ADDENDUM N.1 AL CONTRATTO DI SPERIMENTAZIONE CLINICA	**CLINICAL TRIAL AGREEMENT ADDENDUM NO. 1**
Il presente addendum al contratto di sperimentazione clinica ("**Addendum n. 1**") viene stipulato da e tra:	This Clinical Trial Agreement Addendum ("**Addendum 1**") is by and between:
Immunocore Limited con sede principale al 92 Park Drive, Milton Park - Abingdon, Oxfordshire OX14 4RY, Regno Unito ("**Promotore**"),	Immunocore Limited with its principal place of business at 92 Park Drive, Milton Park - Abingdon, Oxfordshire OX14 4RY, United Kingdom ("**Sponsor**"),
e	and
IRCCS Istituto Nazionale Tumori "Fondazione Giovanni Pascale", con sede e domicilio legale in Via M. Semmola – 80131 Napoli (C.F. e P.IVA 00911350635), rappresentato dal Dott. Maurizio Di Mauro, in qualità di Commissario Straordinario in virtù dei poteri conferitigli con Decreto del Presidente della Giunta Regionale Campania n. 521 dell'11.10.2024, che autorizza alla firma del presente contratto il Direttore Scientifico Dott. Alfredo Budillon, giusta delega n. 854/2018; ("**Ente**"),	IRCCS Istituto Nazionale Tumori "Fondazione Giovanni Pascale", with its registered office and domicile Via M. Semmola – 80131 Naples, (Fiscal code. and VAT no. 00911350635), represented by Dr. Maurizio Di Mauro, in his capacity as Extraordinary Commissioner by virtue of the powers conferred on him by Decree of the President of the Campania Regional Council no. 521 of 11.10.2024, who authorises the Scientific Director Dr. Alfredo Budillon to sign this contract, pursuant to delegation no. 854/2018 ("**Institution**"),
Definiti singolarmente "**Parte**" e collettivamente "**Parti**"	each a **"Party"** and collectively **"the Parties."**
Premesso che	**Whereas**
A. Le Parti hanno stipulato un contratto di sperimentazione clinica datato 15 Aprile 2024 ("**Contratto**") per la conduzione di uno studio di ricerca medica (lo "**Studio**") su IMC-F106C ("**Farmaco in studio**") ai sensi del protocollo del Promotore intitolato "Studio randomizzato e controllato di fase 3 di IMC-F106C più Nivolumab rispetto a regimi di Nivolumab in partecipanti positivi a HLA A*02:01 con melanoma avanzato non trattato in precedenza (PRISM-MEL-301)", con numero di protocollo IMC-F106C-301 ("**Protocollo**");	A. The Parties have entered into a Clinical Trial Agreement dated 15 April 2024 ("**Agreement**") to conduct a medical research study (the "**Study**") of IMC-F106C ("**Study Drug**") under the Sponsor protocol entitled "A Phase 3 Randomized, Controlled Study of IMC-F106C Plus Nivolumab Versus Nivolumab Regimens in HLA-A*02:01-Positive Participants With Previously Untreated Advanced Melanoma (PRISM-MEL-301)" – Protocol Number IMC-F106C-301 ("**Protocol**");

B. Le Parti convengono di modificare il Contratto come indicato nel presente Addendum 1; e	B. The Parties agree to amend the Agreement as set out in this Addendum 1; and
C. Il Promotore ha autorizzato Worldwide Clinical Trials Limited, Fourth Floor, East West, Tollhouse Hill, Nottingham, NG1 5FS Regno Unito, codice fiscale e partita IVA n. GB 945 7590 79 ("**Worldwide /CRO**"), ai sensi di un accordo scritto, a coordinare e eseguire determinate attività autorizzate dal Promotore, incluse, a titolo esemplificativo, la negoziazione e l'esecuzione delle modifiche dell'accordo di sperimentazione clinica.	C. Sponsor has authorized Worldwide Clinical Trials Limited, Fourth Floor, East West, Tollhouse Hill, Nottingham, NG1 5FS UK VAT Reg No: GB 945 7590 79 and its affiliates ("**Worldwide/CRO**"), 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.
D. Il Promotore/CRO ha richiesto ed ottenuto l'approvazione del Protocollo V7.0 datato 12 Agosto 2024, in data 10 Febbraio 2025 da AIFA e in data 20 Novembre 2024 dal Comitato Etico Territoriale.	D. The Sponsor/CRO requested and obtained the approval of the Protocol 7.0 dated 12 August 2024, on 10 February 2025 from AIFA and on 20 November 2024 from the Territorial Ethics Committee.
1. Definizioni	**1. Definition**
1.1. I termini in maiuscolo non altrimenti definiti nel presente Addendum o in precedenti addendum scritti, se del caso, avranno il significato loro attribuito nel Contratto.	1.1. Capitalized terms not otherwise defined in this Addendum or any prior written addendum(s) as applicable will have the meanings ascribed to them in the Agreement.
2. Emendamenti	**2. Amendments**
2.1. Il Contratto viene emendato come segue a decorrere dalla data di approvazione del Protocollo v7.0 ("**Data di decorrenza**"):	2.1. The Agreement is amended as follows with effect from the date of approval of the Protocol v7.0 ("**Effective Date**"):
2.1.1. L'Art. 4.9 - PRODOTTO IN SPERIMENTAZIONE - dell'Allegato C viene eliminato nella sua interezza e sostituito dall'art. 4.9 riformulato come segue: IMC-F106C sarà fornito all'Ente gratuitamente in conformità con il Protocollo.	2.1.1. The Art. 4.9 - INVESTIGATIONAL PRODUCT Annex C is hereby deleted in its entirety and replaced by art. 4.9 to read as follows: IMC-F106C will be provided to Institution free of cost in accordance with the Protocol.

