15th CONGRESS on Lung CANCER

MADRID

23&24 November 2023

#15CongressGECP

Fundación GECP lung cancer research

Session III: GECP trials and Project updated

TRIALS IN ADVANCED STAGES

Elia Sais Girona
Thoracic Oncology Group
Medical Oncology Department
ICO Girona
OncoGirPro, IDIBGI

DISCLOSURE INFORMATION

✓ **Employment:** Medical oncologist ICO Girona (Girona)

✓ **Consultant or Advisory Role**: MSD, Bristol-Myers, Roche, Astrazeneca, Boehringer Ingelheim

✓ **Speaking:** MSD, Bristol-Myers, Roche, Boehringer Ingelheim, Pfizer, Astrazeneca, Lilly, Takeda

✓ **Stock Ownership:** N/A

✓ **Research Funding:** N/A

✓ **Grant support:** N/A

✓ **Other:** N/A

TRIALS IN ADVANCED STAGES

TRIALS IN ADVANCED STAGES

- **OMD**: STEREO, CHESS

TRIALS IN ADVANCED STAGES

- **OMD**: STEREO, CHESS
- **ADVANCED STAGES:** NIVIPIBRAIN, AMAZE-Lung, ADDEPT

OMD (Oligometastatic disease)

Why is oligometastatic disease relevant?

LOCAL DISEASE CONTROL OF PRIMARY/METASTASES WITH RADICAL TREATMENTS

Can...

⇧ OS, DFS, PFS

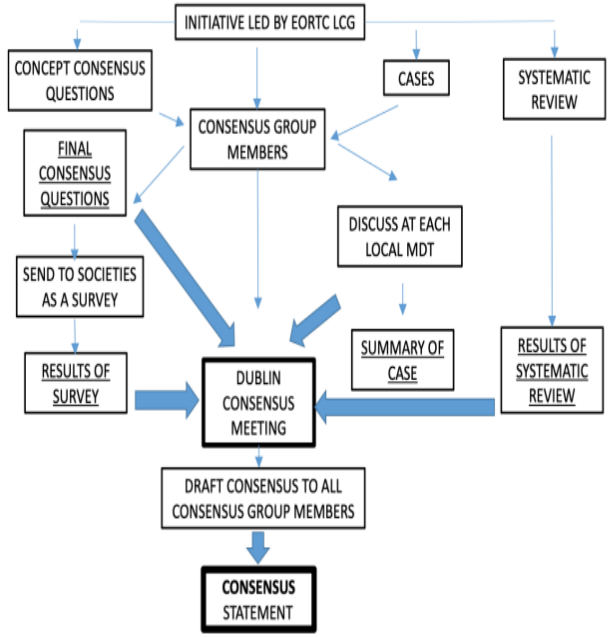
Available evidence:
- Retrospective series
- Phase II studies
- Phase III studies (few yet)

And maybe...

CURE SOME PATIENTS?

Definition of oligometastatic disease (synchronous) in NSCLC

EORTC-LCG Consensus Report



- ✓ Maximum number of metastatic lesions: 5
- ✓ Maximum number of involved organs: 3
- ✓ Excluded: diffuse serosal and bone marrow mets
- ✓ Detected by: 18-FDG PET-TC and brain MRI
- ✓ Mediastinal lymph node is considered local disease, but it could determine whether radical local treatment of the primary is fesasible
- ✓ Concerns: does not take into account histology, genomic alterations and tumor volume

All lesions (both primary and metastatic) should be amenable to radical intent treatment with acceptable toxicity

Intermediate state between purely localized and widely metastatic

Dingermans AC, J Thorac Oncol 2019

OMD (Oligometastatic disease)

Why is oligometastatic disease relevant?

Definition of oligometastatic disease (synchronous) in NSCLC

EORTC-LCG Consensus Report

OligoCare Project by EORTC and ESTRO

System for the characterization and classification of oligometastatic disease

Characterisation and classification of oligometastatic disease: a European Society for Radiotherapy and Oncology and European Organisation for Research and Treatment of Cancer consensus recommendation

Prof Matthias Guckenberger, MD • Prof Yolande Lievens, PhD • Angelique B Bouma, MD • Laurence Collette, PhD • Andre Dekker, PhD • Prof Nandita M deSouza, FRCR • et al. Show all authors

Objective: limit the heterogeneity of patients enrolled in new clinical trials

- Phase II studies
- Phase III studies (few yet)

And maybe...

CURE SOME PATIENTS?

DRAFT CONSENSUS TO ALL CONSENSUS GROUP MEMBERS

CONSENSUS STATEMENT

the primary is resasible

✓ Concerns: does not take into account histology, genomic alterations and tumor volume

All lesions (both primary and metastatic) should be amenable to radical intent treatment with acceptable toxicity

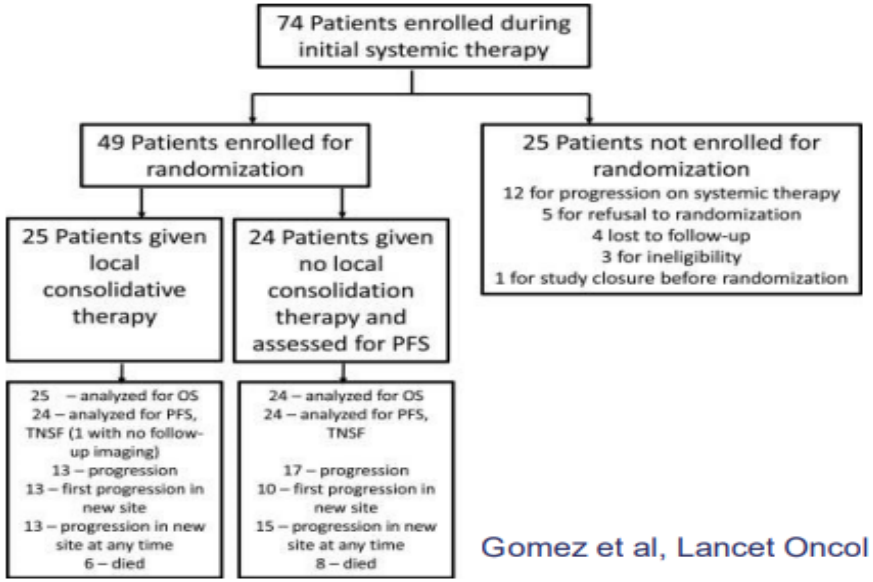
Dingermans AC, J Thorac Oncol 2019

Intermediate state between purely localized and widely metastatic

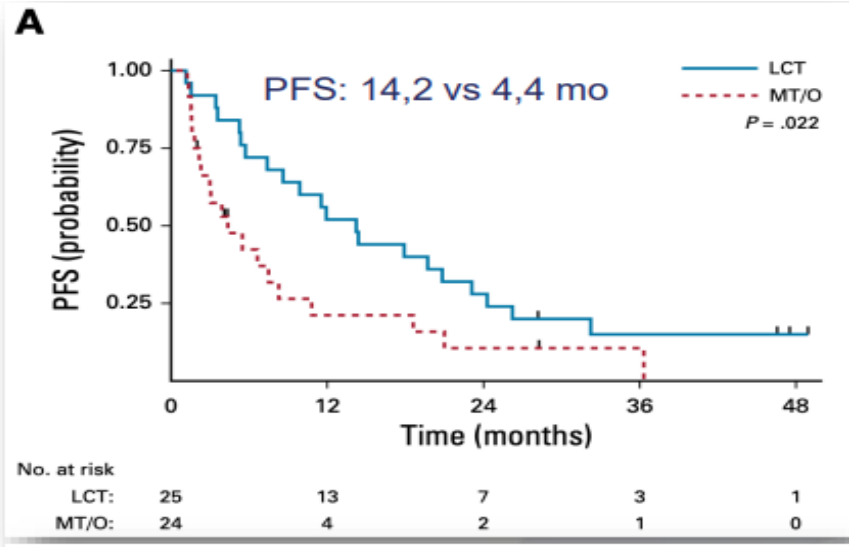
PROSPECTIVE RANDOMIZED PHASE 2 TRIALS "OLIGOMEZ"

