni- Approvazione emendamento alla convenzione Studio “TAK-339-3001” e modifica e integrazione della Delibera n. 198 del 19.02.2026. Sperimentatore principale della Asl di Pescara, Dott. Carmine Liberatore

Letta la relazione del Direttore Sanitario Aziendale che qui si riporta integralmente;

Premesso che la ASL di Pescara e la ICON Clinical Research Limited, (CRO), che agisce in nome proprio ma con effetti vincolanti per Takeda Development Center Americas Inc (Promotore), hanno stipulato una Convenzione per l'esecuzione della Sperimentazione clinica profit denominata “TAK-339-3001”, autorizzata con atto deliberativo n° 198 del 19.02.2026;

Considerato che ICON Clinical Research Limited ha sottomesso al Comitato Etico Territoriale competente l'approvazione di un emendamento al contratto di che trattasi, autorizzato durante la seduta del 28.05.2026;

Vista la delibera n°1546 del giorno 11.10.2024 con cui la ASL di Pescara ha approvato il “Regolamento per la disciplina delle sperimentazioni cliniche e studi condotti presso la ASL di Pescara”;

Vista, altresì, la Delibera n. 1820 del 06.12.2024 che istituisce il Comitato Operativo Multidisciplinare Aziendale per le Sperimentazioni/Studi clinici della Asl di Pescara;

Atteso che le Parti intendono eliminare l'allegato A “Budget” autorizzato con atto deliberativo n° 198 del 19.02.2026 e sostituirlo con l'Allegato A-1/Annex A-1 contenuta nell'emendamento n. 1, che forma parte integrante e sostanziale del presente atto;

Considerato che il Comitato Operativo Multidisciplinare Aziendale per le Sperimentazioni/Studi Clinici della Asl di Pescara si è riunito in data 23.09.2026 e ha espresso parere favorevole di congruità sul nuovo budget proposto per lo studio “TAK-339-3001”, oggetto di emendamento;

Atteso che tutti gli altri termini e condizioni della citata convenzione continueranno ad essere in vigore a tutti gli effetti e sono confermati in tutti i loro aspetti;

Sentito il DPO aziendale per quanto di competenza;

Dato atto dell'attestazione resa dai competenti Responsabili in ordine alla regolarità amministrativo-contabile e tecnica del presente provvedimento:

1. Dirigente nella sua qualità di Direttore delle Attività Amministrative Ospedaliere e Territoriali;

Acquisito il parere tecnico favorevole in merito espresso dal Dirigente ai sensi della legge 7 agosto 1990 n. 241 e s.m.i. che ne attesta la regolarità e la completezza;

Acquisiti per quanto di competenza i pareri favorevoli espressi in merito dal Direttore Amministrativo Aziendale e dal Direttore Sanitario Aziendale;

D E L I B E R A

Per tutto quanto sopra indicato e che qui si intende integralmente richiamato

- 1) DI PRENDERE ATTO** che il Comitato Operativo Multidisciplinare per gli studi clinici della ASL di Pescara ha espresso parere favorevole di congruità sul nuovo budget proposto con l'emendamento n.1, a modifica sostanziale della convenzione per la Sperimentazione clinica "TAK-339-3001", autorizzata con atto deliberativo della Asl di Pescara n° 198 del 19.02.2026;
- 2) DI APPROVARE** l'Emendamento n.1 al budget proposto, che costituisce parte integrante e sostanziale del presente atto, autorizzandone per l'effetto la sottoscrizione;
- 3) DI PREVEDERE** che il finanziamento di cui sopra dovrà essere ripartito nella misura del 15% per il fondo aziendale per la ricerca, del 50% a favore delle UOC coinvolte nella sperimentazione e del 35% per costi generali, in applicazione dell'art. 8.3 "Ripartizione del Finanziamento Sperimentazioni Profit" del succitato Regolamento;
- 4) DI STABILIRE** che tale studio sarà svolto dal personale partecipante alla sperimentazione all'interno dell'orario di lavoro senza arrecare pregiudizio all'attività assistenziale che deve rimanere prevalente, come stabilito nel Regolamento all'art. 5.2 "Sperimentatore";
- 5) DI CONFERMARE** tutti gli altri termini e condizioni della convenzione tra la Asl di Pescara e la ICON Clinical Research Limited, (CRO), che agisce in nome proprio ma vincolando Takeda Development Center Americas Inc (Promotore), continueranno ad essere in vigore a tutti gli effetti e sono confermati in tutti i loro aspetti;
- 6) DI INVIARE** copia del presente atto al Direttore Sanitario Aziendale, alla UOC di Ematologia, al Direttore delle Attività Amministrative Ospedaliere e Territoriali, al Direttore Medico dei PP.OO., alla UOC Controllo di Gestione per quanto di rispettiva competenza;
- 7) DI DARE ATTO** che, ai sensi della l.r. 10/2022, decorsi i termini di pubblicazione di cui alla l. 69/2009, il presente provvedimento sarà soggetto a pubblicazione integrale;
- 8) DI PUBBLICARE** il presente provvedimento nell'albo pretorio online della Asl ai sensi del d. lgs. 33/2013.



**EMENDAMENTO N. 1 AL CONTRATTO PER
LA CONDUZIONE DELLA
SPERIMENTAZIONE CLINICA SU MEDICINALI**

Il presente emendamento n. 1 (di seguito l'“**Emendamento n. 1**”) viene sottoscritto alla data dell'ultima firma, ma le Parti (come definite a seguire) convengono di attribuire effetti retroattivi specificamente e solo alla modifica inclusa nell'Allegato A-1 e convengono che essa entri in vigore a decorrere dal 09 settembre 2026 (di seguito la “**Data di entrata in vigore**”), che corrisponde all'ultima approvazione normativa della modifica sostanziale 2 (di seguito “**SM-2**”) datata 21 maggio 2026

tra

ICON Clinical Research Limited,
un'organizzazione di sperimentazione clinica con sede operativa in South County Business Park, Leopardstown, Dublino 18, Irlanda (di seguito la “**CRO**”), che in virtù del mandato conferito l'11 marzo 2025 agisce in nome proprio ma con effetti vincolanti per **Takeda Development**