Anche Nivolumab (Opdivo) sarà fornito all'Ente gratuitamente in conformità con il Protocollo.	Nivolumab (Opdivo) will also be provided to the Institution free of cost in accordance with the Protocol.
2.1.2. Art. 5.1 del Contratto viene eliminato nella sua interezza e sostituito dall'art. 5.1 riformulato come segue: Il Promotore concede in comodato d'uso gratuito all'Ente, che accetta ai sensi e per gli effetti degli artt. 1803 e ss. c.c., lo/gli Strumento/i meglio descritti in appresso, unitamente al pertinente materiale d'uso (di seguito cumulativamente lo "Strumento"): – Dispositivo: Apple, iPad 6a Gen (A1954) Valore approssimativo € 509 EUR – 1 Digital Camera Kodak, Pixpro WPZ2 / 4767233 – 9427 + SD, valore approssimativo € 260,00. La proprietà dello Strumento, come per legge, non viene trasferita all'Ente. Gli effetti del presente comodato decorreranno dalla data di consegna dello/gli Strumento/i e cesseranno al termine della Sperimentazione, quando lo/gli Strumento/i dovrà/anno essere restituito/i al Promotore senza costi a carico dell'Ente. Le Parti concordano altresì che gli eventuali ulteriori Strumenti ritenuti necessari alla conduzione dello studio nel corso della Sperimentazione, qualora ne ricorrano le caratteristiche e le condizioni, saranno concessi in comodato d'uso gratuito secondo la disciplina di cui al presente Contratto. L'Ente e il Promotore procederanno con una convenzione specifica ovvero con un addendum/emendamento al Contratto, sul comodato qualora gli Strumenti vengano forniti dopo la stipula del presente Contratto.	2.1.2. The 5.1 - of the Agreement is hereby deleted in its entirety and replaced by art. 5.1 to read as follows: The Sponsor shall provide a free loan to the Institution, who accepts pursuant to and for the purposes of 1803 et seq. of the Italian Civil Code; said loan consists of the Instrument(s) described in detail below, together with the related consumables (hereinafter together the "Instrument"): – Device: Apple, iPad 6th Gen (A1954) approximate Value € 509 EUR – 1 Digital Camera Kodak, Pixpro WPZ2 / 4767233 – 9427 + SD, approximate value € 260,00. Ownership of the Instrument, pursuant to the law, is not transferred to the Institution. The effects of this free loan for use shall start on the date of delivery of the Instrument and shall terminate at the end of the Trial, when the Instrument(s) shall be returned to the Sponsor at no cost to the Institution. The Parties also agree that any further Instruments deemed necessary for the performance of the Trial, where the features and conditions subsist, shall be granted as a free loan for use according to the terms of this Agreement. The Institution and the Sponsor will proceed with a specific agreement or addendum/amendment to this Agreement on the loan if the Instruments are provided after the conclusion of this Agreement.
2.1.3. A causa dell'Emendamento al Protocollo (Protocollo V7.0 datato 12 Agosto 2024), l'Allegato A del Contratto viene eliminato nella sua interezza e sostituito dall'Allegato A,	2.1.3. Due to Protocol Amendment (Protocol V7.0 dated 12 August 2024) Annex A of the Agreement is hereby deleted in its entirety and replaced by the Annex A, attached hereto and incorporated into the Agreement by reference.

allegato alla presente e incorporato nel Contratto per riferimento.	
2.1.4. Art. 6.1 del Contratto viene eliminato nella sua interezza e sostituito dall'art. 6.1 riformulato come segue: Il corrispettivo pattuito, preventivamente valutato dall'Ente, per paziente eleggibile, valutabile e che abbia completato il trattamento sperimentale secondo il Protocollo e per il quale sia stata compilata validamente la relativa CRF/eCRF, comprensivo di tutte le spese sostenute dall'Ente per l'esecuzione della Sperimentazione e dei costi di tutte le attività ad essa collegate, è pari ad € 16.001,05 + IVA (se applicabile) per paziente per i Bracci di Studio A & B (complessivi € 64,004.2 + IVA (se applicabile) per n.4 pazienti) e € 6.366,81 + IVA (se applicabile) per il Braccio di Studio C (complessivi € 25.467,24 + IVA (se applicabile) per n.4 pazienti), come meglio dettagliato nel Budget qui allegato sub A.	2.1.4. Art. 6.1 of the Agreement is hereby deleted in its entirety and replaced by art. 5.1 to read as follows: The fee agreed upon - previously evaluate by the Institution - per eligible, assessable patient who completed the trial treatment according to the Protocol and for whom the related CRF/eCRF has been validly completed, inclusive of all expenses incurred by the Institution to carry out the Trial and the costs of all activities connected to it, is equal to EUR 16.001,05 + VAT (if applicable) per patient in Study Arms A and B (a total of EUR 64,004.2 + VAT (if applicable) for no. 4 patients) and € 6.366,81 + VAT (if applicable) for Study Arm C per patient (a total of EUR 25.467,24 + VAT (if applicable for no. 4 patients), as laid out in greater detail in the attached Budget sub A.
3. Conflitto	**3. Conflict**
3.1. In caso di conflitto tra i termini del Contratto (compresi eventuali addendum scritti precedenti, se del caso) e il presente Addendum, prevarranno i termini del presente Addendum.	3.1. In the case of a conflict between the terms of the Agreement (including any prior written addendum(s) as applicable) and this Addendum, the terms of this Addendum shall prevail.
4. Nessun'altra modifica	**4. No Other Change**
4.1. Salvo quanto diversamente previsto nel presente Addendum o qualsiasi precedente addendum scritto, come applicabile, gli altri termini e condizioni del Contratto rimarranno invariati e continueranno ad avere piena validità ed effetto.	4.1. Except as otherwise provided in this Addendum 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.
5. Disposizioni generali	**5. General Provisions**
5.1. Il presente Addendum e qualsiasi addendum successivo potranno essere eseguiti in duplicato, e i duplicati, nel loro insieme, costituiranno un unico accordo.	5.1. This Addendum, and any subsequent addendum(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement.

5.2. Le Parti convengono che una copia della firma originale (inclusa una copia elettronica) potrà essere utilizzata per tutte le finalità per cui verrebbe utilizzata la firma originale. Le Parti convengono che non avranno alcun diritto di contestare l'uso o l'autenticità del presente documento basandosi esclusivamente sull'assenza di una firma originale.	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.
5.3. Il presente Addendum può essere eseguito in due lingue. In caso di discrepanze tra la versione italiana e la versione inglese della presente modifica, prevarrà la versione italiana.	5.3. This Addendum may be executed in two languages. In case of discrepancies between the Italian Language version and the English version of this Amendment, the Italian version shall prevail.
[SEGUONO LE FIRME]	**[SIGNATURES TO FOLLOW]**

SPONSOR by its authorized signatory **WORLDWIDE**	
Name Surname	
Title	
Date DD-MMM-YYYY	
Signature	Firmato digitalmente da: GIULIO TIEZZI Luogo: Arezzo Data: 07/03/2025 16:38:08

INSTITUTION (authorized signatory)	
Name Surname	
Title	
Date DD-MMM-YYYY	
Signature	

PRINCIPAL INVESTIGATOR	
Name Surname	
Title	
Date DD-MMM-YYYY	
Signature	

ELENCO DEGLI ALLEGATI	**LIST OF EXHIBITS**
Allegato A: Budget	**Annex A: Budget**

