

AMENDMENT 2 TO the AGREEMENT

THIS AMENDMENT AGREEMENT (the "**Amendment 2**") is entered into as of the date of last signature hereof between **Syneos Health iVH UK Limited** (hereinafter "**CRO**") with registered offices in Farnborough Business Park 1 Pinehurst Road Farnborough Hants GU14 7BF – United Kingdom, VAT registration number and tax code GB385756207, authorized to undertake clinical trials on behalf of Pfizer Inc. (hereinafter "**Sponsor**"),

and

Hospital facility Azienda Socio Sanitaria (ASST) della Valtellina e dell'Alto Lario (hereinafter "**Institution**") with offices in Sondrio, via Stelvio no 25, Italy office-PEC address: protocollo@pec.asst-val.i, Tax code/VAT registration number 00988090148, represented for the purposes of this Act by Dr. Tommaso Saporito, in his capacity as General Director

WHEREAS, Syneos Health iVH UK Limited is acting on behalf of Pfizer Inc. ("**Pfizer**") to arrange and administer the clinical study **B9991010** A RANDOMIZED, OPEN-LABEL, MULTICENTER, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF AVELUMAB (MSB0010718C) IN COMBINATION WITH AND/OR FOLLOWING CHEMOTHERAPY IN PATIENTS WITH PREVIOUSLY UNTREATED EPITHELIAL OVARIAN CANCER and has entered into an agreement with Sponsor concerning the management of such study; and

EMENDAMENTO 2 ALLA CONVENZIONE CONTRATTO DI SPERIMENTAZIONE CLINICA

IL PRESENTE EMENDAMENTO CONTRATTUALE ("**Emendamento2**") efficace dall'ultima data di sottoscrizione qui apposta tra **Syneos Health iVH UK Limited** con sede legale in Farnborough Business Park 1 Pinehurst Road Farnborough Hants GU14 7BF – United Kingdom P.I. e C.F. n. GB385756207, autorizzata a intraprendere Sperimentazioni cliniche per conto di Pfizer Inc (di seguito per brevità "**Promotore**"),

E

Struttura ospedaliera L'Azienda Socio Sanitaria (ASST) della Valtellina e dell'Alto Lario (di seguito per brevità "**Azienda**"), con sede in Sondrio, via Stelvio n. 25, Italia indirizzo PEC: protocollo@pec.asst-val.it, C.F./P.I. 00988090148, rappresentata ai fini del presente atto dal Dr. Tommaso Saporito in qualità di Direttore Generale

PREMESSO CHE

Syneos Health iVH UK Limited agisce per conto di Pfizer, Inc. ("**Pfizer**") per l'organizzazione e l'amministrazione della sperimentazione clinica n. **B9991010** STUDIO RANDOMIZZATO, IN APERTO, MULTICENTRICO, DI FASE 3 PER VALUTARE L'EFFICACIA E LA SICUREZZA DI AVELUMAB (MSB0010718C) IN ASSOCIAZIONE A E/O SUCCESSIVAMENTE A CHEMIOTERAPIA IN PAZIENTI AFFETTI DA TUMORE OVARICO EPITELIALE NON PRECEDENTEMENTE TRATTATO", sottoscrivendo con lo stesso Sponsor un contratto riguardante la gestione di tale sperimentazione; e

WHEREAS, the parties entered into a certain Clinical Site Agreement, which was fully executed on 17 February, 2017 the “Agreement” and amended on January 26, 2018; and

WHEREAS, the parties wish to amend the Agreement to:

- provide for certain changes in Facility’s payment information due to the addition to the budget of 2 additional maintenance treatments Day 15 and Day 29, not included in previous contract amendment 1 fully executed January 26, 2018.