**AMENDMENT No. 1 TO AGREEMENT FOR
THE CONDUCT OF THE CLINICAL TRIAL
AGREEMENT ON MEDICINAL PRODUCTS**

This amendment No. 1 (hereinafter the “**Amendment No. 1**”) is executed on its last signature date but the Parties (as defined below) agree to give retrospective effects specifically and only to the change in Annex A-1 and agree that it enters into effect as of the 09 September 2026 (hereinafter the “**Effective Date**”), which corresponds to the latest regulatory approval of the substantial modification 2 (hereinafter “**SM-2**”) dated 21 May 2026

by and among

ICON Clinical Research Limited, a
clinical trial organization having a place of business at South County Business Park, Leopardstown, Dublin 18, Ireland (hereinafter the “**CRO**”), which by virtue of the mandate conferred on 11 March 2025 acts in its own name but binding **Takeda Development Center**



Center Americas, Inc., con sede legale in 500 Kendall Street, Cambridge, Massachusetts, 02142 Stati Uniti d'America (di seguito il **"Promotore"**)

Americas, Inc., headquartered in 500 Kendall Street, Cambridge, Massachusetts, 02142 United State of America (hereinafter the **"Sponsor"**)

E

AND

Azienda Sanitaria Locale di Pescara-Presidio Ospedaliero Santo Spirito (di seguito l'**"Ente"**), con sede legale in Via Renato Paolini n. 47, Pescara, Italia, Codice Fiscale e P. IVA n. 01397530682, in persona del legale rappresentante, Dott. Vero Michitelli, in qualità di Direttore Generale munito di idonei poteri di firma

Azienda Sanitaria Locale di Pescara-Presidio Ospedaliero Santo Spirito (hereinafter the **"Institution"**) headquartered in Via Renato Paolini n. 47, Pescara, Italy Tax Code and VAT no. 01397530682, acting through its legal representative Dr. Vero Michitelli, in his capacity as General Director with appropriate signing powers

Ai fini del presente Emendamento n. 1, la CRO e l'Ente possono essere indicati separatamente come **"Parte"** e collettivamente come **"Parti"**.

For purposes of this Amendment No. 1, the CRO and the Institution may be referred to as a **"Party"** and together as the **"Parties"**.

Il presente Emendamento n. 1 ha lo scopo di modificare il contratto per la conduzione della sperimentazione clinica sui medicinali tra le Parti, datato 10 marzo 2026 (di seguito la

This Amendment No. 1 is made for the purpose of amending the agreement for the conduct of the clinical investigation on medical products by and among the Parties, dated 10 March 2026



“Contratto”) relativa alla conduzione della (hereinafter the “**Agreement**”) relating to the ricerca clinica (di seguito la “**Sperimentazione**”) conduct of the clinical research (hereinafter the descritta nel protocollo intitolato “*Studio di fase 3, multicentrico, randomizzato, controllato, in aperto, a gruppi sequenziali, per studiare l’efficacia, la sicurezza e la tollerabilità di gammagard liquido per via endovenosa (infusione di immunoglobuline, 10%) per la profilassi delle infezioni primarie rispetto alla profilassi delle infezioni secondarie in soggetti adulti con mieloma multiplo in terapia con anticorpo bispecifico diretto contro l’antigene di maturazione delle cellule B e CD3*”, Protocollo n. “TAK-339-3001” (di seguito il “**Protocollo**”).

“**Trial**”) described in the protocol entitled “*A Multicenter, Randomized, Controlled, Open-label, Group-Sequential, Phase 3 Study to Investigate the Efficacy, Safety, and Tolerability of Intravenous Gammagard Liquid (Immune Globulin Infusion, 10%) for Primary Infection Prophylaxis Compared With Secondary Infection Prophylaxis in Adult Subjects With Multiple Myeloma Receiving B-Cell Maturation Antigen×CD3–Directed Bispecific Antibody Therapy*”, Protocol No. “TAK-339-3001” (hereinafter the “**Protocol**”).

Tutti i termini in maiuscolo qui inclusi avranno lo stesso significato indicato nel Contratto, salvo ivi diversamente definito.

All capitalized terms herein shall have the same meaning as in the Agreement, unless otherwise defined herein.

CONSIDERANDO che le Parti desiderano modificare il Contratto secondo i termini e le condizioni del presente Emendamento n. 1, a seguito della modifica sostanziale SM-2, datata 21 maggio 2026, che

WHEREAS, the Parties desire to amend the Agreement as per the terms and conditions of this Amendment No. 1, due to the substantial modification SM-2, dated 21 May 2026, which entails an update in the budget linked to Protocol



comporta un aggiornamento del bilancio amendment dated 11 December 2025 collegato alla modifica del Protocollo datata 11 (hereinafter “**PA2**”) and to Protocol amendment dicembre 2025 (di seguito “**PA2**”) e alla modifica dated 01 April 2026 (hereinafter “**PA3**”); del Protocollo datata 01 aprile 2026 (di seguito “**PA3**”);

CONSIDERANDO che PA2 e PA3 WHEREAS, PA2 and PA3 required the richiedevano l'attuazione degli aggiornamenti implementation of financial updates in Annex A-1 finanziari nell'Allegato A-1 del Contratto; of the Agreement;

PERTANTO, in considerazione dei NOW THEREFORE, in consideration of reciproci impegni e degli accordi qui contenuti, le the mutual covenants and agreements herein, Parti, nell'intento di essere legalmente vincolate, the Parties, intending to be legally bound, have hanno sottoscritto il presente Emendamento n. 1 entered into this Amendment No. 1 and do e concordano specificamente quanto segue: specifically agree as follows:

1. A seguito del PA2, datata 11 dicembre 2025, e del PA3, datata 01 aprile 2026, l'Allegato A-1 del Contratto viene soppresso e sostituito dall'Allegato A-1 rivisto accluso e incorporato per riferimento nel presente documento, che riflette le seguenti modifiche:
 - a. In relazione a PA2:
 - Inserimento della descrizione rivista
1. Due to PA2, dated 11 December 2025 and to PA3, dated 01 April 2026, Annex A-1 of the Agreement shall be deleted and replaced with the revised Annex A-1 attached hereto and incorporated by reference herein, reflective of the following changes:
 - a. In relation to PA2:
 - Insertion of the revised optional

dell'assegnazione facoltativa della coorte PK/PD per allinearla alla Sezione 1.3.3, Tabella 4.	PK/PD cohort allocation description to align with Section 1.3.3, Table 4.
b. In relazione a PA3: • aggiunta delle seguenti voci nella tabella delle tariffe fatturabili: - Elettroforesi delle proteine sieriche (SPEP); - Immunofissazione (IFE); - Catene leggere libere (FLC); - Immunoglobuline G totali (IgG); - Prestazioni di laboratorio centrale non programmate: prelievo, preparazione, manipolazione e/o trasporto del sangue; - Intervalli di riferimento di laboratorio - Configurazione iniziale per centro; e, - Gestione successiva degli intervalli di riferimento del laboratorio (per ora).	b. In relation to PA3: • addition of the following items in the table of the invoiceable fees: - Serum protein electrophoresis (SPEP); - Immunofixation electrophoresis (IFE); - Free light chain (FLC); - Total immunoglobulin G (IgG); - Unscheduled Central Laboratory: Blood draw, preparation, handling and/or transportation; - Lab Reference Ranges - Initial Set Up by Site; and, - Subsequent Maintenance of Lab Reference Ranges (per hour).
2. Tutti gli altri termini e condizioni del Contratto continueranno ad avere pieno vigore ed efficacia. In caso di conflitto tra	2. All other terms and conditions of the Agreement shall remain in full force and effect. In the event of any conflict



i termini del Contratto e i termini del presente Emendamento n. 1, prevarranno i termini del presente Emendamento n. 1.

between the terms of the Agreement and this Amendment No. 1 the terms of this Amendment No. 1 shall govern and control.

A CONFERMA DI QUANTO PRECEDE, le Parti, nell'intento di essere legalmente vincolate, hanno sottoscritto il presente Emendamento n. 1 tramite i propri rappresentanti debitamente autorizzati, con efficacia dalla Data di entrata in vigore.

IN WITNESS WHEREOF, the Parties hereto, intending to be legally bound, have executed this Amendment No. 1 by their duly authorized representatives as of the Effective Date.

Le Parti, a mezzo dei propri rappresentanti muniti dei necessari poteri, hanno firmato digitalmente il presente Emendamento n. 1 in conformità all'Art. 24 del Decreto legislativo 82/2005, in conformità alle disposizioni dell'Art. 15, comma 2-bis, della Legge 241/1990 come integrato dall'Art. 6, Decreto Legge 18 ottobre 2012, n. 179, convertito in Legge n. 22 del 17 dicembre 2012.

The Parties have, by their duly empowered representatives, digitally signed this Amendment No. 1 in accordance with Article 24 of Legislative Decree 82 /2005, in accordance with the provisions of Article 15 paragraph 2bis of Law 241/1990 as supplemented by Article 6, Decree Law 18 October 2012, no. 179, converted into Law no. 22 of 17 December 2012.

L'imposta di bollo è pagata elettronicamente da ICON Holdings Clinical Research International Limited – Italian Branch,

The stamp duty is paid electronically by ICON Holdings Clinical Research International Limited – Italian Branch, with registered office in



con sede legale in Via Benigno Crespi 19, 20159 Milano, Italia, consociata italiana della CRO, ai sensi dell'art. 15 del Decreto del Presidente della Repubblica (D.P.R.) 642 del 1972 (Autorizzazione dell'Agenzia delle Entrate di Milano registrata il 14 giugno 2023 sul Registro Ufficiale con il numero 203622).

Pagina delle firme a seguire

Signatures page follows



Per la CRO in nome proprio ma con effetti vincolanti per il Promotore / For the CRO on its own name but binding the Sponsor

Il procuratore delegato / The delegated attorney

Dott./Dr. Francesco Falcicchio

Firma digitale / Digital Signature _____

Per l'Ente / For the Institution

Il rappresentante legale o un suo delegato / The legal Representative or her/his delegate

Dott./ Dr. Vero Michitelli

Firma digitale / Digital Signature _____

Per conferma di presa visione delle disposizioni che lo/la riguardano: lo Sperimentatore Principale / For confirmation of having seen the provisions concerning him: the Principal Investigator

Dott./Dr. Carmine Liberatore

Firma digitale / Digital Signature _____



Allegato A-1/Annex A-1
Coorte 3 settimane, braccio1&2/3 weeks cohort, arm 1&2

Procedure	OH?	Quantity	Selected Cost	Within 8 weeks	Screening Visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
					D1	W1	W3	W6	W9	W12
						±3 d	±3 d	±3 d	±3 d	±3 d
Informed consent	Y	1	41.00	41.00						
Inclusion/exclusion criteria	Y	1	37.00	37.00						
Randomization	Y	1	48.00	48.00						
Response Assessment: Serum M Protein	Y	1	79.00	79.00						
Response Assessment: 24-hour Urine M Protein	Y	1	99.00	99.00						
Concomitant medications and procedures	Y	19	22.00	22.00	22.00	22.00	22.00	22.00	22.00	22.00
Adverse events	Y	19	25.00	25.00	25.00	25.00	25.00	25.00	25.00	25.00
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00	20.00	20.00					
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00	217.00						
Limited Physical exam including weight	Y	18	71.00		71.00	71.00	71.00	71.00	71.00	71.00
Vital Signs	Y	69	34.00		102.00	102.00	102.00	102.00	102.00	102.00
Study drug administration for treatment arm (IV Infusion)	Y	17	121.00		121.00	121.00	121.00	121.00	121.00	121.00
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EROTC Item Library	Y	19	17.00	17.00	17.00	17.00	17.00	17.00	17.00	17.00
Subject Reported Outcomes: EQ-5D-5L	Y	11	34.00	34.00	34.00		34.00			34.00
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	13.00	13.00	13.00	13.00	13.00	13.00	13.00	13.00
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	16.00	16.00	16.00	16.00	16.00	16.00	16.00	16.00
Procedures Sub Total					€ 668.00	€ 441.00	€ 387.00	€ 421.00	€ 387.00	€ 421.00