ALLEGATO A – BUDGET	**ANNEX A - BUDGET**
<u>ONERI E COMPENSI</u>	**<u>FEES AND REIMBURSEMENT</u>**
Parte 1 - Oneri fissi e Compenso per paziente coinvolto nello studio Includere, a titolo di esempio le seguenti voci: - Fornitura del/i Medicinale/i Sperimentale/i e/o di ogni altro materiale in sperimentazione o necessario allo svolgimento della stessa affinché non vi sia aggravio di costi a carico del S.S.N. (kit diagnostici, dispositivi medici, ecc.). - Compenso lordo a paziente coinvolto nello studio: € 16.001,05 per i Bracci di Studio A e B e 6.366,81 per il Braccio di Studio C. - Compenso per screening failure e unscheduled visit, nonché per la eventuale smaltimento del farmaco sperimentale come previsto dall'art. 4.6 del Contratto. - Compenso per il Centro sperimentale a paziente completato (Compenso a paziente coinvolto – overhead aziendale – tutti i costi sostenuti dall'Ente per la sperimentazione[1]): € 16.001,05 per i Bracci di Studio A e B e 6.366,81 per il Braccio di Studio C. - Tutti i costi rimborsabili relativi allo studio, inclusi quelli coperti dal contributo per paziente coinvolto nello studio, non comporteranno aggravio di costi a carico del SSN.	**Part 1 – Fixed fees and payment per patient involved in the study** Include, by way of example, the following items: - Provision of the Trial Drug(s) and/or of any other study material or materials necessary in order to carry out the Trial so as to avoid any increase in costs to be borne by the Italian National Health Service (diagnostic kits, medical devices etc.). - Gross payment per patient involved in the study: € 16.001,05 for Study Arms A and B and 6.366,81 for Study Arm C per patient. - Reimbursement for screening failure and unscheduled visit, as well as for any disposal of the trial drug as set forth in Art. 4.6 of the Agreement. - Payment for the Trial Site per completed patient (payment per involved patient - trust's overhead - all costs incurred by the institution for the Trial[2]): € 16.001,05 for Study Arms A and B and 6.366,81 for Study Arm C per patient. - All reimbursable costs related to the study, including those covered by the contribution per patient involved in the study, will not result in additional costs to the Italian National Health Service.
Parte 2 - Indennità per i pazienti/accompagnatori coinvolti nello studio clinico: Si fa rinvio al modello "Indennità per i partecipanti alla sperimentazione", incluso nel dossier della domanda ai sensi del Regolamento (UE) n. 536/2014, da intendersi richiamato nel presente Contratto come sua parte integrante e sostanziale.	Part 2 - Reimbursement for patients/caregivers included in the clinical study: Please refer to the "Compensation for trial participants" template included in the application file pursuant to Regulation (EU) No. 536/2014, to be referred to in this Agreement as its integral and substantial part.
LIQUIDAZIONE E FATTURE	**SETTLEMENT AND INVOICES**

[1] • costi amministrativi generali, costi sostenuti dal servizio farmaceutico per la gestione del/dei farmaco/i oggetto della Sperimentazione

[2] • general administrative costs, costs incurred by the pharmaceutical service for the management of the drug(s) being the subject to the Trial

- Il compenso deve essere liquidato entro 60 giorni dalla ricezione della fattura. - La fattura deve essere emessa con cadenza prevista semestrale secondo quanto maturato nel periodo di riferimento, sulla base di apposita richiesta di emissione fattura da parte del Promotore.	- The fee must be settled within 60 days of receipt of the invoice. - The invoice must be issued with the following frequency: semi-annually according to the amount accrued in the reference period, based on a specific request for issue of an invoice by the Sponsor.

BUDGET PER PATIENT

ARM A&B

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli													
		Pre-Screening	Screening	Week 1					Week 2				
Procedures & Assessments	ITEM COST (EUR)			Pre	Dose	EOI	4h	Dis	Pre	Dose	EOI	4h	Dis
Informed consent on ICF	*43*	22	43										
Demographics	*24*	24	12										
Medical history and current medical conditions; Cancer history and status	*54*		54										
EQ-5D-5L	*36*			36									
EORTC-QLQ-C30	*17*			17									
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	*22*		22	22					22				
Adverse events occuring during Screening; Adverse events	*25*		25	25					25				
Complete physical examination; Full physical examination	*155*		155	155									
Brief physical examination	*72*								72				
Vital signs (BP, HR, T, RR); height and weight as applicable	*36*		36	36		36		36	36		36		36
Vital signs (O2sat)	*22*		22	22		22		22	22		22		22
Vital signs monitoring; up to 6 hours	*76*											70	
Vital signs monitoring; up to 24 hours	*110*						110						
Single 12-lead ECG	*61*		61	61									
ECOG Performance Status	*20*		20	20									
Blood draw	*13*		13	invoice					13				
Hematology panel	*26*		26	invoice					26				
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	*48*		48	invoice					48				
Chemistry panel: Magnesium	*12*		12	invoice					12				
Chemistry panel: Phosphate	*8*		8	invoice					8				
Chemistry panel: Lactate dehydrogenase (LDH)	*13*		13	invoice					13				
Coagulation panel: Prothrombin time / INR	*11*		11										
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	*16*		16										
Amylase	*11*		11										
Lipase	*26*		26										
Thyroid panel: Thyroid-stimulating hormone (TSH)	*45*		45										
Thyroid panel: free T4	*37*		37										
Cortisol	*38*		39										
Estimated glomerular filtration rate	*16*		16										
Troponin (I or T)	*38*		38										
Collection of urine sample	*13*		13										
Urinalysis	*16*		10										
Collection of blood for HLA-A testing / Brenetafusp PK / Brenetafusp ADA / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	*24*	invoice	invoice	24		24	24		24		24	24	
Lab handling of blood samples for shipment to central laboratory	*21*	invoice	invoice	21		21	21		21		21	21	
Brenetafusp IV infusion; up to 1 hour (Arm A and B)	*95*				95					95			
Nivolumab IV infusion; up to 1 hour (Arm A and B)	*95*				95								
Inclusion/exclusion criteria	*38*		39										
Study Coordinator fee (including Randomization; Survival status)	*83*	18	83	17	17	17	17	17	17	17	17	17	17
Principal Investigator fee (including BRAF V600 mutation status)	*166*	83	166	33	33	33	33	33	33	33	33	33	33
Data Entry fee	*31*	16	31	6	6	6	6	6	6	6	6	6	6
Pharmacy fee - Preparation / Dispense Brenetafusp (Arm A and B)	*45*				45					45			
Pharmacy fee - Preparation / Dispense Nivolumab (Arm A and B)	*45*				45								
Subtotal:		**162**	**1,151**	**495**	**336**	**159**	**211**	**114**	**398**	**196**	**159**	**171**	**114**
Overhead	*15%*	30.83	218.69	94.05	63.84	30.21	40.09	21.66	75.62	37.24	30.21	32.49	21.66
		193.09	**1,369.69**	**589.05**	**399.84**	**189.21**	**251.09**	**135.66**	**473.62**	**233.24**	**189.21**	**203.49**	**135.66**
	Payment at 90%	**173.78**	**1,232.72**	**530.15**	**359.86**	**170.29**	**225.98**	**122.09**	**426.26**	**209.92**	**170.29**	**183.14**	**122.09**
	10% Withholding	**19.31**	**136.97**	**58.91**	**39.98**	**18.92**	**25.11**	**13.57**	**47.36**	**23.32**	**18.92**	**20.35**	**13.57**