NOW THEREFORE, in consideration of the promises and mutual covenants herein contained, the sufficiency of which all parties acknowledge, the parties agree to the following amendments to the Agreement:

1. The budget table included as Annex A – Trial Budget to the Agreement will be replaced in its entirety with that attached as Annex A – Trial Budget hereto and made a part hereof.
2. Except as provided for in this Amendment 2, all other provisions of the Agreement will remain unchanged and will be fully applicable to this Amendment 2.
3. This Amendment 2 may be executed in two or more counterparts, each of which will be deemed an original, but all of which will constitute one in the same instrument. A facsimile transmission of this signed Amendment 2 or email transmission of a PDF of this signed Amendment 2 bearing a signature on

CHE le Parti hanno sottoscritto un Contratto di Sperimentazione clinica, entrato in vigore il 17 Febbraio 2017 di seguito il “Contratto” ed emendato il 26 Gennaio 2018); e

CHE le Parti intendono modificare il Contratto per

- provvedere a una serie di modifiche nelle informazioni di pagamento dell’Ente dovute all’aggiunta nel budget di due visite di Additional maintenance treatments Day 15 and Day 29 non incluse nel precedente emendamento al contratto Emendamento 1 26gennaio 2018;

TUTTO CIÒ PREMESSO, in considerazione delle premesse e dei patti reciproci qui contenuti e riconosciuti adeguati da tutti i contraenti, le parti accettano le seguenti modifiche al Contratto:

1. La tabella budget inclusa come *Annex A - Budget* dello studio al contratto sarà sostituita nella sua interezza come Annex A – Budget dello studio del presente documento e farà una parte del presente.
2. Salvo quanto previsto nel presente Emendamento 2 tutte le altre clausole del Contratto rimarranno invariate e saranno pienamente applicabili all’Emendamento 2 stesso.
3. Il presente Emendamento 2 potrà essere firmato in due o più copie, ciascuna delle quali sarà considerata esemplare originale e avendo riguardo che tutte le copie rappresenteranno un unico e medesimo atto. La trasmissione a mezzo apparecchiatura fax del presente Emendamento 2 firmato oppure la

<p>behalf of a party will be legal and binding on such a party.</p> <p>4. This Amendment 2 embodies the entire agreement and understanding of the Parties regarding its subject matter.</p> <p>5. This Amendment 2 may be modified only in a writing signed by the Parties.</p> <p>IN WITNESS WHEREOF, the parties hereto have set their hands in duplicate with the intention that this be a binding agreement as provided herein.</p> <p>Read, approved and signed.</p> <p>For the Institution: I'A.S.S.T. della Valtellina e dell'Alto Lario</p> <p>The delegate General Director</p> <p>Dr. Tommaso Saporito</p> <p>Date : _____</p> <p>Signature : _____</p> <p>For the Sponsor/CRO: inVentiv Health Clinical UK Ltd.</p> <p>Dr. Elena Vigorelli</p>	<p>trasmissione per posta elettronica del presente Emendamento 2 sottoscritto in formato PDF recante la firma di rappresentanza di una parte, sarà valida e vincolante nei confronti di tale parte.</p> <p>4. Il presente Emendamento2 racchiude l'intero accordo e l'intesa delle Parti riguardo all'oggetto dello stesso.</p> <p>5. Il presente Emendamento 2 potrà essere oggetto di cambiamenti soltanto in forma scritta firmata dalle Parti.</p> <p>IN FEDE DI CHE, le parti qui convenute hanno apposto di proprio pugno la firma in duplice copia con l'intento di rendere vincolante il presente contratto come qui previsto.</p> <p>Letto, approvato e sottoscritto.</p> <p>per l'Azienda : I'A.S.S.T. della Valtellina e dell'Alto Lario</p> <p>Il Direttore Generale</p> <p>Dott. Tommaso Saporito</p> <p>Data : _____</p> <p>Firma : _____</p> <p>P. il Promotore/CRO: inVentiv Health Clinical UK Ltd</p> <p>Dr.ssa Elena Vigorelli</p>
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AS