					Screening Visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
						W1	W3	W6	W9	W12
					D1	D21	D42	D63	D84	
Non-Procedure	OH?	Quantity	Selected Cost	Within 8 weeks	±3 d	±3 d	±3 d	±3 d	±3 d	
Study Coordinator	Y	19	86.00	120.40	86.00	86.00	86.00	86.00	86.00	
Physician Fee	Y	19	151.00	211.40	151.00	151.00	151.00	151.00	151.00	
Study Nurse	Y	19	124.00	310.00	124.00	124.00	124.00	124.00	124.00	
Laboratory Technician	Y	19	54.00	54.00	54.00	54.00	54.00	54.00	54.00	
Pharmacy Preparation & Dispensing	Y	17	47.00		47.00	47.00	47.00	47.00	47.00	
Data Entry	Y	19	33.00	33.00	33.00	33.00	33.00	33.00	33.00	
Non Procedures Sub Total				€ 728.80	€ 495.00	€ 495.00	€ 495.00	€ 495.00	€ 495.00	
Costs Charged with Overhead					€ 1,396.80	€ 936.00	€ 882.00	€ 916.00	€ 882.00	€ 916.00
Overhead at 18%					€ 251.42	€ 168.48	€ 158.76	€ 164.88	€ 158.76	€ 164.88
Selected Cost Per Visit					€ 1,648.22	€ 1,104.48	€ 1,040.76	€ 1,080.88	€ 1,040.76	€ 1,080.88



				Study Observation Period					
				Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11
				W15	W18	W21	W24	W27	W30
				D105	D126	D147	D168	D189	D210
Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	±3 d	±3 d	±3 d	±3 d
Informed consent	Y	1	41.00						
Inclusion/exclusion criteria	Y	1	37.00						
Randomization	Y	1	48.00						
Response Assessment: Serum M Protein	Y	1	79.00						
Response Assessment: 24-hour Urine M Protein	Y	1	99.00						
Concomitant medications and procedures	Y	19	22.00	22.00	22.00	22.00	22.00	22.00	22.00
Adverse events	Y	19	25.00	25.00	25.00	25.00	25.00	25.00	25.00
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00						
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00						
Limited Physical exam including weight	Y	18	71.00	71.00	71.00	71.00	71.00	71.00	71.00
Vital Signs	Y	69	34.00	102.00	102.00	102.00	102.00	102.00	102.00
Study drug administration for treatment arm (IV Infusion)	Y	17	121.00	121.00	121.00	121.00	121.00	121.00	121.00
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EORTC Item Library	Y	19	17.00	17.00	17.00	17.00	17.00	17.00	17.00
Subject Reported Outcomes: EQ-5D-5L	Y	11	34.00		34.00		34.00		34.00
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	13.00	13.00	13.00	13.00	13.00	13.00	13.00
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	16.00	16.00	16.00	16.00	16.00	16.00	16.00
Procedures Sub Total				€ 387.00	€ 421.00	€ 387.00	€ 421.00	€ 387.00	€ 421.00



				Study Observation Period					
				Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11
				W15	W18	W21	W24	W27	W30
				D105	D126	D147	D168	D189	D210
Non-Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	±3 d	±3 d	±3 d	±3 d
Study Coordinator	Y	19	86.00	86.00	86.00	86.00	86.00	86.00	86.00
Physician Fee	Y	19	151.00	151.00	151.00	151.00	151.00	151.00	151.00
Study Nurse	Y	19	124.00	124.00	124.00	124.00	124.00	124.00	124.00
Laboratory Technician	Y	19	54.00	54.00	54.00	54.00	54.00	54.00	54.00
Pharmacy Preparation & Dispensing	Y	17	47.00	47.00	47.00	47.00	47.00	47.00	47.00
Data Entry	Y	19	33.00	33.00	33.00	33.00	33.00	33.00	33.00
Non Procedures Sub Total				€ 495.00	€ 495.00	€ 495.00	€ 495.00	€ 495.00	€ 495.00
Costs Charged with Overhead				€ 882.00	€ 916.00	€ 882.00	€ 916.00	€ 882.00	€ 916.00
Overhead at 18%				€ 158.76	€ 164.88	€ 158.76	€ 164.88	€ 158.76	€ 164.88
Selected Cost Per Visit				€ 1,040.76	€ 1,080.88	€ 1,040.76	€ 1,080.88	€ 1,040.76	€ 1,080.88



Procedure	OH?	Quantity	Selected Cost	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16
				W33	W36	W39	W42	W45
				D231	D252	D273	D294	D315
				±3 d	±3 d	±3 d	±3 d	±3 d
Informed consent	Y	1	41.00					
Inclusion/exclusion criteria	Y	1	37.00					
Randomization	Y	1	48.00					
Response Assessment: Serum M Protein	Y	1	79.00					
Response Assessment: 24-hour Urine M Protein	Y	1	99.00					
Concomitant medications and procedures	Y	19	22.00	22.00	22.00	22.00	22.00	22.00
Adverse events	Y	19	25.00	25.00	25.00	25.00	25.00	25.00
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00					
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00					
Limited Physical exam including weight	Y	18	71.00	71.00	71.00	71.00	71.00	71.00
Vital Signs	Y	69	34.00	102.00	102.00	102.00	102.00	102.00
Study drug administration for treatment arm (IV Infusion)	Y	17	121.00	121.00	121.00	121.00	121.00	121.00
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EROTC Item Library	Y	19	17.00	17.00	17.00	17.00	17.00	17.00
Subject Reported Outcomes: EQ-5D-5L	Y	11	34.00		34.00		34.00	
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	13.00	13.00	13.00	13.00	13.00	13.00
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	16.00	16.00	16.00	16.00	16.00	16.00
Procedures Sub Total				€ 387.00	€ 421.00	€ 387.00	€ 421.00	€ 387.00



				Visit 12	Visit 13	Visit 14	Visit 15	Visit 16
				W33	W36	W39	W42	W45
				D231	D252	D273	D294	D315
Non-Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	±3 d	±3 d	±3 d
Study Coordinator	Y	19	86.00	86.00	86.00	86.00	86.00	86.00
Physician Fee	Y	19	151.00	151.00	151.00	151.00	151.00	151.00
Study Nurse	Y	19	124.00	124.00	124.00	124.00	124.00	124.00
Laboratory Technician	Y	19	54.00	54.00	54.00	54.00	54.00	54.00
Pharmacy Preparation & Dispensing	Y	17	47.00	47.00	47.00	47.00	47.00	47.00
Data Entry	Y	19	33.00	33.00	33.00	33.00	33.00	33.00
Non Procedures Sub Total				€ 495.00	€ 495.00	€ 495.00	€ 495.00	€ 495.00
Costs Charged with Overhead				€ 882.00	€ 916.00	€ 882.00	€ 916.00	€ 882.00
Overhead at 18%				€ 158.76	€ 164.88	€ 158.76	€ 164.88	€ 158.76
Selected Cost Per Visit				€ 1,040.76	€ 1,080.88	€ 1,040.76	€ 1,080.88	€ 1,040.76