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli		ITALY										
	ITEM COST (EUR)	Week 3					Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
Procedures & Assessments		Pre	Dose	EOI	4h	Dis						
Informed consent on ICF	43											
Demographics	24											
Medical history and current medical conditions; Cancer history and status	54											
EQ-5D-5L	36											36
EORTC-QLQ-C30	17											17
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	22	22					22	22	22	22	22	22
Adverse events occuring during Screening; Adverse events	25	25					25	25	25	25	25	25
Complete physical examination; Full physical examination	155											
Brief physical examination	72	72						72				72
Vital signs (BP, HR, T, RR); height and weight as applicable	36	36		36		36	72	72	72	72	72	72
Vital signs (O2sat)	22	22		22		22	44	44	44	44	44	44
Vital signs monitoring; up to 6 hours	70				70		70	70	70	70	70	70
Vital signs monitoring; up to 24 hours	116											
Single 12-lead ECG	61							122				122
ECOG Performance Status	20							20				20
Blood draw	13	13					13	13	13	13	13	13
Hematology panel	26	26					26	26	26	26	26	26
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	48	48					48	48	48	48	48	48
Chemistry panel: Magnesium	12	12					12	12	12	12	12	12
Chemistry panel: Phosphate	8	8					8	8	8	8	8	8
Chemistry panel: Lactate dehydrogenase (LDH)	13	13					13	13	13	13	13	13
Coagulation panel: Prothrombin time / INR	11											
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	16											
Amylase	11							11				11
Lipase	26							26				26
Thyroid panel: Thyroid-stimulating hormone (TSH)	45							45				45
Thyroid panel: free T4	37							37				37
Cortisol	38											
Estimated glomerular filtration rate	16											
Troponin (I or T)	38											
Collection of urine sample	13											
Urinalysis	16											
Collection of blood for HLA-A testing / Brenetafusp PK / Brenetafusp ADA / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	24	24		24	24			48				48
Lab handling of blood samples for shipment to central laboratory	21	21		21	21			21				21
Brenetafusp IV infusion; up to 1 hour (Arm A and B)	95		95				95	95	95	95	95	95
Nivolumab IV infusion; up to 1 hour (Arm A and B)	95							95				95
Inclusion/exclusion criteria	38											
Study Coordinator fee (including Randomization; Survival status)	83	17	17	17	17	17	83	83	83	83	83	83
Principal Investigator fee (including BRAF V600 mutation status)	166	33	33	33	33	33	166	166	166	166	166	166
Data Entry fee	31	6	6	6	6	6	31	31	31	31	31	31
Pharmacy fee - Preparation / Dispense Brenetafusp (Arm A and B)	45		45				45	45	45	45	45	45
Pharmacy fee - Preparation / Dispense Nivolumab (Arm A and B)	45							45				45
Subtotal:		**398**	**196**	**159**	**171**	**114**	**773**	**1,315**	**773**	**773**	**773**	**1,368**
Overhead	18%	75.62	37.24	30.21	32.49	21.66	146.87	249.85	146.87	146.87	146.87	259.92
		473.62	233.24	189.21	203.49	135.66	919.87	1,564.85	919.87	919.87	919.87	1,627.92
	Payment at 90%	426.26	209.92	170.29	183.14	122.09	827.88	1,408.37	827.88	827.88	827.88	1,465.13
	10% Withholding	47.36	23.32	18.92	20.35	13.57	91.99	156.49	91.99	91.99	91.99	162.79

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli												
Procedures & Assessments	ITEM COST (EUR)	Week 10	Week 11	Week 12	End of Treatment	Item Total	Overnight stay	Week 13, 29, 37, 53, 61, 65, 73, 77, 85, 89, 97, 101	Week 17, 25, 41, 49	Week 21, 45	Week 33, 57, 69, 81, 93	Week 15, 19, 23, 27, 31, 35, 39, 43, 47, 51
Informed consent on ICF	*43*					65						
Demographics	*24*					36						
Medical history and current medical conditions; Cancer history and status	*54*					54						
EQ-5D-5L	*36*				36	108				36	36	
EORTC-QLQ-C30	*17*				17	51				17	17	
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	*22*	22	22	22	22	308		22	22	22	22	22
Adverse events occuring during Screening; Adverse events	*25*	25	25	25	25	350		25	25	25	25	25
Complete physical examination; Full physical examination	*155*				155	465						
Brief physical examination	*72*					288		72	72	72	72	
Vital signs (BP, HR, T, RR); height and weight as applicable	*36*	72	72	72	36	1,044		72	72	72	72	72
Vital signs (O2sat)	*22*	44	44	44	22	638		44	44	44	44	44
Vital signs monitoring; up to 6 hours	*76*	70	70	70		770						
Vital signs monitoring; up to 24 hours	*110*					110						
Single 12-lead ECG	*61*				61	427						
ECOG Performance Status	*26*				20	100		20	20	20	20	
Blood draw	*13*				13	130		13	13	13	13	
Hematology panel	*26*				26	260		26	26	26	26	
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	*48*				48	480		48	48	48	48	
Chemistry panel: Magnesium	*12*				12	120		12	12	12	12	
Chemistry panel: Phosphate	*8*				8	80		8	8	8	8	
Chemistry panel: Lactate dehydrogenase (LDH)	*13*				13	130		13	13	13	13	
Coagulation panel: Prothrombin time / INR	*11*				11	22						
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	*16*				16	32						
Amylase	*11*				11	44		11	11	11	11	
Lipase	*26*				26	104		26	26	26	26	
Thyroid panel: Thyroid-stimulating hormone (TSH)	*45*				45	180		45	45	45	45	
Thyroid panel: free T4	*37*				37	148		37	37	37	37	
Cortisol	*39*					39						
Estimated glomerular filtration rate	*16*					16						
Troponin (I or T)	*38*					38						
Collection of urine sample	*13*				13	26						
Urinalysis	*10*				10	20						
Collection of blood for HLA-A testing / Brenetafusp PK / Brenetafusp ADA / Blood for mRNA / Blood for PBMC / Blood for otDNA samples as applicable	*24*				24	336			48		48	
Lab handling of blood samples for shipment to central laboratory	*21*				21	252			21		21	
Brenetafusp IV infusion; up to 1 hour (Arm A and B)	*95*	95	95	95		1,140		95	95	95	95	95
Nivolumab IV infusion; up to 1 hour (Arm A and B)	*95*					285		95	95	95	95	
Inclusion/exclusion criteria	*39*					39						
Study Coordinator fee (including Randomization; Survival status)	*83*	83	83	83	83	1,180	83	83	83	83	83	83
Principal Investigator fee (including BRAF V600 mutation status)	*166*	166	166	166	166	2,407	166	166	166	166	166	166
Data Entry fee	*31*	31	31	31	31	450	31	31	31	31	31	31
Pharmacy fee - Preparation / Dispense Brenetafusp (Arm A and B)	*45*	45	45	45		540		45	45	45	45	45
Pharmacy fee - Preparation / Dispense Nivolumab (Arm A and B)	*45*					135		45	45	45	45	
Subtotal:		**653**	**653**	**653**	**1,008**	**13,446**	**280**	**1,054**	**1,123**	**1,107**	**1,176**	**583**
Overhead	*15%*	124.07	124.07	124.07	191.52	2,554.79	53.20	200.26	213.37	210.33	223.44	110.77
		777.07	777.07	777.07	1,199.52	16,001.05	333.20	1,254.26	1,336.37	1,317.33	1,399.44	693.77
	Payment at 90%	699.36	699.36	699.36	1,079.57	14,400.94	299.88	1,128.83	1,202.73	1,185.60	1,259.50	624.39
	10% Withholding	77.71	77.71	77.71	119.95	1,600.10	33.32	125.43	133.64	131.73	139.94	69.38