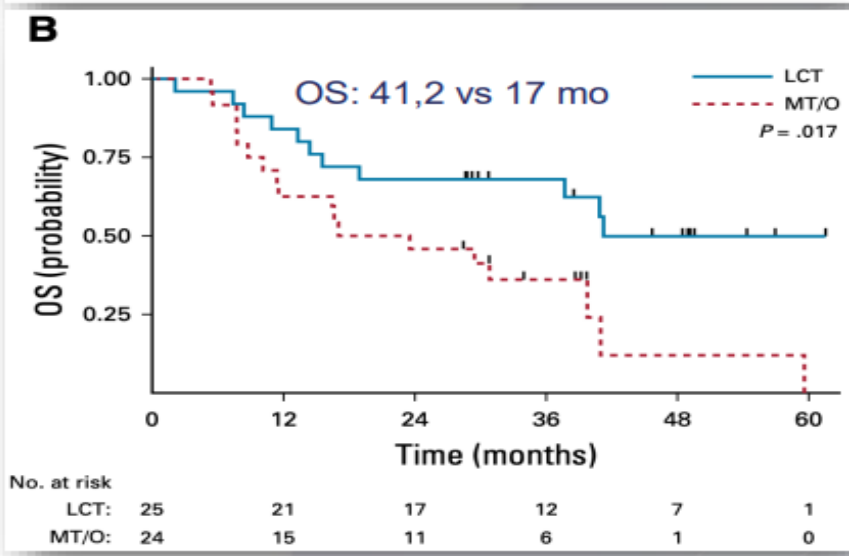
Local consolidative therapy (surgery/RT) vs maintenance/obs

- 49 patients with stage IV NSCLC (8 EGFR/ALK)
- 1-3 metastatic sites
- 2012-2016
- Prior standard chemotherapy whithout progression (at least 4 CT cycles or 3 months of erlotinib or crizotinib)
- Metachronous 6% / Synchronous 94%
- Primary endpoint: PFS



Gomez et al, Lancet Oncol 2016; Gomez et al, J Clin Oncol 2019

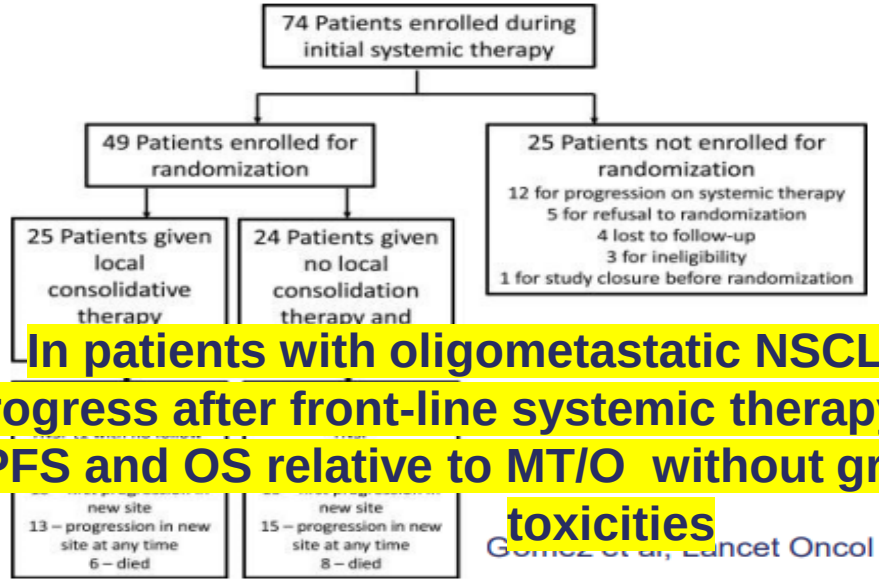




PROSPECTIVE RANDOMIZED PHASE 2 TRIALS "OLIGOMEZ"

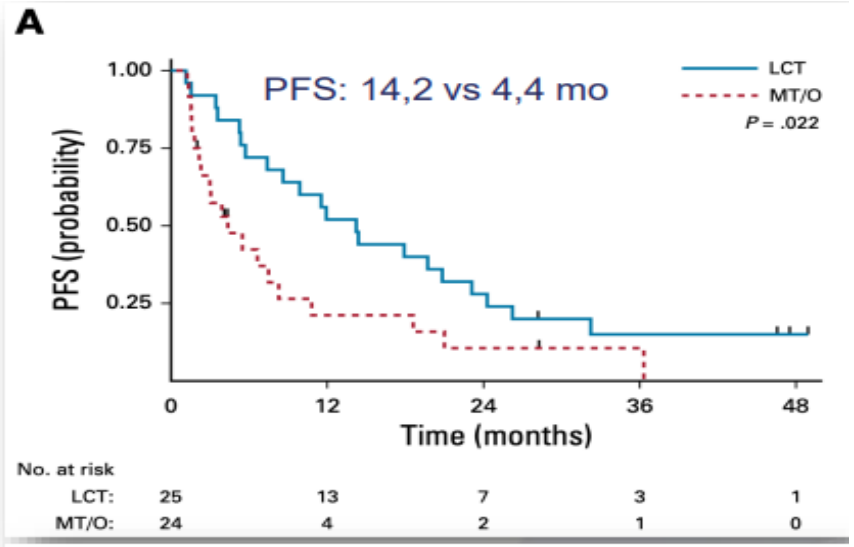
Local consolidative therapy (surgery/RT) vs maintenance/obs

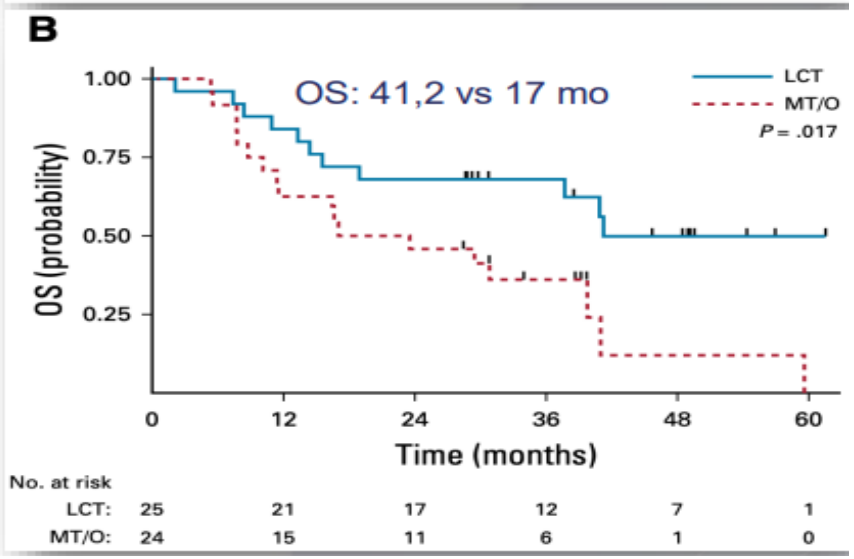
- 49 patients with stage IV NSCLC (8 EGFR/ALK)
- 1-3 metastatic sites
- 2012-2016
- Prior standard chemotherapy whithout progression (at least 4 CT cycles or 3 months of erlotinib or crizotinib)
- Metachronous 6% / Synchronous 94%
- Primary endpoint: PFS



In patients with oligometastatic NSCLC that did not progress after front-line systemic therapy, LCT prolonged PFS and OS relative to MT/O without grade 3 or greater toxicities

Gomez et al, Lancet Oncol 2016; Gomez et al, J Clin Oncol 2019





Rational for OMD trials?