				Visit 17 W48 D336	EOS/ET W51 D357	Unscheduled Visits (Invoiceable)
				±3 d	±3 d	
Procedure	OH?	Quantity	Selected Cost			
Informed consent	Y	1	41.00			
Inclusion/exclusion criteria	Y	1	37.00			
Randomization	Y	1	48.00			
Response Assessment: Serum M Protein	Y	1	79.00			
Response Assessment: 24-hour Urine M Protein	Y	1	99.00			
Concomitant medications and procedures	Y	19	22.00	22.00	22.00	
Adverse events	Y	19	25.00	25.00	25.00	
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00			
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00			
Limited Physical exam including weight	Y	18	71.00	71.00	71.00	
Vital Signs	Y	69	34.00	102.00	34.00	
Study drug administration for treatment arm (IV Infusion)	Y	17	121.00	121.00		
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EORTC Item Library	Y	19	17.00	17.00	17.00	
Subject Reported Outcomes: EQ-5D-5L	Y	11	34.00	34.00	34.00	
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	13.00	13.00	13.00	
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	19	16.00	16.00	16.00	
Procedures Sub Total				€ 421.00	€ 232.00	€ -



						Unscheduled Visits (Invoiceable)
				Visit 17	EOS/ET	
				W48	W51	
				D336	D357	
Non-Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	
Study Coordinator	Y	19	86.00	120.40	86.00	43.00
Physician Fee	Y	19	151.00	211.40	151.00	75.50
Study Nurse	Y	19	124.00	310.00	124.00	62.00
Laboratory Technician	Y	19	54.00	54.00	54.00	54.00
Pharmacy Preparation & Dispensing	Y	17	47.00	47.00		
Data Entry	Y	19	33.00	33.00	33.00	16.50
Non Procedures Sub Total				€ 775.80	€ 448.00	€ 251.00
Costs Charged with Overhead				€ 1,196.80	€ 680.00	€ 251.00
Overhead at 18%				€ 215.42	€ 122.40	€ 45.18
Selected Cost Per Visit				€ 1,412.22	€ 802.40	€ 296.18

Total Cost Per Subject	€ 20,859.57
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Invoiceable Fees (inclusive of Overhead)*	Payment Terms	Payment Frequency	Selected Cost	Selected Cost w/Overhead	Total Selected Cost*
Urine Hemosiderin (if performed locally)	Invoice	Per Occurrence	€ 37.00	€ 44.00	€ 44.00
Serum protein electrophoresis (SPEP)	Invoice	Per Occurrence	€ 37.00	€ 44.00	€ 44.00
Immunofixation electrophoresis (IFE)	Invoice	Per Occurrence	€ 66.00	€ 78.00	€ 78.00
Free light chain (FLC)	Invoice	Per Occurrence	€ 50.00	€ 59.00	€ 59.00
Total immunoglobulin G (IgG)	Invoice	Per Occurrence	€ 29.00	€ 34.00	€ 34.00
Unscheduled Central Laboratory: Blood draw, preparation, handling and/or transportation	Invoice	Per Occurrence	€ 29.00	€ 34.00	€ 34.00
Response Assessment: Serum M Protein	Invoice	3	€ 79.00	€ 93.00	€ 279.00
Response Assessment: 24-hour Urine M Protein	Invoice	3	€ 99.00	€ 117.00	€ 351.00
Follow-up contact after infusion (3-5 days after completion of infusion)	Invoice	17	€ 27.00	€ 32.00	€ 544.00
Hospitalization (per night) (must be study related and not considered SOC)	Invoice	Per Occurrence	€ 223.00	€ 263.00	€ 263.00
Outpatient admission (must be study related and not considered SOC)	Invoice	Per Occurrence	€ 106.00	€ 125.00	€ 125.00
Tedistamab weekly administration (Subcutaneous Injection)	Invoice	Per Occurrence	€ 38.00	€ 45.00	€ 45.00
Tedistamab Pharmacy Preparation & Dispensing	Invoice	Per Occurrence	€ 47.00	€ 55.00	€ 55.00
Dry Ice, Per Shipment	Invoice	Per Occurrence	€ 18.00	€ 21.00	€ 21.00
Optional PK/PD Sampling: Specific antibodies, Total IgG, IgG subclasses, SPEP/IFE Inclusive of Central Laboratory: Blood Draw, Preparation, Handling and/or transportation, Lab Tech and Data Entry Arms 1 & 2, Cohort 1: optional visits 1, 4, 5, 8 Arms 1 & 2, Cohort 2: optional visits 2, 3, 6, 7	Invoice	Per Occurrence	€ 116.00	€ 137.00	€ 137.00
Lab Reference Ranges - Initial Set Up by Site	Invoice	Per Occurrence	€ 33.00	€ 39.00	€ 39.00
Subsequent Maintenance of Lab Reference Ranges (per hour)	Invoice	Per Occurrence	€ 33.00	€ 39.00	€ 39.00

Subjects who discontinue Tedistamab should complete all assessments per the SoA, with the exception of the healthcare resource utilization and patient-reported outcomes assessments



Invoiceable Fees (inclusive of Overhead)*	Payment Terms	Payment Frequency	Selected Cost	Selected Cost w/Overhead	Total Selected Cost*
<u>Optional Reimbursement fees if site/subject opt out of using the 3rd party vendor</u>					
Transportation Reimbursement (Ride share or Public transportation per 50-mile/80-km transfer)	Invoice	Per Occurrence	up to 230.00	up to 230.00	INV
Transportation Reimbursement (Sedan & Airport per 50-mile/80-km transfer)	Invoice	Per Occurrence	up to 248.00	up to 248.00	INV
Mileage Reimbursement (Reasonable mileage costs up to one-hundred (100) miles/one hundred twenty (160) kilometers round-trip, per study visit)	Invoice	Per Occurrence	up to 54.00	up to 54.00	INV
Parking/Tolls (per Visit Day)	Invoice	Per Occurrence	up to 18.00	up to 18.00	INV
Meals (per Day- 3x)	Invoice	Per Occurrence	up to 55.00	up to 55.00	INV
Domestic Air: Economy (per Roundtrip) Requires Prior Sponsor Approval	Invoice	Per Occurrence	up to 413.00	up to 413.00	INV
Regional Train (per Roundtrip) Requires Prior Sponsor Approval	Invoice	Per Occurrence	up to 253.00	up to 253.00	INV
Hotel (per night) Requires Prior Sponsor Approval	Invoice	Per Occurrence	up to 184.00	up to 184.00	INV