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli									
Procedures & Assessments	ITEM COST (EUR)	Week 105 and every 4 weeks thereafter until Disease Progression	Week 105 and every 12 weeks thereafter until Disease Progression	30 Days Post Last Dose Site visit	30 Days Post Last Dose virtual / remote visit	60 Days Post Last Dose Site visit	60 Days Post Last Dose virtual / remote visit	90 Days Post Last Dose for WoCBP (Site visit)	90 Days Post Last Dose for WoCBP (virtual / remote
Informed consent on ICF	43								
Demographics	24								
Medical history and current medical conditions; Cancer history and status	54								
EQ-5D-5L	36		36	36					
EORTC-QLQ-C30	17		17	17					
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	22	22		22	22	22	22		
Adverse events occuring during Screening; Adverse events	25	25		25	25	25	25		
Complete physical examination; Full physical examination	155								
Brief physical examination	72	72							
Vital signs (BP, HR, T, RR); height and weight as applicable	36	72							
Vital signs (O2sat)	22	44							
Vital signs monitoring; up to 6 hours	76								
Vital signs monitoring; up to 24 hours	116								
Single 12-lead ECG	61			invoice	invoice	invoice	invoice		
ECOG Performance Status	26	20							
Blood draw	13	13		invoice	invoice	invoice	invoice	invoice	invoice
Hematology panel	26	26		invoice	invoice	invoice	invoice		
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	48	48		invoice	invoice	invoice	invoice		
Chemistry panel: Magnesium	12	12		invoice	invoice	invoice	invoice		
Chemistry panel: Phosphate	8	8		invoice	invoice	invoice	invoice		
Chemistry panel: Lactate dehydrogenase (LDH)	13	13		invoice	invoice	invoice	invoice		
Coagulation panel: Prothrombin time / INR	11			invoice	invoice	invoice	invoice		
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	16			invoice	invoice	invoice	invoice		
Amylase	11	11		invoice	invoice	invoice	invoice		
Lipase	26	26		invoice	invoice	invoice	invoice		
Thyroid panel: Thyroid-stimulating hormone (TSH)	45	45		invoice	invoice	invoice	invoice		
Thyroid panel: free T4	37	37		invoice	invoice	invoice	invoice		
Cortisol	38								
Estimated glomerular filtration rate	16								
Troponin (I or T)	38								
Collection of urine sample	13			invoice	invoice	invoice	invoice		
Urinalysis	16			invoice	invoice	invoice	invoice		
Collection of blood for HLA-A testing / Brenetafusp PK / Brenetafusp ADA / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	24		48						
Lab handling of blood samples for shipment to central laboratory	21		21						
Brenetafusp IV infusion; up to 1 hour (Arm A and B)	95	95							
Nivolumab IV infusion; up to 1 hour (Arm A and B)	95	95							
Inclusion/exclusion criteria	38								
Study Coordinator fee (including Randomization; Survival status)	83	83		83	21	83	21	42	21
Principal Investigator fee (including BRAF V600 mutation status)	166	166		166		166			
Data Entry fee	31	31		31	8	31	8	16	8
Pharmacy fee - Preparation / Dispense Brenetafusp (Arm A and B)	45	45							
Pharmacy fee - Preparation / Dispense Nivolumab (Arm A and B)	45	45							
Subtotal:		**1,054**	**122**	**380**	**76**	**327**	**76**	**57**	**29**
Overhead	15%	200.26	23.18	72.20	14.35	62.13	14.35	10.83	5.42
		1,254.26	**145.18**	**452.20**	**89.85**	**389.13**	**89.85**	**67.83**	**33.92**
	Payment at 90%	**1,128.83**	**130.66**	**406.98**	**80.86**	**350.22**	**80.86**	**61.05**	**30.52**
	10% Withholding	**125.43**	**14.52**	**45.22**	**8.98**	**38.91**	**8.98**	**6.78**	**3.39**

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli										
Procedures & Assessments	ITEM COST (EUR)	100 Days Post Last Dose Site visit	100 Days Post Last Dose virtual / remote visit	120 Days Post Last Dose for VoCBP (Site visit)	120 Days Post Last Dose for VoCBP (virtual / remote	150 Days Post Last Dose for VoCBP (Site visit)	150 Days Post Last Dose for VoCBP (virtual / remote	6 Months Post Last Dose then Q3M	Disease assessment after EOT until progression is confirmed by BICR: Q8W (±1 week) until Week 57 ONLY IF Disease assessment falls outside regularly scheduled Follow-Up visit to Site
Informed consent on ICF	*43*								
Demographics	*24*								
Medical history and current medical conditions; Cancer history and status	*54*								
EQ-5D-5L	*36*								
EORTC-QLQ-C30	*17*								
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	*22*	22	22					22	
Adverse events occuring during Screening; Adverse events	*25*	25	25						
Complete physical examination; Full physical examination	*155*								
Brief physical examination	*72*								
Vital signs (BP, HR, T, RR); height and weight as applicable	*36*								
Vital signs (O2sat)	*22*								
Vital signs monitoring; up to 6 hours	*76*								
Vital signs monitoring; up to 24 hours	*116*								
Single 12-lead ECG	*61*	invoice	invoice						
ECOG Performance Status	*26*								
Blood draw	*13*	invoice	invoice	invoice	invoice	invoice	invoice		
Hematology panel	*26*	invoice	invoice						
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	*46*	invoice	invoice						
Chemistry panel: Magnesium	*12*	invoice	invoice						
Chemistry panel: Phosphate	*8*	invoice	invoice						
Chemistry panel: Lactate dehydrogenase (LDH)	*13*	invoice	invoice						
Coagulation panel: Prothrombin time / INR	*11*	invoice	invoice						
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	*16*	invoice	invoice						
Amylase	*11*	invoice	invoice						
Lipase	*26*	invoice	invoice						
Thyroid panel: Thyroid-stimulating hormone (TSH)	*45*	invoice	invoice						
Thyroid panel: free T4	*37*	invoice	invoice						
Cortisol	*38*								
Estimated glomerular filtration rate	*16*								
Troponin (I or T)	*38*								
Collection of urine sample	*13*	invoice	invoice						
Urinalysis	*16*	invoice	invoice						
Collection of blood for HLA-A testing / Brenetafusp PK / Brenetafusp ADA / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	*24*								
Lab handling of blood samples for shipment to central laboratory	*21*								
Brenetafusp IV infusion; up to 1 hour (Arm A and B)	*35*								
Nivolumab IV infusion; up to 1 hour (Arm A and B)	*35*								
Inclusion/exclusion criteria	*38*								
Study Coordinator fee (including Randomization; Survival status)	*83*	83	21	42	21	42	21	21	83
Principal Investigator fee (including BRAF V600 mutation status)	*166*	166							166
Data Entry fee	*31*	31	8	16	8	16	8	8	31
Pharmacy fee - Preparation / Dispense Brenetafusp (Arm A and B)	*45*								
Pharmacy fee - Preparation / Dispense Nivolumab (Arm A and B)	*45*								
Subtotal:		**327**	**76**	**57**	**29**	**57**	**29**	**51**	**280**
Overhead	*18%*	62.13	14.35	10.83	5.42	10.83	5.42	9.60	53.20
		389.13	**89.85**	**67.83**	**33.92**	**67.83**	**33.92**	**60.10**	**333.20**
Payment at 90%		**350.22**	**80.86**	**61.05**	**30.52**	**61.05**	**30.52**	**54.09**	**299.88**
10% Withholding		**38.91**	**8.98**	**6.78**	**3.39**	**6.78**	**3.39**	**6.01**	**33.32**