✓ Better results in the era of targeted therapy and immunotherapy **Oligometastatic disease more present than ever**

✓ We have may unresolved questions: best timing (upfront, consolidation), best LAT technique (SBRT?, surgery?), best companion systemic treatment, does it matter T size or N

✓ We need more high quality research (large randomized trials to have better evidence and compare different LAT strategies)

Ongoing prospective trials in OM NSCLC

Study	Phase	N	Type OMD	Timing	LAT type	Endpoint
LAT with first line citotoxic chemotherapy						
NRG-L002 (NCT03137771)	II/III randomized	400	Synchronous ≤ 5 mtx ≤ 3 organs	After systemic CT	SBRT/IMRT	PFS and OS
SARON (NCT02417662)	III randomized	340	Synchronous ≤ 5 mtx ≤ 3 organs	After systemic CT	SBRT	OS
LAT with targeted therapy or immunotherapy						
NORTHSTAR (NCT03410043)	II randomized	143 EGFR+	Oligo/Poly	After initial osimertinib	RT/surgery	PFS
BRIGHTSTAR (NCT03707938)	I	35 ALK+	Oligo/Poly	After initial brigatinib	RT/surgery	Safety/feasibility
LONESTAR (NCT03391869)	III randomized	360	Oligo/Poly	After initial Nivo + Ipilimumab	RT/surgery	OS in OMD subgrup
STEREO (NCT04908956)	II single arm	60	Synchronous	Upfront or after response	SBRT to primary and mtx	Safety Hierarchical PFS

Ongoing prospective trials in OM NSCLC

Study	Phase	N	Type OMD	Timing	LAT type	Endpoint
LAT with first line citotoxic chemotherapy						
NRG-L002 (NCT03137771)	II/III randomized	400	Synchronous ≤ 5 mtx ≤ 3 organs	After systemic CT	SBRT/IMRT	PFS and OS
SARON (NCT02417662)	III randomized	340	Synchronous ≤ 5 mtx ≤ 3 organs	After systemic CT	SBRT	OS
LAT with targeted therapy or immunotherapy						
NORTHSTAR (NCT03410043)	II randomized	143 EGFR+	Oligo/Poly	After initial osimertinib	RT/surgery	PFS
BRIGHTSTAR (NCT03707938)	I	35 ALK+	Oligo/Poly	After initial brigatinib	RT/surgery	Safety/feasibility
LONESTAR (NCT03391869)	III randomized	360	Oligo/Poly	After initial Nivo + Ipilimumab	RT/surgery	OS in OMD subgrup
STEREO (NCT04908956)	II single arm	60	Synchronous	Upfront or after response	SBRT to primary and mtx	Safety Hierarchical PFS

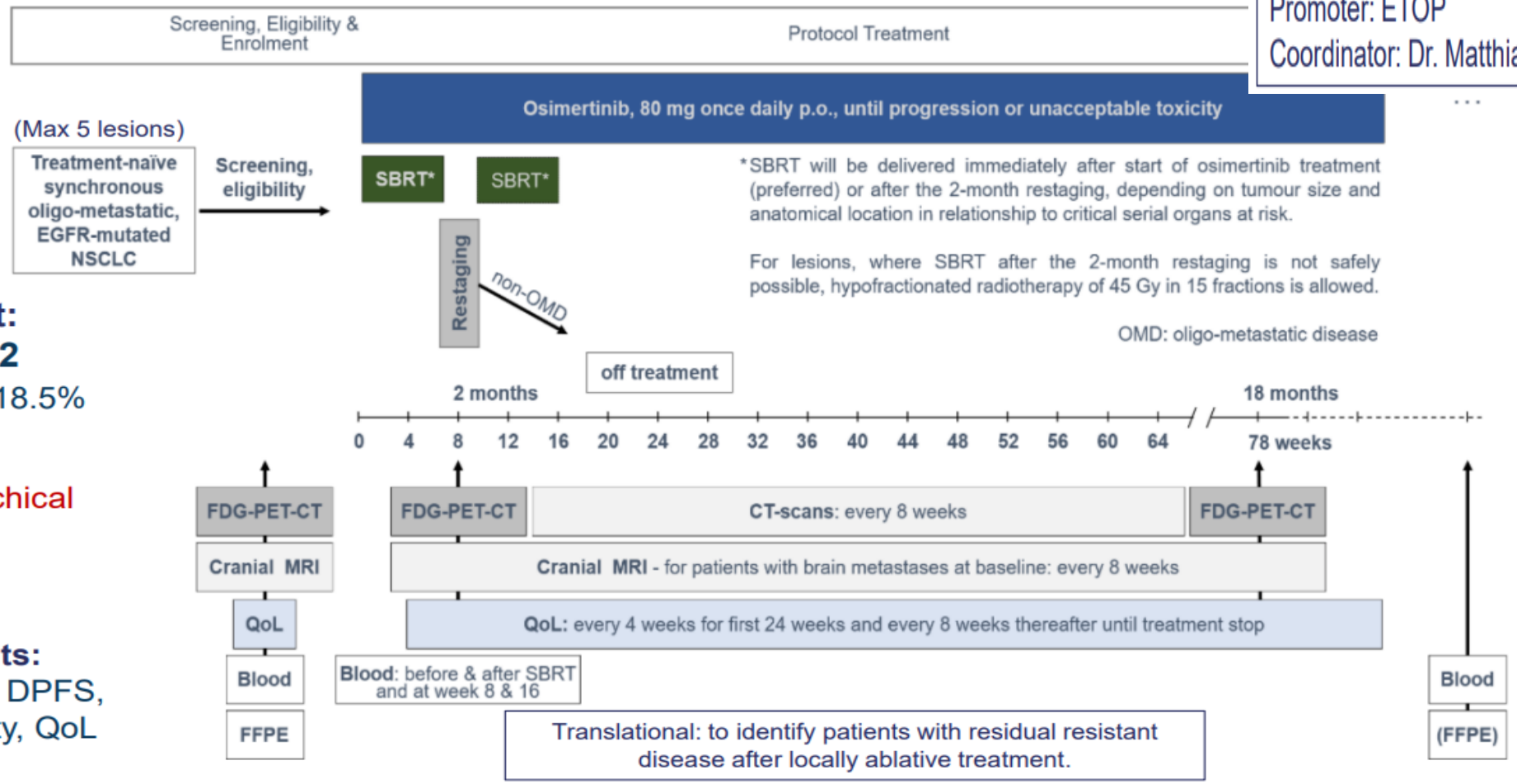
Ongoing prospective trials in OM NSCLC

Study	Phase	N	Type OMD	Timing	LAT type	Endpoint
LAT with first line citotoxic chemotherapy						
NRG-L002 (NCT03137771)	II/III randomized	400	Synchronous ≤ 5 mtx ≤ 3 organs	After systemic CT	SBRT/IMRT	PFS and OS
SARON (NCT02417662)	III randomized	340	Synchronous ≤ 5 mtx ≤ 3 organs	After systemic CT	SBRT	OS
LAT with targeted therapy or immunotherapy						
NORTHSTAR (NCT03410043)	II randomized	143 EGFR+	Oligo/Poly	After initial osimertinib	RT/surgery	PFS
BRIGHTSTAR (NCT03707938)	I	35 ALK+	Oligo/Poly	After initial brigatinib	RT/surgery	Safety/feasibility
LONESTAR (NCT03391869)	III randomized	360	Oligo/Poly	After initial Nivo + Ipilimumab	RT/surgery	OS in OMD subgrup
STEREO (NCT04908956)	II single arm	60	Synchronous	Upfront or after response	SBRT to primary and mtx	Safety Hierarchical PFS

STEREO: Phase II: Multicentre single arm assessing the safety and efficacy of first line osimertinib and locally ablative radiotherapy in patients with synchronous oligo-metastasic EGFR-mutant NSCLC

Promoter: ETOP
Coordinator: Dr. Matthias Gukenberger

Study Outline:



Primary End Point:

- **Rate of grade ≥2 pneumonitis** (<18.5% safety cohort)

Hierarchical

- **PFS:** (67% 18m efficacy cohort)