<p>Date : _____</p> <p>Signature : _____</p> <p>In acknowledgement and acceptance</p> <p>The Principal Investigator</p> <p>Dr. Alessandro Bertolini</p> <p>Date : _____</p> <p>Signature : _____</p>	<p>Data : _____</p> <p>Firma : _____</p> <p>Per presa visione e accettazione</p> <p>Lo Sperimentatore Principale</p> <p>Dott. Alessandro Bertolini</p> <p>Data : _____</p> <p>Firma : _____</p>
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ANNEX A
TRIAL BUDGET/BUDGET DELLO STUDIO



ANNEX A
TRIAL BUDGET/BUDGET DELLO STUDIO

COMPOUND :	MSB0010718C	AMENDMENT :	1/2
STUDY NUMBER :	B9991010	ARM/COHORT :	1/2
TITLE :	A RANDOMIZED, OPEN-LABEL, MULTICENTER, PHASE 3 STUDY TO EVALUATE THE EFFICACY AND SAFETY OF AVELUMAB (MSB0010718C) IN COMBINATION WITH AND/OR FOLLOWING CHEMOTHERAPY IN PATIENTS WITH PREVIOUSLY UNTREATED EPITHELIAL OVARIAN CANCER		
COUNTRY/Currency :	Italy - EUR		
OVERHEAD	15,00%		

INVESTIGATOR: Alessandro Bertolini
INSTITUTION: Azienda Socio Sanitaria Territoriale
CCID:

	DESCRIPTION OF COST	Comments	Frequency of Procedure		
			COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC
Per Subject Cost	Informed Consent/Medical History	Includes: Oncological History	74.00	1.0	74
	Physical Examination	Includes: ECOG Performance Status	103.00	13.0	1339
	Hematology		21.00	12.0	252
	Full Blood Chemistry		160.00	12.0	1920
	Coagulation		12.00	12.0	144
	CA-125		48.00	13.0	624
	Thyroid Function Test & ACTH		108.00	4.0	432
	HBV and HCV		53.00	6.0	318
	Urinalysis		4.00	6.0	24
	12-Lead ECG (Single)		55.00	5.0	275
	Sample Collection (collection, processing, shipment to central labs)	Includes: banked blood biospecimen for genotyping, banked blood biospecimen for exploratory biomarker assessments	31.00	8.0	248
	Study Coordinator Fee	Includes: contraception check, blood pressure, pulse rate, BRCA 1/2 mutation status, randomization, AE monitoring and review with PI, concomitant medications and treatments, dispense and monitor patient reported outcomes (FOSI-18, EQ-5D-5L)	78.00	28.5	2223
	Admin/Data Entry		28.00	28.5	798
			PSC Subtotal w/out Overhead		8,671.00
			PSC Subtotal with Overhead		10,058.36

VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5		VISIT 6	
f	Screening	f	Chemotherapy Phase Cycle 1 Day 1	f	Chemotherapy Phase Cycle 1 Day 8	f	Chemotherapy Phase Cycle 1 Day 15	f	Chemotherapy Phase Cycle 2 Day 1	f	Chemotherapy Phase Cycle 2 Day 8
1.00	74.00		0.00		0.00		0.00		0.00		0.00
1.00	103.00	1.00	103.00		0.00		0.00	1.00	103.00		0.00
1.00	21.00		0.00		0.00		0.00	1.00	21.00		0.00
1.00	160.00		0.00		0.00		0.00	1.00	160.00		0.00
1.00	12.00		0.00		0.00		0.00	1.00	12.00		0.00
1.00	48.00	1.00	48.00		0.00		0.00	1.00	48.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
1.00	53.00		0.00		0.00		0.00		0.00		0.00
1.00	4.00		0.00		0.00		0.00		0.00		0.00
1.00	55.00	1.00	55.00		0.00		0.00		0.00		0.00
1.00	31.00	1.00	31.00		0.00		0.00	1.00	31.00		0.00
1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00
1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00
	667.00		343.00		106.00		106.00		481.00		106.00
	773.72		397.88		122.96		122.96		557.96		122.96

VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11		VISIT 12	
f	Chemotherapy Phase Cycle 2 Day 15	f	Chemotherapy Phase Cycle 3 Day 1	f	Chemotherapy Phase Cycle 3 Day 8	f	Chemotherapy Phase Cycle 3 Day 15	f	Chemotherapy Phase Cycle 4 Day 1	f	Chemotherapy Phase Cycle 4 Day 8
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	103.00		0.00		0.00	1.00	103.00		0.00
	0.00	1.00	21.00		0.00		0.00	1.00	21.00		0.00
	0.00	1.00	160.00		0.00		0.00	1.00	160.00		0.00
	0.00	1.00	12.00		0.00		0.00	1.00	12.00		0.00
	0.00	1.00	48.00		0.00		0.00	1.00	48.00		0.00
	0.00	1.00	108.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	55.00		0.00		0.00		0.00		0.00
	0.00	1.00	31.00		0.00		0.00	1.00	31.00		0.00
1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00
1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00
	106.00		644.00		106.00		106.00		481.00		106.00
	122.96		747.04		122.96		122.96		557.96		122.96

VISIT 13		VISIT 14		VISIT 15		VISIT 16		VISIT 17		VISIT 18	
f	Chemotherapy Phase Cycle 4 Day 15	f	Chemotherapy Phase Cycle 5 Day 1	f	Chemotherapy Phase Cycle 5 Day 8	f	Chemotherapy Phase Cycle 5 Day 15	f	Chemotherapy Phase Cycle 6 Day 1	f	Chemotherapy Phase Cycle 6 Day 8
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	103.00		0.00		0.00	1.00	103.00		0.00
	0.00	1.00	21.00		0.00		0.00	1.00	21.00		0.00
	0.00	1.00	160.00		0.00		0.00	1.00	160.00		0.00
	0.00	1.00	12.00		0.00		0.00	1.00	12.00		0.00
	0.00	1.00	48.00		0.00		0.00	1.00	48.00		0.00
	0.00	1.00	108.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	55.00		0.00		0.00		0.00		0.00
	0.00	1.00	31.00		0.00		0.00		0.00		0.00
1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00	1.00	78.00
1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00	1.00	28.00
	106.00		644.00		106.00		106.00		450.00		106.00
	122.96		747.04		122.96		122.96		522.00		122.96

VISIT 19		VISIT 20		VISIT 21		VISIT 22		VISIT 23		VISIT 24	
f	Chemotherapy Phase Cycle 6 Day 15	f	Maintenance Phase Cycle 1 Day 1	f	Maintenance Phase Cycle 1 Day 15	f	Maintenance Phase Cycle 1 Day 29	f	Maintenance Phase Cycle 2 Day 1	f	Maintenance Phase Cycle 2 Day 15
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	103.00		0.00		0.00	1.00	103.00		0.00
	0.00	1.00	21.00		0.00		0.00	1.00	21.00		0.00
	0.00	1.00	160.00		0.00		0.00	1.00	160.00		0.00
	0.00	1.00	12.00		0.00		0.00	1.00	12.00		0.00
	0.00	1.00	48.00		0.00		0.00	1.00	48.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	53.00		0.00		0.00	1.00	53.00		0.00
	0.00	1.00	4.00		0.00		0.00	1.00	4.00		0.00
	0.00	1.00	55.00		0.00		0.00		0.00		0.00
	0.00	1.00	31.00		0.00		0.00	1.00	31.00		0.00
1.00	78.00	1.00	78.00		0.00		0.00	1.00	78.00		0.00
1.00	28.00	1.00	28.00		0.00		0.00	1.00	28.00		0.00
	106.00		593.00		0.00		0.00		538.00		0.00
	122.96		687.88		0.00		0.00		624.08		0.00