ARM C

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli		ITALY							
	ITEM COST (EUR)	Pre-Screening	Screening	Week 1		Week 5	Week 9	End of Treatment	Item Total
Procedures & Assessments				Pre	Dose				
Informed consent on ICF	43	22	43						65
Demographics	24	24	12						36
Medical history and current medical conditions; Cancer history and status	54		54						54
EQ-5D-5L	36			36			36	36	108
EORTC-QLQ-C30	17			17			17	17	51
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	22		22	22		22	22	22	110
Adverse events occuring during Screening; Adverse events	25		25	25		25	25	25	125
Complete physical examination; Full physical examination	155		155	155				155	465
Brief physical examination	72					72	72		144
Vital signs (BP, HR, T, RR); height and weight as applicable	36		36	36		72	72	36	252
Vital signs (O2sat)	22		22	22		44	44	22	154
Single 12-lead ECG	61		61	61		122	122	61	427
ECOG Performance Status	20		20	20		20	20	20	100
Blood draw	13		13	invoice		13	13	13	52
Hematology panel	26		26	invoice		26	26	26	104
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	48		48	invoice		48	48	48	192
Chemistry panel: Magnesium	12		12	invoice		12	12	12	48
Chemistry panel: Phosphate	8		8	invoice		8	8	8	32
Chemistry panel: Lactate dehydrogenase (LDH)	13		13	invoice		13	13	13	52
Coagulation panel: Prothrombin time / INR	11		11					11	22
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	16		16					16	32
Amylase	11		11			11	11	11	44
Lipase	26		26			26	26	26	104
Thyroid panel: Thyroid-stimulating hormone (TSH)	45		45			45	45	45	180
Thyroid panel: free T4	37		37			37	37	37	148
Cortisol	39		39						39
Estimated glomerular filtration rate	16		16						16
Troponin (I or T)	38		38						38
Collection of urine sample	13		13					13	26
Urinalysis	10		10					10	20
Collection of blood for HLA-A testing / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	24	invoice	invoice	24			24	24	72
Lab handling of blood samples for shipment to central laboratory	21	invoice	invoice	21			21	21	63
Nivolumab or nivolumab + relatlimab IV infusion; up to 1 hour (Arm C)	95				95	95	95		285
Inclusion/exclusion criteria	39		39						39
Study Coordinator fee (including Randomization; Survival status)	83	18	83	42	42	83	83	83	433
Principal Investigator fee (including BRAF V600 mutation status)	166	83	166	83	83	166	166	166	913
Data Entry fee	31	16	31	16	16	31	31	31	171
Pharmacy fee - Preparation / Dispense Nivolumab or relatlimab + nivolumab (Arm C)	45				45	45	45		135
Subtotal:		**162**	**1,151**	**579**	**280**	**1,036**	**1,134**	**1,008**	**5,350**
Overhead	19%	30.83	218.69	110.01	53.20	196.84	215.46	191.52	1,016.55
		193.09	**1,369.69**	**689.01**	**333.20**	**1,232.84**	**1,349.46**	**1,199.52**	**6,366.81**
	Payment at 90%	**173.78**	**1,232.72**	**620.11**	**299.88**	**1,109.56**	**1,214.51**	**1,079.57**	**5,730.13**
	10% Withholding	**19.31**	**136.97**	**68.90**	**33.32**	**123.28**	**134.95**	**119.95**	**636.68**

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli					
Procedures & Assessments	ITEM COST (EUR)	Week 13, 29, 37, 53, 61, 65, 73, 77, 85, 89, 97, 101	Week 17, 25, 41, 49	Week 21, 45	Week 33, 57, 69, 81, 93
Informed consent on ICF	43				
Demographics	24				
Medical history and current medical conditions; Cancer history and status	54				
EQ-5D-5L	36			36	36
EORTC-QLQ-C30	17			17	17
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	22	22	22	22	22
Adverse events occuring during Screening; Adverse events	25	25	25	25	25
Complete physical examination; Full physical examination	155				
Brief physical examination	72	72	72	72	72
Vital signs (BP, HR, T, RR); height and weight as applicable	36	72	72	72	72
Vital signs (O2sat)	22	44	44	44	44
Single 12-lead ECG	61				
ECOG Performance Status	26	20	20	20	20
Blood draw	13	13	13	13	13
Hematology panel	26	26	26	26	26
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	48	48	48	48	48
Chemistry panel: Magnesium	12	12	12	12	12
Chemistry panel: Phosphate	8	8	8	8	8
Chemistry panel: Lactate dehydrogenase (LDH)	13	13	13	13	13
Coagulation panel: Prothrombin time / INR	11				
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	16				
Amylase	11	11	11	11	11
Lipase	26	26	26	26	26
Thyroid panel: Thyroid-stimulating hormone (TSH)	45	45	45	45	45
Thyroid panel: free T4	37	37	37	37	37
Cortisol	38				
Estimated glomerular filtration rate	16				
Troponin (I or T)	38				
Collection of urine sample	13				
Urinalysis	16				
Collection of blood for HLA-A testing / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	24		24		24
Lab handling of blood samples for shipment to central laboratory	21		21		21
Nivolumab or nivolumab + relatlimab IV infusion; up to 1 hour (Arm C)	95	95	95	95	95
Inclusion/exclusion criteria	38				
Study Coordinator fee (including Randomization; Survival status)	83	83	83	83	83
Principal Investigator fee (including BRAF V600 mutation status)	166	166	166	166	166
Data Entry fee	31	31	31	31	31
Pharmacy fee - Preparation / Dispense Nivolumab or relatlimab + nivolumab (Arm C)	45	45	45	45	45
Subtotal:		**914**	**959**	**967**	**1,012**
Overhead	19%	173.66	182.21	183.73	192.28
		1,087.66	**1,141.21**	**1,150.73**	**1,204.28**
	Payment at 90%	**978.89**	**1,027.09**	**1,035.66**	**1,083.85**
	10% Withholding	**108.77**	**114.12**	**115.07**	**120.43**