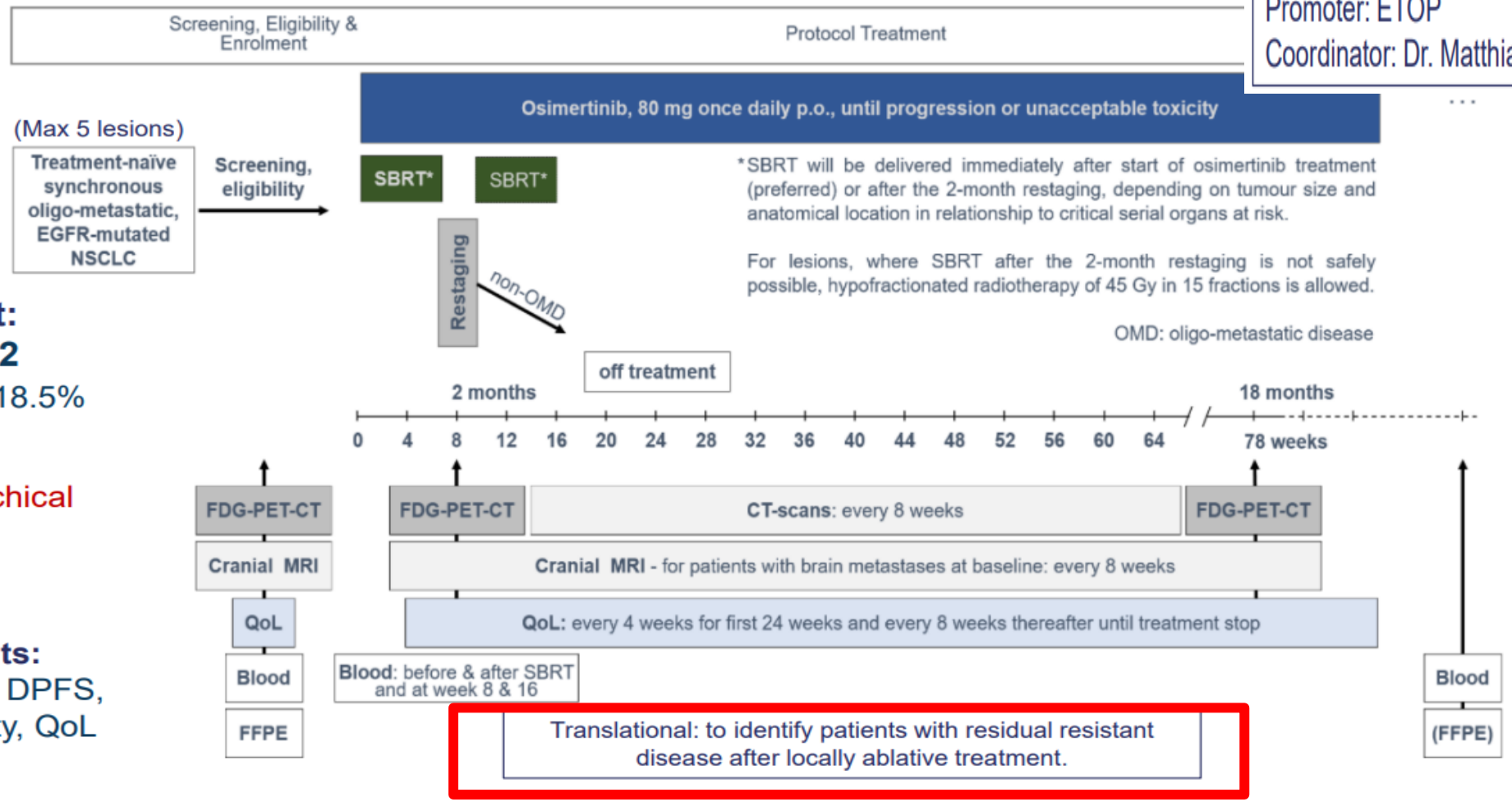
Secondary End Points:

- OS, pattern of PD, DPFS,
- ORR, DOR, Toxicity, QoL

STEREO: Phase II: Multicentre single arm assessing the safety and efficacy of first line osimertinib and locally ablative radiotherapy in patients with synchronous oligo-metastasic EGFR-mutant NSCLC

Promoter: ETOP
Coordinator: Dr. Matthias Gukenberger

Study Outline:



Primary End Point:

- **Rate of grade ≥2 pneumonitis** (<18.5% safety cohort)

Hierarchical

- **PFS:** (67% 18m efficacy cohort)

Secondary End Points:

- OS, pattern of PD, DPFS,
- ORR, DOR, Toxicity, QoL

STEREO: Phase II: Multicentre single arm assessing the safety and efficacy of first line osimertinib and locally ablative radiotherapy in patients with synchronous oligo-metastasic EGFR-mutant NSCLC

Expected patients: **60** (safety cohort 54+ eficacy cohort 6)
Randomized patients: 2

HOSPITAL	IP	FECHA APERTURA	SCREENING	INCLUIDOS	NO VÁLIDOS	VÁLIDOS
H. Gral. de Alicante	Dr. Bartomeu Massutí	*22/06/2022*	*1*	*1*	*0*	*1*
H. Univ. Vall d'Hebrón	Dra. Nuria Pardo	*16/09/2022*	*1*	*1*	*0*	*1*
H. HM Sanchinarro	Dra. Miriam Dorta	*01/06/2022*	*1*	*0*	*0*	*0*
ICO Bellvitge	Dr. Ernest Nadal	*16/08/2022*	*1*	*0*	*0*	*0*
H. Clín. Univ. de Valencia	Dra. Paloma Martín	*14/03/2023*	*0*	*0*	*0*	*0*

PAISES PARTICIPANTES Y ESTADO INTERNACIONAL:

PAÍS	CENTROS	ESTADO	INCLUIDOS
COREA DEL SUR	2	*2 centros activos*	4
ITALIA	3	*2 centros activos* *1 centro pte. SIV*	0
SUIZA	2	*2 centros activos*	0
SINGAPUR	1	*1 centro activo*	0
PAISES BAJOS	2	*1 centro pte. activación* *1 centro pte. SIV*	-
POLONIA	1	*Pte. SIV*	-
SUECIA	2	*Pte. contrato*	-
REINO UNIDO	2	*Pte. Submission*	-

STEREO: Phase II: Multicentre single arm assessing the safety and efficacy of first line osimertinib and locally ablative radiotherapy in patients with synchronous oligo-metastasic EGFR-mutant NSCLC

Expected patients: **60** (safety cohort 54+ eficacy cohort 6)
Randomized patients: 2

HOSPITAL	IP	FECHA APERTURA	SCREENING	INCLUIDOS	NO VÁLIDOS	VÁLIDOS
H. Gral. de Alicante	Dr. Bartomeu Massutí	*22/06/2022*	*1*	*1*	*0*	*1*
H. Univ. Vall d'Hebrón	Dra. Nuria Pardo	*16/09/2022*	*1*	*1*	*0*	*1*
H. HM Sanchinarro	Dra. Miriam Dorta	*01/06/2022*	*1*	*0*	*0*	*0*
ICO Bellvitge	Dr. Ernest Nadal	*16/08/2022*	*1*	*0*	*0*	*0*
H. Clín. Univ. de Valencia	Dra. Paloma Martín	*14/03/2023*	*0*	*0*	*0*	*0*

PAISES PARTICIPANTES Y ESTADO INTERNACIONAL:

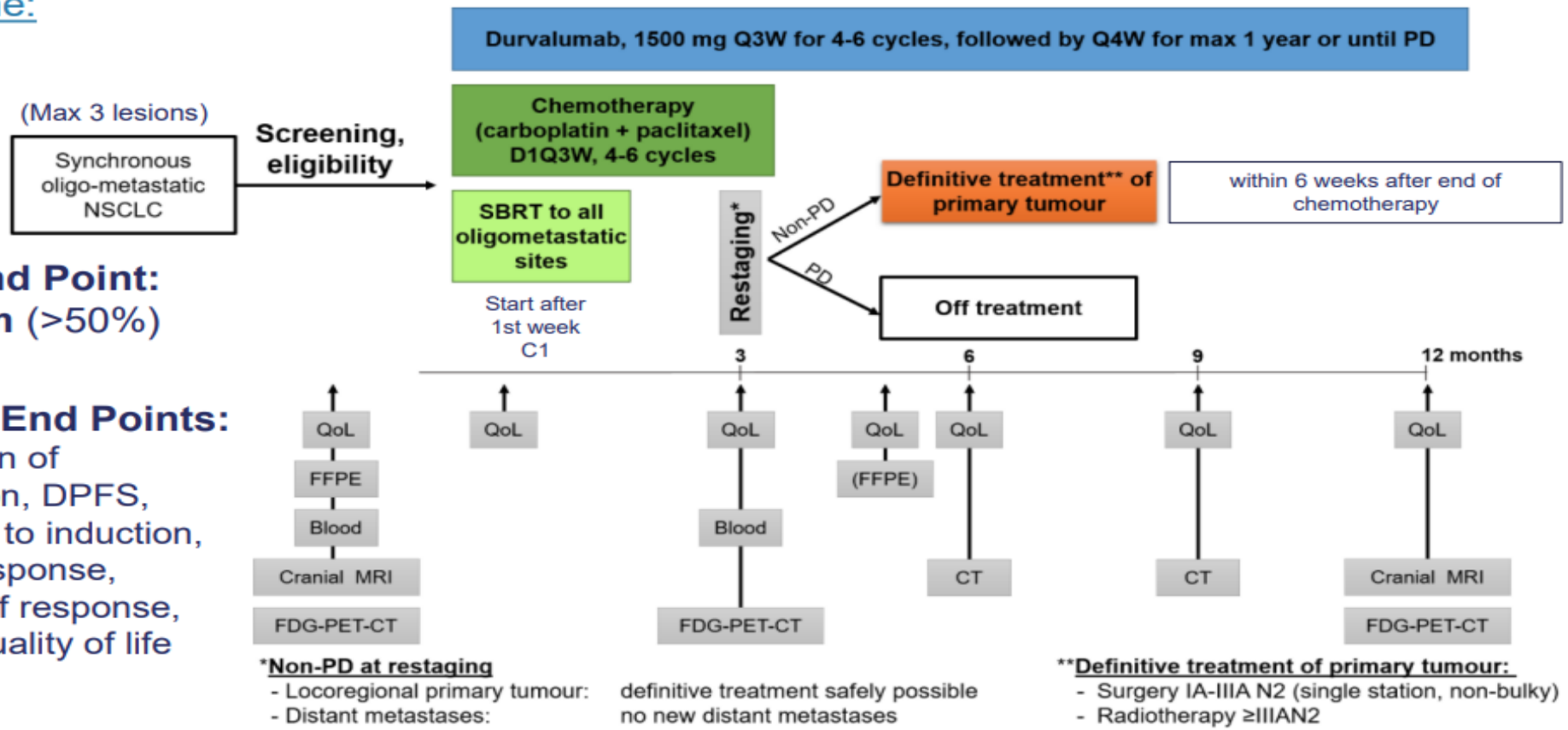
PAÍS	CENTROS	ESTADO	INCLUIDOS
COREA DEL SUR	2	*2 centros activos*	4
ITALIA	3	*2 centros activos* *1 centro pte. SIV*	0
SUIZA	2	*2 centros activos*	0
SINGAPUR	1	*1 centro activo*	0
PAISES BAJOS	2	*1 centro pte. activación* *1 centro pte. SIV*	-
POLONIA	1	*Pte. SIV*	-
SUECIA	2	*Pte. contrato*	-
REINO UNIDO	2	*Pte. Submission*	-

✓ **EL 31/10/2023** se dio por finalizado del reclutamiento y screening de pacientes en el estudio por bajo reclutamiento. Han sido incluidos un total de **6 pacientes.** El estudio continúa abierto dado que todavía hay pacientes en tratamiento y seguimiento.

CHESS: A multicentre single arm phase II trial assessing the efficacy of radical immunotherapy and chemotherapy, stereotactic radiotherapy and surgery in patients with synchronous oligo-metastatic NSCLC

Promoter: ETOP
Coordinator: Dr. Walter Weder

Study Outline:



Primary End Point:

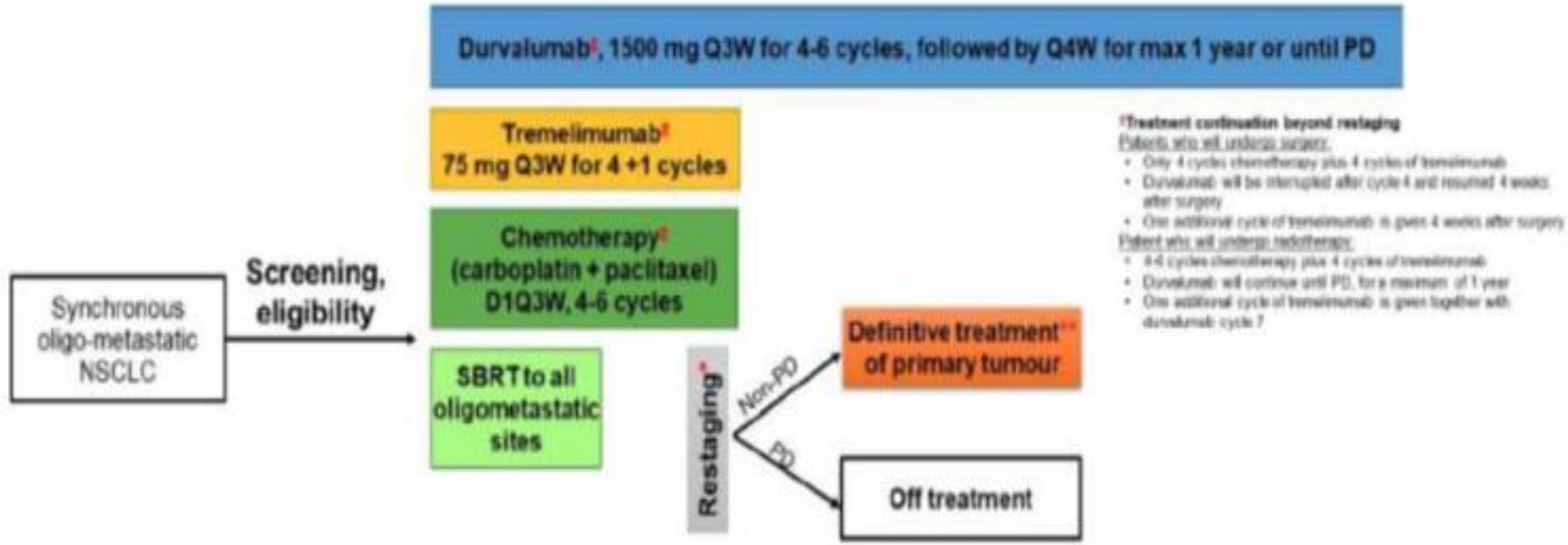
- **PFS 12m** (>50%)

Secondary End Points:

- OS, pattern of progression, DPFS, Response to induction, Overall response, Duration of response, Toxicity, quality of life

El estudio tiene como objetivo reducir el riesgo de progresión sistémica y mejorando así la PFS

CHESS – ETOP 14-18: A multicentre single arm phase II trial assessing the efficacy of radical immunotherapy and chemotherapy, stereotactic radiotherapy and surgery in patients with synchronous oligo-metastatic NSCLC

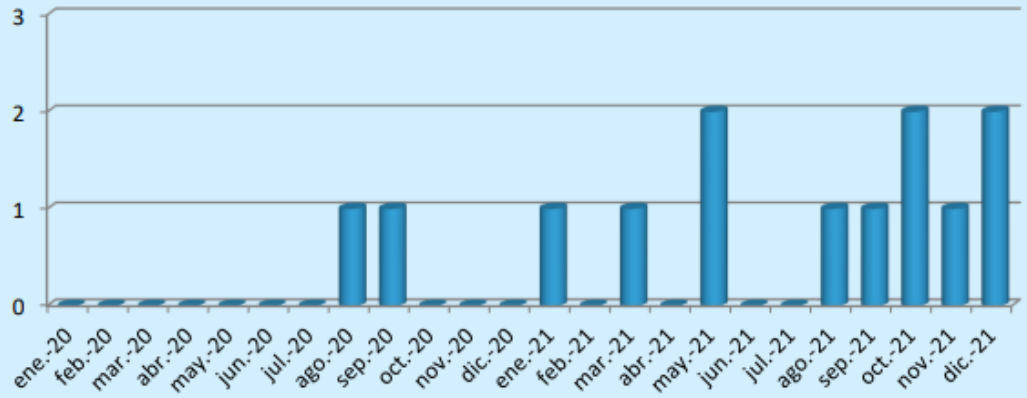


El 9 de julio de 2022 el promotor ETOP suspendió el reclutamiento del estudio ETOP 14-18 CHESS, **pendiente de aprobación de enmienda al protocolo para la inclusión de nueva cohorte de pacientes (tremelimumab + durvalumab, QT, SBRT antes de tto local definitivo)**