Coorte 4 settimane, braccio 1&2/4 weeks cohort, arm 1&2

Procedure	OH?	Quantity	Selected Cost	Within 8 weeks				
					Screening Visit	Visit 1	Visit 2	Visit 3
						W1	W4	W8
						D1	D28	D56
						±3 d	±3 d	±3 d
Informed consent	Y	1	41.00	41.00				
Inclusion/exclusion criteria	Y	1	37.00	37.00				
Randomization	Y	1	48.00	48.00				
Response Assessment: Serum M Protein	Y	1	79.00	79.00				
Response Assessment: 24-hour Urine M Protein	Y	1	99.00	99.00				
Concomitant medications and procedures	Y	15	22.00	22.00	22.00	22.00	22.00	22.00
Adverse events	Y	15	25.00	25.00	25.00	25.00	25.00	25.00
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00	20.00	20.00			
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00	217.00				
Limited Physical exam including weight	Y	14	71.00		71.00	71.00	71.00	71.00
Vital Signs	Y	40	34.00		102.00	102.00	102.00	102.00
Study drug administration for treatment arm (IV Infusion)	Y	13	121.00		121.00	121.00	121.00	121.00
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EORTC Item Library	Y	15	17.00	17.00	17.00	17.00	17.00	17.00
Subject Reported Outcomes: EQ-5D-5L	Y	9	34.00	34.00	34.00		34.00	
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	13.00	13.00	13.00	13.00	13.00	13.00
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	16.00	16.00	16.00	16.00	16.00	16.00
Procedures Sub Total				€ 668.00	€ 441.00	€ 387.00	€ 421.00	€ 387.00



					Screening Visit	Visit 1	Visit 2	Visit 3	Visit 4
						W1	W4	W8	W12
					D1	D28	D56	D84	
Non-Procedure	OH?	Quantity	Selected Cost	Within 8 weeks	±3 d	±3 d	±3 d	±3 d	
Study Coordinator	Y	15	86.00	120.40	86.00	86.00	86.00	86.00	
Physician Fee	Y	15	151.00	211.40	151.00	151.00	151.00	151.00	
Study Nurse	Y	15	124.00	310.00	124.00	124.00	124.00	124.00	
Laboratory Technician	Y	15	54.00	54.00	54.00	54.00	54.00	54.00	
Pharmacy Preparation & Dispensing	Y	13	47.00		47.00	47.00	47.00	47.00	
Data Entry	Y	15	33.00	33.00	33.00	33.00	33.00	33.00	
Non Procedures Sub Total				€ 728.80	€ 495.00	€ 495.00	€ 495.00	€ 495.00	
Costs Charged with Overhead					€ 1,396.80	€ 936.00	€ 882.00	€ 916.00	€ 882.00
Overhead at 18%					€ 251.42	€ 168.48	€ 158.76	€ 164.88	€ 158.76
Selected Cost Per Visit					€ 1,648.22	€ 1,104.48	€ 1,040.76	€ 1,080.88	€ 1,040.76



				Study Observation Period			
				Visit 5	Visit 6	Visit 7	Visit 8
				W16	W20	W24	W28
				D112	D140	D168	D196
Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	±3 d	±3 d
Informed consent	Y	1	41.00				
Inclusion/exclusion criteria	Y	1	37.00				
Randomization	Y	1	48.00				
Response Assessment: Serum M Protein	Y	1	79.00				
Response Assessment: 24-hour Urine M Protein	Y	1	99.00				
Concomitant medications and procedures	Y	15	22.00	22.00	22.00	22.00	22.00
Adverse events	Y	15	25.00	25.00	25.00	25.00	25.00
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00				
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00				
Limited Physical exam including weight	Y	14	71.00	71.00	71.00	71.00	71.00
Vital Signs	Y	40	34.00	102.00	102.00	102.00	102.00
Study drug administration for treatment arm (IV Infusion)	Y	13	121.00	121.00	121.00	121.00	121.00
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EROTC Item Library	Y	15	17.00	17.00	17.00	17.00	17.00
Subject Reported Outcomes: EQ-5D-5L	Y	9	34.00	34.00		34.00	
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	13.00	13.00	13.00	13.00	13.00
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	16.00	16.00	16.00	16.00	16.00
Procedures Sub Total				€ 421.00	€ 387.00	€ 421.00	€ 387.00



				Study Observation Period			
				Visit 5	Visit 6	Visit 7	Visit 8
				W16	W20	W24	W28
				D112	D140	D168	D196
Non-Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	±3 d	±3 d
Study Coordinator	Y	15	86.00	86.00	86.00	86.00	86.00
Physician Fee	Y	15	151.00	151.00	151.00	151.00	151.00
Study Nurse	Y	15	124.00	124.00	124.00	124.00	124.00
Laboratory Technician	Y	15	54.00	54.00	54.00	54.00	54.00
Pharmacy Preparation & Dispensing	Y	13	47.00	47.00	47.00	47.00	47.00
Data Entry	Y	15	33.00	33.00	33.00	33.00	33.00
Non Procedures Sub Total				€ 495.00	€ 495.00	€ 495.00	€ 495.00
Costs Charged with Overhead				€ 916.00	€ 882.00	€ 916.00	€ 882.00
Overhead at 18%				€ 164.88	€ 158.76	€ 164.88	€ 158.76
Selected Cost Per Visit				€ 1,080.88	€ 1,040.76	€ 1,080.88	€ 1,040.76