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli									
Procedures & Assessments	ITEM COST (EUR)	Week 105 and every 4 weeks thereafter until Disease Progression	Week 105 and every 12 weeks thereafter until Disease Progression	30 Days Post Last Dose Site visit	30 Days Post Last Dose virtual / remote visit	60 Days Post Last Dose Site visit	60 Days Post Last Dose virtual / remote visit	90 Days Post Last Dose for VoCBP (Site visit)	90 Days Post Last Dose for VoCBP (virtual / remote visit)
Informed consent on ICF	43								
Demographics	24								
Medical history and current medical conditions; Cancer history and status	54								
EQ-5D-5L	36		36	36					
EORTC-QLQ-C30	17		17	17					
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	22	22		22	22	22	22		
Adverse events occuring during Screening; Adverse events	25	25		25	25	25	25		
Complete physical examination; Full physical examination	155								
Brief physical examination	72	72							
Vital signs (BP, HR, T, RR); height and weight as applicable	36	72							
Vital signs (O2sat)	22	44							
Single 12-lead ECG	61			invoice	invoice	invoice	invoice		
ECOG Performance Status	26	20							
Blood draw	13	13		invoice	invoice	invoice	invoice	invoice	invoice
Hematology panel	26	26		invoice	invoice	invoice	invoice		
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	48	48		invoice	invoice	invoice	invoice		
Chemistry panel: Magnesium	12	12		invoice	invoice	invoice	invoice		
Chemistry panel: Phosphate	8	8		invoice	invoice	invoice	invoice		
Chemistry panel: Lactate dehydrogenase (LDH)	13	13		invoice	invoice	invoice	invoice		
Coagulation panel: Prothrombin time / INR	11			invoice	invoice	invoice	invoice		
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	16			invoice	invoice	invoice	invoice		
Amylase	11	11		invoice	invoice	invoice	invoice		
Lipase	26	26		invoice	invoice	invoice	invoice		
Thyroid panel: Thyroid-stimulating hormone (TSH)	45	45		invoice	invoice	invoice	invoice		
Thyroid panel: free T4	37	37		invoice	invoice	invoice	invoice		
Cortisol	38								
Estimated glomerular filtration rate	16								
Troponin (I or T)	38								
Collection of urine sample	13			invoice	invoice	invoice	invoice		
Urinalysis	16			invoice	invoice	invoice	invoice		
Collection of blood for HLA-A testing / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	24		24						
Lab handling of blood samples for shipment to central laboratory	21		21						
Nivolumab or nivolumab + relatlimab IV infusion; up to 1 hour (Arm C)	95	95							
Inclusion/exclusion criteria	38								
Study Coordinator fee (including Randomization; Survival status)	83	83		83	21	83	21	42	21
Principal Investigator fee (including BRAF V600 mutation status)	166	166		166		166			
Data Entry fee	31	31		31	8	31	8	16	8
Pharmacy fee - Preparation / Dispense Nivolumab or relatlimab + nivolumab (Arm C)	45	45							
Subtotal:		**914**	**98**	**380**	**76**	**327**	**76**	**57**	**29**
Overhead	18%	173.66	18.62	72.20	14.35	62.13	14.35	10.83	5.42
		1,087.66	**116.62**	**452.20**	**89.85**	**389.13**	**89.85**	**67.83**	**33.92**
	Payment at 90%	**978.89**	**104.96**	**406.98**	**80.86**	**350.22**	**80.86**	**61.05**	**30.52**
	10% Withholding	**108.77**	**11.66**	**45.22**	**8.98**	**38.91**	**8.98**	**6.78**	**3.39**

PI: Prof. Paolo Antonio Ascierto Site: INT "Fondazione G. Pascale" di Napoli									
Procedures & Assessments	ITEM COST (EUR)	100 Days Post Last Dose Site visit	100 Days Post Last Dose virtual / remote visit	120 Days Post Last Dose for WoCBP (Site visit)	120 Days Post Last Dose for WoCBP (virtual / remote visit)	150 Days Post Last Dose for WoCBP (Site visit)	150 Days Post Last Dose for WoCBP (virtual / remote visit)	6 Months Post Last Dose then Q3M	Disease assessment after EOT until progression is confirmed by BICR: Q8W (±1 week) until Week 57 ONLY IF Disease assessment falls outside regularly scheduled Follow-Up visit to Site
Informed consent on ICF	*43*								
Demographics	*24*								
Medical history and current medical conditions; Cancer history and status	*54*								
EQ-5D-5L	*36*								
EORTC-QLQ-C30	*17*								
Prior anticancer therapy; Prior and concomitant medications; Subsequent cancer therapy	*22*	22	22					22	
Adverse events occuring during Screening; Adverse events	*25*	25	25						
Complete physical examination; Full physical examination	*155*								
Brief physical examination	*72*								
Vital signs (BP, HR, T, RR); height and weight as applicable	*36*								
Vital signs (O2sat)	*22*								
Single 12-lead ECG	*61*	invoice	invoice						
ECOG Performance Status	*26*								
Blood draw	*13*	invoice	invoice	invoice	invoice	invoice	invoice		
Hematology panel	*26*	invoice	invoice						
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	*46*	invoice	invoice						
Chemistry panel: Magnesium	*12*	invoice	invoice						
Chemistry panel: Phosphate	*8*	invoice	invoice						
Chemistry panel: Lactate dehydrogenase (LDH)	*13*	invoice	invoice						
Coagulation panel: Prothrombin time / INR	*11*	invoice	invoice						
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	*16*	invoice	invoice						
Amylase	*11*	invoice	invoice						
Lipase	*26*	invoice	invoice						
Thyroid panel: Thyroid-stimulating hormone (TSH)	*45*	invoice	invoice						
Thyroid panel: free T4	*37*	invoice	invoice						
Cortisol	*38*								
Estimated glomerular filtration rate	*16*								
Troponin (I or T)	*36*								
Collection of urine sample	*13*	invoice	invoice						
Urinalysis	*16*	invoice	invoice						
Collection of blood for HLA-A testing / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	*24*								
Lab handling of blood samples for shipment to central laboratory	*21*								
Nivolumab or nivolumab + relatlimab IV infusion; up to 1 hour (Arm C)	*55*								
Inclusion/exclusion criteria	*38*								
Study Coordinator fee (including Randomization; Survival status)	*63*	83	21	42	21	42	21	21	83
Principal Investigator fee (including BRAF V600 mutation status)	*166*	166							166
Data Entry fee	*31*	31	8	16	8	16	8	8	31
Pharmacy fee - Preparation / Dispense Nivolumab or relatlimab + nivolumab (Arm C)	*45*								
Subtotal:		**327**	**76**	**57**	**29**	**57**	**29**	**51**	**280**
Overhead	*18%*	62.13	14.35	10.83	5.42	10.83	5.42	9.60	53.20
		389.13	**89.85**	**67.83**	**33.92**	**67.83**	**33.92**	**60.10**	**333.20**
	Payment at 90%	**350.22**	**80.86**	**61.05**	**30.52**	**61.05**	**30.52**	**54.09**	**299.88**
	10% Withholding	**38.91**	**8.98**	**6.78**	**3.39**	**6.78**	**3.39**	**6.01**	**33.32**