El estudio sigue ABIERTO puesto que todavía hay pacientes en tratamiento y seguimiento

CHESS – ETOP 14-18

RITMO DE INCLUSIÓN EN ESPAÑA:



Pacientes incluidos: 18

Total centros: 5 Centros abiertos: 5

Spain Randomized patients: 18

Expected patients: 47 Randomized patients: 49*

RECLUTAMIENTO Y STATUS DE CENTROS:

Nº	HOSPITAL	IP	FECHA APERTURA	INCLUIDOS	NO VÁLIDOS	VÁLIDOS
ESP057	H. De la Santa Creu i Sant Pau	Dra. I. Sullivan	*17/01/2020*	*10*	*2*	*8*
ESP330	H.U. HM Sanchinarro	Dra. B. Jiménez	*03/06/2020*	*7*	*2*	*5*
ESP006	H.U. Vall d'Hebron	Dra. A. Callejo	*28/04/2021*	*6*	*1*	*5*
ESP056	H.U. Politècnic La Fe	Dr. O. Juan-Vidal	*27/10/2020*	*4*	*4*	-
ESP331	H.U. Virgen de las Nieves	Dr. J. Valdivia	*03/06/2020*	-	-	-
			TOTAL	***27***	***9***	***18***

MÁXIMOS RECLUTADORES Y ESTADO INTERNACIONAL:

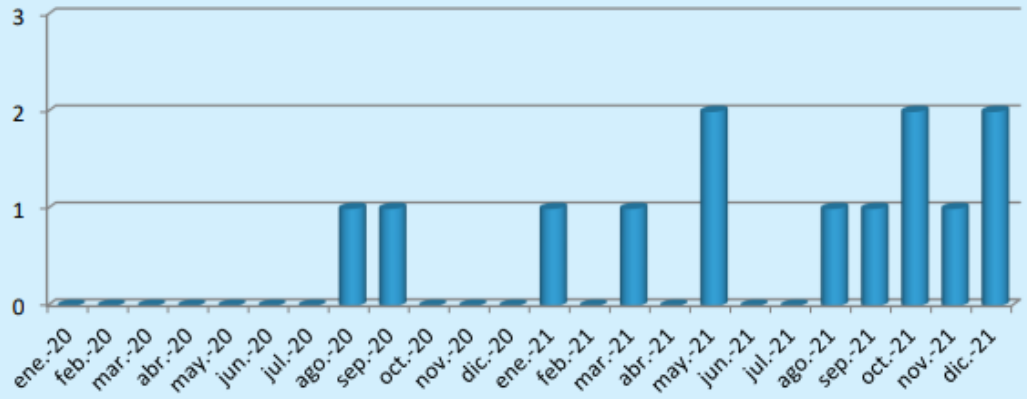
HOSPITAL	PAÍS	INCLUIDOS
Inselspital Bern	Suiza	9
University Hospital Zürich	Suiza	8
H. De la Santa Creu i Sant Pau	España	8
H.U. Vall d'Hebron	España	5
H.U. HM Sanchinarro	España	5
Univ. Medical Centre Maastricht	P. Bajos	5

PAÍS	INCLUIDOS
SUIZA	22
ESPAÑA	18
PAÍSES BAJOS	8
ITALIA	1
TOTAL	***49***

&Tremelimumab is under review by global regulatory authorities in combination with Durvalumab and chemotherapy in 1st-line mNSCLC based on the results of the POSEIDON trial (benefit in PFS and OS vs chemotherapy)

CHESS – ETOP 14-18

RITMO DE INCLUSIÓN EN ESPAÑA:



Pacientes incluidos: 18

Total centros: 5 Centros abiertos: 5

Spain Randomized patients: 18

Expected patients: 47 Randomized patients: 49*

RECLUTAMIENTO Y STATUS DE CENTROS:

Nº	HOSPITAL	IP	FECHA APERTURA	INCLUIDOS	NO VÁLIDOS	VÁLIDOS
ESP057	H. De la Santa Creu i Sant Pau	Dra. I. Sullivan	*17/01/2020*	*10*	*2*	*8*
ESP330	H.U. HM Sanchinarro	Dra. B. Jiménez	*03/06/2020*	*7*	*2*	*5*
ESP006	H.U. Vall d'Hebron	Dra. A. Callejo	*28/04/2021*	*6*	*1*	*5*
ESP056	H.U. Politècnic La Fe	Dr. O. Juan-Vidal	*27/10/2020*	*4*	*4*	-
ESP331	H.U. Virgen de las Nieves	Dr. J. Valdivia	*03/06/2020*	-	-	-
			TOTAL	***27***	***9***	***18***

MÁXIMOS RECLUTADORES Y ESTADO INTERNACIONAL:

HOSPITAL	PAÍS	INCLUIDOS
Inselspital Bern	Suiza	9
University Hospital Zürich	Suiza	8
H. De la Santa Creu i Sant Pau	España	8
H.U. Vall d'Hebron	España	5
H.U. HM Sanchinarro	España	5
Univ. Medical Centre Maastricht	P. Bajos	5

PAÍS	INCLUIDOS
SUIZA	22
ESPAÑA	18
PAÍSES BAJOS	8
ITALIA	1
TOTAL	***49***

&Tremelimumab is under review by global regulatory authorities in combination with Durvalumab and chemotherapy in 1st-line mNSCLC based on the results of the POSEIDON trial (benefit in PFS and OS vs chemotherapy)

NIVIPI-Brain: Nivolumab plus ipilimumab plus two cycles of platinum-based chemotherapy as first line treatment for stage IV/recurrent non-small cell lung cancer (NSCLC) patients with synchronous Brain metastases

Study Outline:

Cohort A: CNS asymptomatic
Cohort B: CNS symptomatic

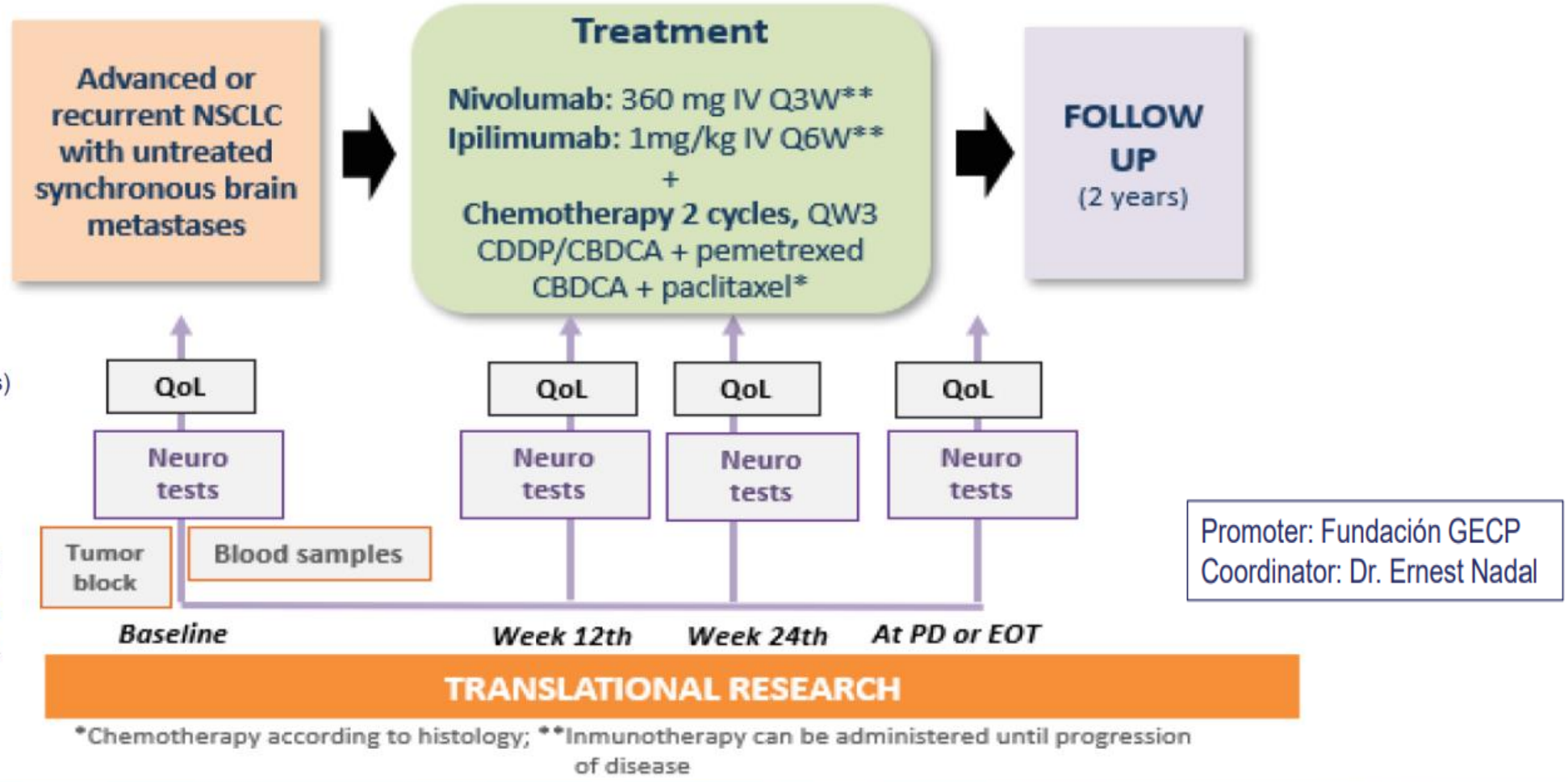
Primary End Point:

- Intracranial clinical benefit: DCR

(no clinical/radiological PD 6 months)

Secondary End Points:

- PFS, OS, ORR, DOR, Safety and tolerability, QoL.



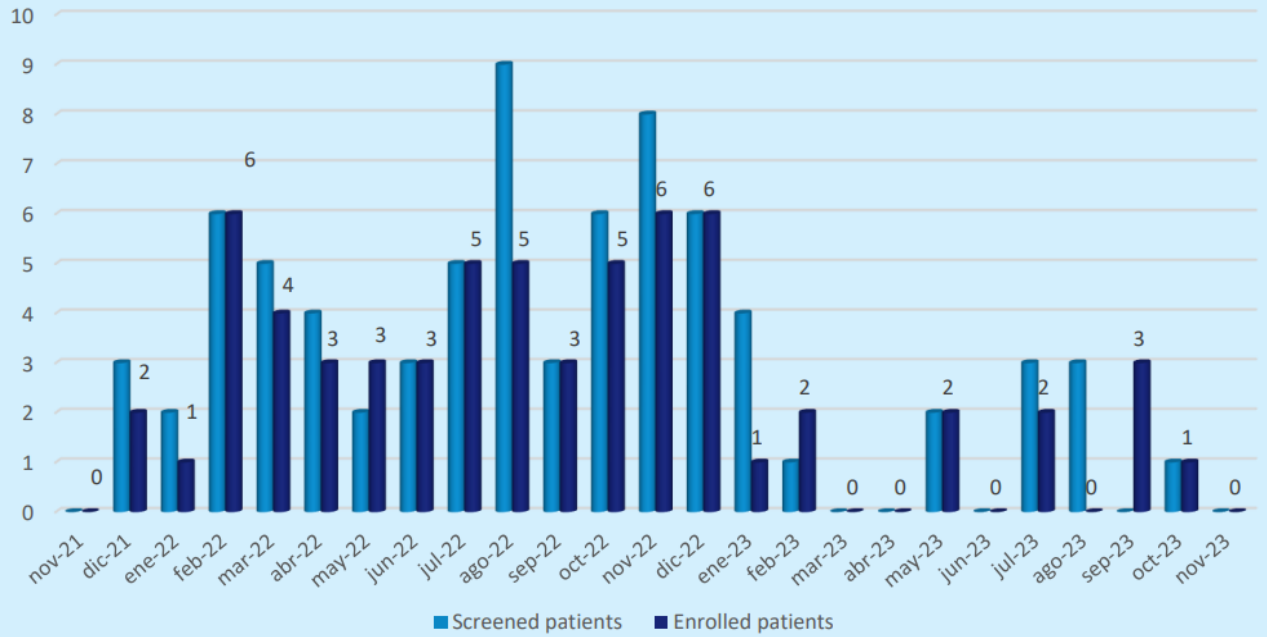
Promoter: Fundación GECP
Coordinator: Dr. Ernest Nadal

NIVIPI-Brain

Expected patients: 71 (44 cohort A+ 27 Cohort B)

RITMO DE INCLUSIÓN:

Pacientes incluidos: 63
Cohorte A: **36** Cohorte B: **27**



RECLUTAMIENTO Y ESTADO DE CENTROS:

Nº	HOSPITAL	IP	FECHA APERTURA	SCREENING	INCLUIDOS	NO VALIDOS	VALIDOS
004	H. REGIONAL DE MÁLAGA	Dra. Cantero	17/12/2021	16	13	1	12
028	C. H. DE JAÉN	Dra. Ortega	18/11/2021	8	8	1	7
020	H. U. 12 DE OCTUBRE	Dr. Paz-Ares	08/02/2022	7	7	0	7
008	ICO BELLVITGE	Dr. Nadal	28/12/2021	8	7	0	7
010	H. DE SANT PAU	Dr. Barba	18/11/2021	7	5	0	5
016	H. VALL D'HEBRON	Dra. Iranzo	09/03/2022	7	5	0	5
007	FUNDACIÓN JIMENEZ DIAZ	Dr. Domine	13/12/2021	3	3	0	3
022	H. SON LLATZER	Dr. García	29/11/2021	3	3	0	3
013	H. INSULAR GRAN CANARIA	Dr. Rodriguez	16/12/2021	3	3	1	2
003	H. G. U. DE VALENCIA	Dra. Blasco	18/11/2021	2	2	0	2
015	H. TERESA HERRERA	Dra. García	30/11/2021	2	2	0	2
051	H. CLÍNICO DE VALLADOLID	Dr. López	07/01/2022	2	2	0	2
035	H. U. Y POLITÉCNICO LA FE	Dr. Vidal	24/01/2022	2	1	0	1
037	C. H. DE LEÓN	Dra. Diz	28/03/2022	2	1	0	1
005	H. PUERTA DE HIERRO	Dr. Provencio	*22/12/2022*	1	1	0	1
072	H. LUCUS AUGUSTI	Dr. Vázquez	01/12/2021	3	0	0	0
012	C. H. PROV. DE CASTELLÓ	Dr. Sanchez	07/02/2022	0	0	0	0
002	ICO BADALONA	Dra. Hernández	11/02/2022	0	0	0	0
			TOTAL	**76**	**63**	**3**	**60**

Congress communications: IASLC 2022: EP08.01-029

***There are no SLOTs left for Cohort B, **but 8 patients remain to be included in the Cohort A** that remains open without the need for SLOT