VISIT 25		VISIT 26		VISIT 27		VISIT 28		VISIT 29		VISIT 30	
<i>f</i>	Maintenance Phase Cycle 2 Day 29	<i>f</i>	Maintenance Phase Cycle 3 Day 1	<i>f</i>	Maintenance Phase Cycle 3 Day 15	<i>f</i>	Maintenance Phase Cycle 3 Day 29	<i>f</i>	Maintenance Phase Cycle 4 Day 1	<i>f</i>	Maintenance Phase Cycle 4 Day 15
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	103.00		0.00		0.00	1.00	103.00		0.00
	0.00	1.00	21.00		0.00		0.00	1.00	21.00		0.00
	0.00	1.00	160.00		0.00		0.00	1.00	160.00		0.00
	0.00	1.00	12.00		0.00		0.00	1.00	12.00		0.00
	0.00	1.00	48.00		0.00		0.00	1.00	48.00		0.00
	0.00	1.00	108.00		0.00		0.00		0.00		0.00
	0.00	1.00	53.00		0.00		0.00	1.00	53.00		0.00
	0.00	1.00	4.00		0.00		0.00	1.00	4.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	78.00		0.00		0.00	1.00	78.00		0.00
	0.00	1.00	28.00		0.00		0.00	1.00	28.00		0.00
	0.00		615.00		0.00		0.00		507.00		0.00
	0.00		713.40		0.00		0.00		588.12		0.00

VISIT 31		VISIT 32		VISIT 33		VISIT 34		VISIT 35	
<i>f</i>	Maintenance Phase Cycle 4 Day 29	<i>f</i>	Maintenance Phase Cycle 5 Day 1	<i>f</i>	Maintenance Phase Cycle 5 Day 15	<i>f</i>	Maintenance Phase Cycle 5 Day 29	<i>f</i>	End of Treatment/ Withdrawal
	0.00		0.00		0.00		0.00		0.00
	0.00	1.00	103.00		0.00		0.00	1.00	103.00
	0.00	1.00	21.00		0.00		0.00	1.00	21.00
	0.00	1.00	160.00		0.00		0.00	1.00	160.00
	0.00	1.00	12.00		0.00		0.00	1.00	12.00
	0.00	1.00	48.00		0.00		0.00	1.00	48.00
	0.00		0.00		0.00		0.00	1.00	108.00
	0.00	1.00	53.00		0.00		0.00		0.00
	0.00	1.00	4.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00
	0.00	1.00	78.00		0.00		0.00	1.00	78.00
	0.00	1.00	28.00		0.00		0.00	1.00	28.00
	0.00		507.00		0.00		0.00		558.00
	0.00		588.12		0.00		0.00		647.28

Additional Treatment Related Costs	Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC
TO BE INVOICED	Serum Pregnancy Test	Applicable to WOCBP	21.00	2.0	42
	Urine Pregnancy Test	Applicable to WOCBP	12.00	13.0	156
	Hematology	Applicable to C1D1 if not performed within last 7 days	21.00	1.0	21
	Full Blood Chemistry	Applicable to C1D1 if not performed within last 7 days	160.00	1.0	160
	Coagulation	Applicable to C1D1 if not performed within last 7 days	12.00	1.0	12
	Thyroid Function Test & ACTH	To be performed at screening or cycle 1 day 1.	108.00	2.0	216
	Archival FFPE Tumor Tissue Block	Applicable to subjects with tumor tissue available at screening	32.00	1.0	32
	De Novo Tumor Biopsy - Excision	Applicable to subjects who do not have tumor tissue available at screening	323.00	1.0	323
	De Novo Tumor Biopsy - Core Needle	Applicable to subjects who do not have tumor tissue available at screening	432.00	1.0	432
	De Novo Tumor Biopsy - Excision	Applicable to EoT if subject discontinues due to disease progression.	323.00	1.0	323
	De Novo Tumor Biopsy - Core Needle	Applicable to EoT if subject discontinues due to disease progression.	432.00	1.0	432
	Physical Examination	Applicable to Arm B and C, optional for Arm A at days 15 and 29 for maintenance phase.	103.00	10.0	1030
	Hematology	Applicable days 8 and 15 for subjects on QW paclitaxel during chemotherapy phase. Applicable to Arm B and C, optional for Arm A at days 15 and 29 for maintenance phase.	21.00	22.0	462
	Core Blood Chemistry	Applicable to Arm B and C, optional for Arm A at days 15 and 29 for maintenance phase.	40.00	10.0	400
	Paclitaxel and Carboplatin Administration - QW Administration	If applicable	203.00	18.0	3654
	Paclitaxel and Carboplatin Administration - Q3 Administration	If applicable	203.00	6.0	1218
	Administration of Avelumab	Applicable to Arms B and C only.	203.00	21.0	4263
	Sample Collection (collection, processing, shipment to central labs)	Includes: banked blood biospecimen for exploratory biomarker assessments. Applicable to Arms B and C only.	31.00	4.0	124
	Study Coordinator Fee	Applicable at days 15 and 29 for maintenance phase.	78.00	10.0	780
	Admin/Data Entry	Applicable at days 15 and 29 for maintenance phase.	28.00	10.0	280
	Paclitaxel PK		20.00	8.0	160
	Carboplatin PK		20.00	8.0	160
	Avelumab PK/ADA Arm B	Applicable to Arm B subjects only	20.00	25.0	500
Avelumab PK/ADA Arm C - Taxl q3 weeks	Applicable to Arm C subjects only	20.00	37.0	740	
Avelumab PK/ADA Arm C - Taxl weekly	Applicable to Arm C subjects only	20.00	45.0	900	
Summary Costs	Per Subject Cost Subtotal				8,671.00
	Additional Cost Subtotal				16,820.00
	Subtotal				25,491.00
	Overhead				4,078.56
	INVESTIGATOR COST PER SUBJECT with Overhead				29,569.56