INVOICEABLE ITEMS for ARMS A, B &C

INVOICEABLE ITEMS (inclusive of Overhead)	COST	FREQUENCY
IRB/EC Fees	Invoice	As Needed
Reconsent Fee	38.38	As Needed
Vital signs (BP, HR, T, RR)	42.84	Per Protocol, As Needed
Vital signs (O2sat)	26.18	Per Protocol, As Needed
Vital signs monitoring; up to 6 hours	83.30	Per Protocol, As Needed
Vital signs monitoring; up to 24 hours	130.90	Per Protocol, As Needed
Single 12-lead ECG	72.59	Per Protocol, As Needed
12-lead ECG (triplicate)	138.04	Per Protocol, As Needed
Blood draw	15.47	As Needed
Hematology panel	30.94	Per Protocol, As Needed
Chemistry panel: Includes Albumin; Bilirubin, total; Calcium; Bicarbonate; Chloride; Creatinine; Glucose; Phosphatase, alkaline; Potassium; Sodium; Transferase, alanine amino (ALT); Transferase, aspartate amino (AST); Urea Nitrogen (BUN)	57.12	Per Protocol, As Needed
Chemistry panel: Magnesium	14.28	Per Protocol, As Needed
Chemistry panel: Phosphate	9.52	Per Protocol, As Needed
Chemistry panel: Lactate dehydrogenase (LDH)	15.47	Per Protocol, As Needed
Chemistry panel: Bilirubin; direct	11.90	Per Protocol, As Needed
Coagulation panel: Prothrombin time / INR	13.09	Per Protocol, As Needed
Coagulation panel: activated partial thromboplastin time (aPTT) and/or aPTT ratio [partial thromboplastin time [PTT] acceptable]	19.04	Per Protocol, As Needed
Amylase	13.09	Per Protocol, As Needed
Lipase	30.94	Per Protocol, As Needed
Thyroid panel: Thyroid-stimulating hormone (TSH)	53.55	Per Protocol, As Needed
Thyroid panel: free T4	44.03	Per Protocol, As Needed
Thyroid panel: free T3	58.31	Per Protocol, As Needed
Collection of urine sample	15.47	Per Protocol, As Needed
Urinalysis	11.90	Per Protocol, As Needed
HBV viral load	103.53	Per Protocol, As Needed
HCV viral load	164.22	Per Protocol, As Needed
HIV viral load	154.70	Per Protocol, As Needed
CD4 T-cell count	91.63	Per Protocol, As Needed
FSH	51.17	Per Protocol, As Needed
High-sensitivity serum pregnancy (women of childbearing potential)	32.13	Per Protocol, As Needed
Pregnancy (WoCBP) - urine	22.61	Per Protocol, As Needed
Collection of blood for HLA-A testing / Brenetafusp PK / Brenetafusp ADA / Blood for mRNA / Blood for PBMC / Blood for ctDNA samples as applicable	28.56	Per Protocol, As Needed
Lab handling of blood samples for shipment to central laboratory	24.99	Per Protocol, As Needed
HLA-A testing (optional local testing with participant consent)	217.77	Per Protocol, As Needed
Brain CT Scan; with contrast; including Interpretation and Report	797.30	Per Protocol, As Needed
Brain CT Scan; without contrast; including Interpretation and Report	742.56	Per Protocol, As Needed
Brain MRI; with contrast; including Interpretation and Report	1455.37	Per Protocol, As Needed
Brain MRI; without contrast; including Interpretation and Report	1345.89	Per Protocol, As Needed
Neck CT Scan; with contrast; including Interpretation and Report	877.03	Per Protocol, As Needed
Neck CT Scan; without contrast; including Interpretation and Report	811.58	Per Protocol, As Needed
Neck MRI; with contrast; including Interpretation and Report	1498.21	Per Protocol, As Needed
Neck MRI; without contrast; including Interpretation and Report	882.98	Per Protocol, As Needed
Chest CT Scan; with contrast; including Interpretation and Report	896.07	Per Protocol, As Needed
Chest CT Scan; without contrast; including Interpretation and Report	818.72	Per Protocol, As Needed
Chest MRI; with contrast; including Interpretation and Report	1411.34	Per Protocol, As Needed
Chest MRI; without contrast; including Interpretation and Report	1314.95	Per Protocol, As Needed
Abdomen CT Scan; with contrast; including Interpretation and Report	1079.33	Per Protocol, As Needed
Abdomen CT Scan; without contrast; including Interpretation and Report	956.76	Per Protocol, As Needed
Abdomen MRI; with contrast; including Interpretation and Report	1155.49	Per Protocol, As Needed
Abdomen MRI; without contrast; including Interpretation and Report	1073.38	Per Protocol, As Needed
Pelvis CT Scan; with contrast; including Interpretation and Report	892.50	Per Protocol, As Needed
Pelvis CT Scan; without contrast; including Interpretation and Report	834.19	Per Protocol, As Needed
Pelvis MRI; with contrast; including Interpretation and Report	1231.65	Per Protocol, As Needed
Pelvis MRI; without contrast; including Interpretation and Report	1130.50	Per Protocol, As Needed

RECIST 1.1	26.18	Per Protocol, As Needed
Retrieve archival tumor tissue sample	65.45	Per Protocol, As Needed
Tumor biopsy	1143.59	Per Protocol, As Needed
Preparation of tumor tisse sample for shipment to central laboratory	138.04	Per Protocol, As Needed
BRAF V600 mutation status (local)	264.18	Per Protocol, As Needed
Skin punch biopsy	122.57	Per Protocol, As Needed
Hydration IV; up to 1 hour (Arm A and B)	114.24	Per Protocol, As Needed
Corticosteroids [hydrocortisone / methylprednisolone / dexamethasone] IV administration (Arm A and B)	91.63	Per Protocol, As Needed
acetaminophen/paracetamol IV administration (Arm A and B)	91.63	Per Protocol, As Needed
Diphenhydramine [or equivalent per protocol] IV administration (Arm A and B)	91.63	Per Protocol, As Needed
Ondansetron [or equivalent per protocol] IV administration (Arm A and B)	91.63	Per Protocol, As Needed
Pharmacy fee - Dispense [oral] acetaminophen/paracetamol (Arm A and B)	38.08	Per Protocol, As Needed
Pharmacy fee - Dispense IV acetaminophen/paracetamol (Arm A and B)	53.55	Per Protocol, As Needed
Pharmacy fee - Dispense [oral] Diphenhydramine [or equivalent per protocol] (Arm A and B)	38.08	Per Protocol, As Needed
Pharmacy fee - Dispense IV Diphenhydramine [or equivalent per protocol] (Arm A and B)	53.55	Per Protocol, As Needed
Pharmacy fee - Dispense IV fluids (Arm A and B)	53.55	Per Protocol, As Needed
Pharmacy fee - Dispense [oral] Ondansetron [or equivalent per protocol] (Arm A and B)	38.08	Per Protocol, As Needed
Pharmacy fee - Dispense IV Ondansetron [or equivalent per protocol] (Arm A and B)	53.55	Per Protocol, As Needed
Pharmacy fee - Dispense IV corticosteroids [hydrocortisone / methylprednisolone / dexamethasone] (Arm A and B)	53.55	Per Protocol, As Needed
Tocilizumab IV infusion; up to 1 hour (Arm A and B)	113.05	Per Protocol, As Needed
Pharmacy fee - Dispense IV Tocilizumab (Arm A and B)	53.55	Per Protocol, As Needed
Daily Facility Charge	566.44	As Needed
Overnight Facility Charge	1608.88	As Needed
Subject Travel Expense Reimbursement *up to*	33.32	1 x clinic visit
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's applicable expense reimbursements)	Invoice	As Needed
Screen Failures	1,369.69	Each Screen Failure(s) to be reimbursed in amount equal to Screening visit

INVOICEABLE SITE COST ITEMS (inclusive of Overhead)	**COST**	**FREQUENCY**
Protocol Amendment (admin costs)	3,000	Per Protocol Amendment. amount due before signing the amendment
Study Start-Up Fee + Document Storage / Record Retention (fee for ICTC Fund-Internal Clinical Trials Commission [CISC Commissione interna per le Sperimentazioni Cliniche]	3,000	1x, at FE CTA