				Visit 9	Visit 10	Visit 11	Visit 12
				W32	W36	W40	W44
				D224	D252	D280	D308
Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	±3 d	±3 d
Informed consent	Y	1	41.00				
Inclusion/exclusion criteria	Y	1	37.00				
Randomization	Y	1	48.00				
Response Assessment: Serum M Protein	Y	1	79.00				
Response Assessment: 24-hour Urine M Protein	Y	1	99.00				
Concomitant medications and procedures	Y	15	22.00	22.00	22.00	22.00	22.00
Adverse events	Y	15	25.00	25.00	25.00	25.00	25.00
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00				
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00				
Limited Physical exam including weight	Y	14	71.00	71.00	71.00	71.00	71.00
Vital Signs	Y	40	34.00	102.00	102.00	102.00	102.00
Study drug administration for treatment arm (IV Infusion)	Y	13	121.00	121.00	121.00	121.00	121.00
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EROTC Item Library	Y	15	17.00	17.00	17.00	17.00	17.00
Subject Reported Outcomes: EQ-5D-5L	Y	9	34.00	34.00		34.00	
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	13.00	13.00	13.00	13.00	13.00
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if positive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	16.00	16.00	16.00	16.00	16.00
Procedures Sub Total				€ 421.00	€ 387.00	€ 421.00	€ 387.00



				Visit 9	Visit 10	Visit 11	Visit 12
				W32	W36	W40	W44
				D224	D252	D280	D308
Non-Procedure	OH?	Quantity	Selected Cost	£ d	£ d	£ d	£ d
Study Coordinator	Y	15	86.00	86.00	86.00	86.00	86.00
Physician Fee	Y	15	151.00	151.00	151.00	151.00	151.00
Study Nurse	Y	15	124.00	124.00	124.00	124.00	124.00
Laboratory Technician	Y	15	54.00	54.00	54.00	54.00	54.00
Pharmacy Preparation & Dispensing	Y	13	47.00	47.00	47.00	47.00	47.00
Data Entry	Y	15	33.00	33.00	33.00	33.00	33.00
Non Procedures Sub Total				€ 495.00	€ 495.00	€ 495.00	€ 495.00
Costs Charged with Overhead				€ 916.00	€ 882.00	€ 916.00	€ 882.00
Overhead at 18%				€ 164.88	€ 158.76	€ 164.88	€ 158.76
Selected Cost Per Visit				€ 1,080.88	€ 1,040.76	€ 1,080.88	€ 1,040.76



						Unscheduled Visits (Invoiceable)
				Visit 13	EOS/ET	
				W48	W52	
				D336	D364	
Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	
Informed consent	Y	1	41.00			
Inclusion/exclusion criteria	Y	1	37.00			
Randomization	Y	1	48.00			
Response Assessment: Serum M Protein	Y	1	79.00			
Response Assessment: 24-hour Urine M Protein	Y	1	99.00			
Concomitant medications and procedures	Y	15	22.00	22.00	22.00	
Adverse events	Y	15	25.00	25.00	25.00	
ECOG PS (Eastern Cooperative Oncology Group Performance Status)	Y	2	20.00			
Initial comprehensive Physical exam including medical history, demographics, concurrent medical conditions, height, weight, BMI, and vital signs	Y	1	217.00			
Limited Physical exam including weight	Y	14	71.00	71.00	71.00	
Vital Signs	Y	40	34.00	102.00	34.00	
Study drug administration for treatment arm (IV Infusion)	Y	13	121.00	121.00		
Subject Reported Outcomes: EORTC QLQ-C30 and additional items from EROTC Item Library	Y	15	17.00	17.00	17.00	
Subject Reported Outcomes: EQ-5D-5L	Y	9	34.00	34.00	34.00	
Central Laboratory: Blood draw and preparation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if postitive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	13.00	13.00	13.00	
Central Laboratory: Handling and/or transportation: Chemistry panel, Hematology panel, Hemolysis (hemoglobin, LDH, serum haptoglobin, plasma free unbound hemoglobin, serum direct antiglobulin (direct Coombs test; if postitive, repeat direct Coombs test), number and percentage of reticulocytes and urine hemosiderin if performed centrally), Viral pathogen evaluation, IgA, IgM, Serum pregnancy test, Urinalysis, Serum retention samples and PK and PD: Specific IgG antibody levels, total IgG level and IgG subclass (IgG1, IgG2, IgG3 and IgG4) levels	Y	15	16.00	16.00	16.00	
Procedures Sub Total				€ 421.00	€ 232.00	€ -



				Visit 13	EOS/ET	Unscheduled Visits (Invoiceable)
				W48	W52	
				D336	D364	
Non-Procedure	OH?	Quantity	Selected Cost	±3 d	±3 d	
Study Coordinator	Y	15	86.00	86.00	86.00	43.00
Physician Fee	Y	15	151.00	151.00	151.00	75.50
Study Nurse	Y	15	124.00	124.00	124.00	62.00
Laboratory Technician	Y	15	54.00	54.00	54.00	54.00
Pharmacy Preparation & Dispensing	Y	13	47.00	47.00		
Data Entry	Y	15	33.00	33.00	33.00	16.50
Non Procedures Sub Total				€ 495.00	€ 448.00	€ 251.00
Costs Charged with Overhead				€ 916.00	€ 680.00	€ 251.00
Overhead at 18%				€ 164.88	€ 122.40	€ 45.18
Selected Cost Per Visit				€ 1,080.88	€ 802.40	€ 296.18
Total Cost Per Subject				€ 16,284.94		



Invoiceable Fees (inclusive of Overhead)*	Payment Terms	Payment Frequency	Selected Cost	Selected Cost w/Overhead	Total Selected Cost*
Urine Hemosiderin (if performed locally)	Invoice	Per Occurrence	€ 37.00	€ 44.00	€ 44.00
Serum protein electrophoresis (SPEP)	Invoice	Per Occurrence	€ 37.00	€ 44.00	€ 44.00
Immunofixation electrophoresis (IFE)	Invoice	Per Occurrence	€ 66.00	€ 78.00	€ 78.00
Free light chain (FLC)	Invoice	Per Occurrence	€ 50.00	€ 59.00	€ 59.00
Total immunoglobulin G (IgG)	Invoice	Per Occurrence	€ 29.00	€ 34.00	€ 34.00
Unscheduled Central Laboratory: Blood draw, preparation, handling and/or transportation	Invoice	Per Occurrence	€ 29.00	€ 34.00	€ 34.00
Response Assessment: Serum M Protein	Invoice	3	€ 79.00	€ 93.00	€ 279.00
Response Assessment: 24-hour Urine M Protein	Invoice	3	€ 99.00	€ 117.00	€ 351.00
Follow-up contact after infusion (3-5 days after completion of infusion)	Invoice	13	€ 27.00	€ 32.00	€ 416.00
Hospitalization (per night) (must be study related and not considered SOC)	Invoice	Per Occurrence	€ 223.00	€ 263.00	€ 263.00
Outpatient admission (must be study related and not considered SOC)	Invoice	Per Occurrence	€ 106.00	€ 125.00	€ 125.00
Tedistamab weekly administration (Subcutaneous Injection)	Invoice	Per Occurrence	€ 38.00	€ 45.00	€ 45.00
Tedistamab Pharmacy Preparation & Dispensing	Invoice	Per Occurrence	€ 47.00	€ 55.00	€ 55.00
Dry Ice, Per Shipment	Invoice	Per Occurrence	€ 18.00	€ 21.00	€ 21.00
Optional PK/PD Sampling: Specific antibodies, Total IgG, IgG subclasses, SPEP/IFE Inclusive of Central Laboratory: Blood Draw, Preparation, Handling and/or transportation, Lab Tech and Data Entry Arms 1 & 2, Cohort 1: optional visits 1, 3, 5, 7 Arms 1 & 2, Cohort 1: optional visits 2, 4, 6, 8	Invoice	Per Occurrence	€ 116.00	€ 137.00	€ 137.00
Lab Reference Ranges - Initial Set Up by Site	Invoice	Per Occurrence	€ 33.00	€ 39.00	€ 39.00
Subsequent Maintenance of Lab Reference Ranges (per hour)	Invoice	Per Occurrence	€ 33.00	€ 39.00	€ 39.00