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<i>f</i>	Screening	<i>f</i>	Chemotherapy Phase Cycle 1 Day 1	<i>f</i>	Chemotherapy Phase Cycle 1 Day 8	<i>f</i>	Chemotherapy Phase Cycle 1 Day 15	<i>f</i>	Chemotherapy Phase Cycle 2 Day 1	<i>f</i>	Chemotherapy Phase Cycle 2 Day 8
1.00	21.00	1.00	21.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00	1.00	12.00		0.00
	0.00	1.00	21.00		0.00		0.00		0.00		0.00
	0.00	1.00	160.00		0.00		0.00		0.00		0.00
	0.00	1.00	12.00		0.00		0.00		0.00		0.00
1.00	108.00	1.00	108.00		0.00		0.00		0.00		0.00
1.00	32.00		0.00		0.00		0.00		0.00		0.00
1.00	323.00		0.00		0.00		0.00		0.00		0.00
1.00	432.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00	1.00	21.00	1.00	21.00		0.00	1.00	21.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	1.00	203.00	1.00	203.00	1.00	203.00	1.00	203.00	1.00	203.00
	0.00	1.00	203.00		0.00		0.00	1.00	203.00		0.00
	0.00	1.00	203.00		0.00		0.00	1.00	203.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00	8.00	160.00		0.00
	0.00		0.00		0.00		0.00	8.00	160.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00
	0.00	3.00	60.00		0.00		0.00	3.00	60.00		0.00
	0.00	3.00	60.00	1.00	20.00	1.00	20.00	3.00	60.00	1.00	20.00
	667.00		343.00		106.00		106.00		481.00		106.00
	916.00		1,051.00		244.00		244.00		1,061.00		244.00
	1,583.00		1,394.00		350.00		350.00		1,542.00		350.00
	253.28		223.04		56.00		56.00		246.72		56.00
	1,836.28		1,617.04		406.00		406.00		1,788.72		406.00