Subjects who discontinue Tedistamab should complete all assessments per the SoA, with the exception of the healthcare resource utilization and patient-reported outcomes assessments



Invoiceable Fees (inclusive of Overhead)*	Payment Terms	Payment Frequency	Selected Cost	Selected Cost w/Overhead	Total Selected Cost*
<u>Optional Reimbursement fees if site/subject opt out of using the 3rd party vendor</u>					
Transportation Reimbursement (Ride share or Public transporation per 50-mile/80-km transfer)	Invoice	Per Occurrence	up to 230.00	up to 230.00	INV
Transportation Reimbursement (Sedan & Airport per 50-mile/80-km transfer)	Invoice	Per Occurrence	up to 248.00	up to 248.00	INV
Mileage Reimbursement (Reasonable mileage costs up to one-hundred (100) miles/one hundred twenty (160) kilometers round-trip, per study visit)	Invoice	Per Occurrence	up to 54.00	up to 54.00	INV
Parking/Tolls (Per Visit Day)	Invoice	Per Occurrence	up to 18.00	up to 18.00	INV
Meals (Per Day- 3x)	Invoice	Per Occurrence	up to 55.00	up to 55.00	INV
Domestic Air: Economy (per Roundtrip) Requires Prior Sponsor Approval	Invoice	Per Occurrence	up to 413.00	up to 413.00	INV
Regional Train (per Roundtrip) Requires Prior Sponsor Approval	Invoice	Per Occurrence	up to 253.00	up to 253.00	INV
Hotel (per night) Requires Prior Sponsor Approval	Invoice	Per Occurrence	up to 184.00	up to 184.00	INV



TRIAL SITE COSTS

Start-Up Fees (One-time fee inclusive of Overhead)	Payment Terms	Payment Frequency	Selected Cost	Selected Cost w/Overhead	Total Selected Cost
Site Start-Up Costs	Invoice	1	€ 1,658.00	€ 1,658.00	€ 1,658.00
Pharmacy set-up fee	Invoice	1	€ 827.00	€ 827.00	€ 827.00
Lab set-up fee	Invoice	1	€ 533.00	€ 533.00	€ 533.00
Close-Out Fees (One-time fee inclusive of Overhead)	Payment Terms	Payment Frequency	Selected Cost	Selected Cost w/Overhead	Total Selected Cost
Study Close-out fee	Completion of Close-Out visit Invoice	1	€ 877.00	€ 877.00	€ 877.00
Pharmacy Close-out fee	Completion of Close-Out visit Invoice	1	€ 321.00	€ 321.00	€ 321.00
Archiving/Document storage	Completion of Close-Out visit Invoice	1	€ 967.00	€ 967.00	€ 967.00
Other Site Fees (inclusive of Overhead)	Payment Terms	Payment Frequency	Selected Cost	Selected Cost w/Overhead	Total Selected Cost
Subject Reconsent	Invoice	Per Occurrence	€ 37.00	€ 37.00	€ 37.00
Chart Review fee (per report)	Invoice	6	€ 45.00	€ 45.00	€ 270.00

Il Dirigente Amministrativo, con la presente sottoscrizione, attesta la regolarità tecnica e amministrativa nonché la legittimità del provvedimento

Il Dirigente Amministrativo

Federico De Nicola

firmato digitalmente

Il Direttore dell'UOC Controllo di Gestione attesta che la spesa risulta corrispondente al bilancio di previsione dell'anno corrente.

Il Direttore

firmato digitalmente

Il Direttore dell'UOC Bilancio e Gestione Economica Finanziaria attesta che la spesa risulta imputata sulla voce di conto del Bilancio n.

Anno

Il Direttore

firmato digitalmente

Ai sensi del D. Lgs. 502/92 e successive modificazioni ed integrazioni, i sottoscritti esprimono il seguente parere sul presente provvedimento:

Parere favorevole

IL DIRETTORE AMMINISTRATIVO

Dott. Francesca Rancitelli

firmato digitalmente

Parere favorevole

IL DIRETTORE SANITARIO

Dott. Rossano Di Luzio

firmato digitalmente

IL DIRETTORE GENERALE

Dott. Vero Michitelli

firmato digitalmente

Deliberazione n. 1720 del 23/10/2026 ad oggetto:

DETERMINAZIONI: APPROVAZIONE EMENDAMENTO ALLA CONVENZIONE STUDIO "TAK-339-3001" E MODIFICA E INTEGRAZIONE DELLA DELIBERA N. 198 DEL 19.02.2026. SPERIMENTATORE PRINCIPALE DELLA ASL DI PESCARA, DOTT. CARMINE LIBERATORE

CERTIFICATO DI PUBBLICAZIONE

- Si attesta che il presente atto viene pubblicato, in forma integrale, all'ALBO ON LINE dell'ASL di Pescara (art. 32 L. 69/09 e s.m.i.), in data 26/10/2026 per un periodo non inferiore a 15 giorni consecutivi.

Atto soggetto al controllo della Regione (art. 4, co. 8 L. 412/91): NO

Il Funzionario Incaricato