f	Chemotherapy Phase Cycle 6 Day 15	f	Maintenance Phase Cycle 1 Day 1	f	Maintenance Phase Cycle 1 Day 15	f	Maintenance Phase Cycle 1 Day 29	f	Maintenance Phase Cycle 2 Day 1	f	Maintenance Phase Cycle 2 Day 15	f
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00	1.00	12.00		0.00		0.00	1.00	12.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00	1.00	103.00	1.00	103.00		0.00	1.00	103.00	1.00
1.00	21.00		0.00	1.00	21.00	1.00	21.00		0.00	1.00	21.00	1.00
	0.00		0.00	1.00	40.00	1.00	40.00		0.00	1.00	40.00	1.00
1.00	203.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00	1.00	203.00	1.00	203.00	1.00	203.00	1.00	203.00	1.00	203.00	1.00
	0.00		0.00	1.00	31.00	1.00	31.00		0.00	1.00	31.00	1.00
	0.00		0.00	1.00	78.00	1.00	78.00		0.00	1.00	78.00	1.00
	0.00		0.00	1.00	28.00	1.00	28.00		0.00	1.00	28.00	1.00
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00		0.00		0.00		0.00		0.00		0.00	
	0.00	3.00	60.00	3.00	60.00	2.00	40.00	3.00	60.00	1.00	20.00	
	0.00	3.00	60.00	3.00	60.00	2.00	40.00	3.00	60.00	1.00	20.00	
	0.00	3.00	60.00	3.00	60.00	2.00	40.00	3.00	60.00	1.00	20.00	
	106.00		593.00		0.00		0.00		538.00		0.00	
	224.00		395.00		684.00		624.00		395.00		564.00	
	330.00		988.00		684.00		624.00		933.00		564.00	
	52.80		158.08		109.44		99.84		149.28		90.24	
	382.80		1,146.08		793.44		723.84		1,082.28		654.24	

Maintenance Phase Cycle 2 Day 29	f	Maintenance Phase Cycle 3 Day 1	f	Maintenance Phase Cycle 3 Day 15	f	Maintenance Phase Cycle 3 Day 29	f	Maintenance Phase Cycle 4 Day 1	f	Maintenance Phase Cycle 4 Day 15	f	Maintenance Phase Cycle 4 Day 29	f	Maintenance Phase Cycle 5 Day 1
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00	1.00	12.00		0.00		0.00	1.00	12.00		0.00		0.00	1.00	12.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
103.00		0.00	1.00	103.00	1.00	103.00		0.00	1.00	103.00	1.00	103.00		0.00
21.00		0.00	1.00	21.00	1.00	21.00		0.00	1.00	21.00	1.00	21.00		0.00
40.00		0.00	1.00	40.00	1.00	40.00		0.00	1.00	40.00	1.00	40.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00	1.00	0.00
203.00		203.00		203.00		203.00		203.00		203.00		203.00		203.00
31.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
78.00		0.00	1.00	78.00	1.00	78.00		0.00	1.00	78.00	1.00	78.00		0.00
28.00		0.00	1.00	28.00	1.00	28.00		0.00	1.00	28.00	1.00	28.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00		0.00		0.00		0.00		0.00		0.00		0.00		0.00
0.00	3.00	60.00		0.00		0.00	3.00	60.00		0.00		0.00	3.00	60.00
0.00	3.00	60.00		0.00		0.00	3.00	60.00		0.00		0.00	3.00	60.00
0.00	3.00	60.00		0.00		0.00	3.00	60.00		0.00		0.00	3.00	60.00
0.00		615.00		0.00		0.00		507.00		0.00		0.00		507.00
504.00		395.00		473.00		473.00		395.00		473.00		473.00		395.00
504.00		1,010.00		473.00		473.00		902.00		473.00		473.00		902.00
80.64		161.60		75.68		75.68		144.32		75.68		75.68		144.32
584.64		1,171.60		548.68		548.68		1,046.32		548.68		548.68		1,046.32

AB

f	Maintenance Phase Cycle 5 Day 15	f	Maintenance Phase Cycle 5 Day 29	f	End of Treatment/ Withdrawal	f	Safety Follow-Up Day 30	f	Safety Follow-Up Day 60	f	Safety Follow-Up Day 90	f	Survival Follow-Up
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00	1.00	12.00	1.00	12.00	1.00	12.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00	1.00	323.00		0.00		0.00		0.00		0.00
	0.00		0.00	1.00	432.00		0.00		0.00		0.00		0.00
1.00	103.00	1.00	103.00		0.00		0.00		0.00		0.00		0.00
1.00	21.00	1.00	21.00		0.00		0.00		0.00		0.00		0.00
1.00	40.00	1.00	40.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
1.00	203.00	1.00	203.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
1.00	78.00	1.00	78.00		0.00		0.00		0.00		0.00		0.00
1.00	28.00	1.00	28.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00		0.00		0.00		0.00		0.00		0.00
	0.00		0.00	2.00	40.00	2.00	40.00		0.00		0.00		0.00
	0.00		0.00	2.00	40.00	2.00	40.00		0.00		0.00		0.00
	0.00		0.00	2.00	40.00	2.00	40.00		0.00		0.00		0.00
	0.00		0.00	2.00	40.00	2.00	40.00		0.00		0.00		0.00
	0.00		0.00		558.00		106.00		106.00		106.00		53.00
	473.00		473.00		887.00		132.00		12.00		0.00		0.00
	473.00		473.00		1,445.00		238.00		118.00		106.00		53.00
	75.68		75.68		231.20		38.08		18.88		16.96		8.48
	548.68		548.68		1,676.20		276.08		136.88		122.96		61.48

AB

Other Study Level Costs	Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit)		
	Procedure	Comments	Cost
	Central IRB Fees		To be paid directly.
	Local IRB/EC Fees - Initial Review		To be paid directly.
	Local IRB/EC Fees - Amendment		To be paid directly.
	Local IRB/EC Fees - Annual Review		To be paid directly.
	Screen Fails	Applicable to subjects who SF at Visit 1. Max 1 SF per 3 randomized subjects per site.	500.25
	CT Chest	Either CT or MRI to be performed, not both.	655.00
	CT Abdomen	Either CT or MRI to be performed, not both.	696.00
	CT Pelvis	Either CT or MRI to be performed, not both.	518.00
	CT Brain	Either CT or MRI to be performed, not both.	490.00
	MRI Chest	Either CT or MRI to be performed, not both.	912.00
	MRI Abdomen	Either CT or MRI to be performed, not both.	822.00
	MRI Pelvis	Either CT or MRI to be performed, not both.	794.00
	MRI Brain	Either CT or MRI to be performed, not both.	955.00
	Bone Scan	To be invoiced as necessary.	405.00
	Hematology	To be performed if clinically indicated.	21.00
	Core Blood Chemistry	To be performed if clinically indicated.	40.00
	Coagulation	To be performed if clinically indicated.	12.00
	ALT, AST, Total Bilirubin, and Alkaline Phosphate	To be performed weekly for first 6 weeks of treatment for patients with liver metastases.	38.00
	Thyroid Function Test & ACTH	To be performed if clinically indicated.	108.00
	Urinalysis	To be performed if clinically indicated.	4.00
	Microscopic Urinalysis	To be performed if dipstick urinalysis is abnormal.	8.00
	12-Lead ECG (Single)	To be performed if clinically indicated.	55.00
	Urine Pregnancy Test	To be performed if requested by IRB/IEC or required by local regulations.	12.00
	Additional Maintenance Treatments - Day 1	Applicable to subjects that receive additional cycles of maintenance treatment beginning at Cycle 6.	588.12
	Additional Maintenance Treatments - Day 15	Applicable to Arm B and C, optional for Arm A at days 15 and 29 for maintenance phase beginning at Cycle 6.	548.68
	Additional Maintenance Treatments - Day 29	Applicable to Arm B and C, optional for Arm A at days 15 and 29 for maintenance phase beginning at Cycle 6.	548.68
	Additional Survival Follow-Up Visit	To be invoiced as necessary.	61.48
	Additional Maintenance Treatments - Administration of Avelumab	Applicable to subject that receive additional cycles of maintenance treatment.	203.00
	Additional Maintenance Treatments - Avelumab PK/ADA	Applicable to subject that receive additional cycles of maintenance treatment.	20.00
	Paclitaxel Reimbursement	To be provided to site directly.	
	Carboplatin Reimbursement	To be provided to site directly.	

Bo