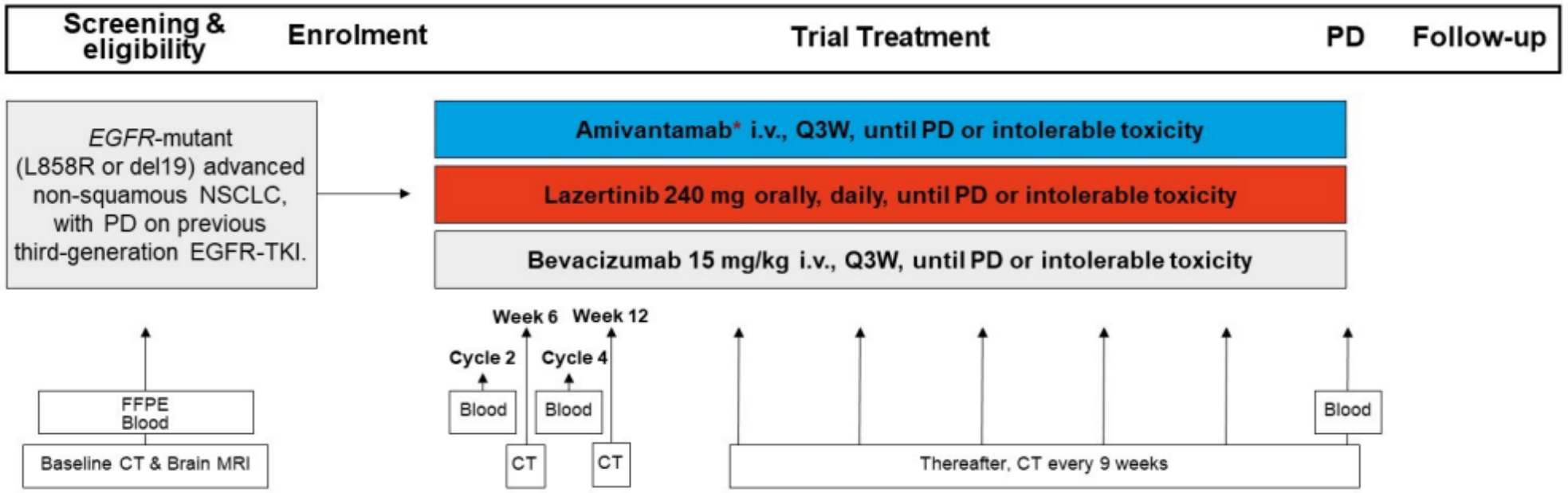
Total trial duration: 4.5 years, 1.5 years of recruitment, 1 year of treatment approximately and 2 years of follow up. Approval of the study and start up (4-6 months) and close out (4-6 months).

AMAZE-Lung: A multicentre single-arm phase II trial of amivantamab, lazertinib plus bevacizumab in patients with EGFR-mutant advanced NSCLC with progression on first line Osimertinib

Primary endpoints
Objective response rate **(ORR)** at 12 weeks according to RECIST v1.1

Secondary endpoints
DoR, PFS, DCR, OS, Safety and tolerability (CTCAE v5.0)

Trial schema:



*Amivantamab dose and schedule:

Cycle 1,	day 1:	350 mg
	day 2:	1050 mg (1400 mg, if body weight is ≥80 kg)
	day 8:	1400 mg (1750 mg)
	day 15:	1400 mg (1750 mg)
Cycle 2,	day 1:	1400 mg (1750 mg)
From cycle 3 on:		**1750 mg (2100 mg)** → **until disease progression, or intolerable toxicity**

Translational endpoints: Analysis of tumour sample for EGFR-mutation and MET-expression testing, Analysis of ctDNA in blood (plasma) samples to correlate with the efficacy outcome

Promoter: ETOP, Coordinator: Dr. Ross Soo/Dr. Sanjay Popat

AMAZE-Lung

Expected patients: **60**

Number of participating centers: **8 centers** in Spain

RITMO DE INCLUSIÓN EN ESPAÑA:

Pacientes incluidos: 13

Total centros: 8 Centros abiertos: 8

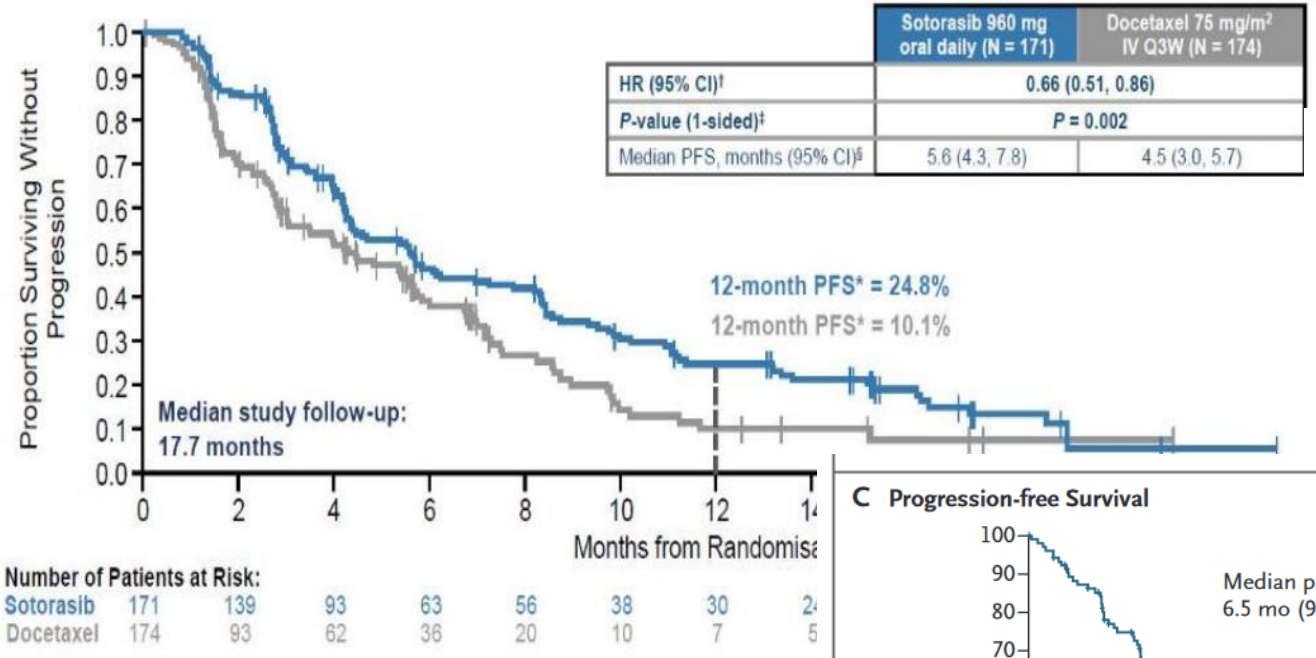
RECLUTAMIENTO Y ESTADO DE CENTROS:

Nº	HOSPITAL	INVESTIGADOR PRINCIPAL	FECHA APERTURA	REGISTRADOS	INCLUIDOS
ESP248	H. DE BASURTO	Dr Mª Ángeles Sala	*11/04/2023*	*5*	*3*
ESP058	ICO BADALONA	Dr Marc Cucurull	*26/05/2023*	*3*	*3*
ESP006	H. VALL D'HEBRÓN	Dr Patricia Iranzo	*08/06/2023*	*3*	*3*
ESP059	ICO BELLVITGE	Dr Ernest Nadal	*04/05/2023*	*7*	*2*
ESP185	H. FUNDACIÓN JIMÉNEZ DÍAZ	Dr Manuel Dominé	*17/07/2023*	*1*	*1*
ESP289	H.CL.U. VALLADOLID	Dr Rafael López Castro	*23/05/2023*	*1*	*1*
ESP240	CHU A CORUÑA	Dr Joaquin Mosquera	*11/04/2023*	-	-
ESP055	H. U. ALICANTE Dr BALMÍS	Dr Bartomeu Massutí	*25/04/2023*	-	-
			TOTAL	***20***	***13***

MÁXIMOS RECLUTADORES

HOSPITAL	PAÍS	INCLUIDOS
Kantonsspital St. Gallen	SUIZA	5
H. de Basurto	ESPAÑA	3
ICO Badalona	ESPAÑA	3
H. Vall d'Hebrón	ESPAÑA	3
Cancer Institute Amsterdam	NETHERLANDS	3
TOTAL reclutados (n = 60)		**29**

KRAS inhibitors: Similar results in underrepresented populations?



	Sotorasib 960 mg oral daily (N = 171)	Docetaxel 75 mg/m² IV Q3W (N = 174)
HR (95% CI)†	0.66 (0.51, 0.86)	
P-value (1-sided)‡	*P* = 0.002	
Median PFS, months (95% CI)§	5.6 (4.3, 7.8)	4.5 (3.0, 5.7)

CodeBreaK 200 trial

Johnson, ESMO 2022

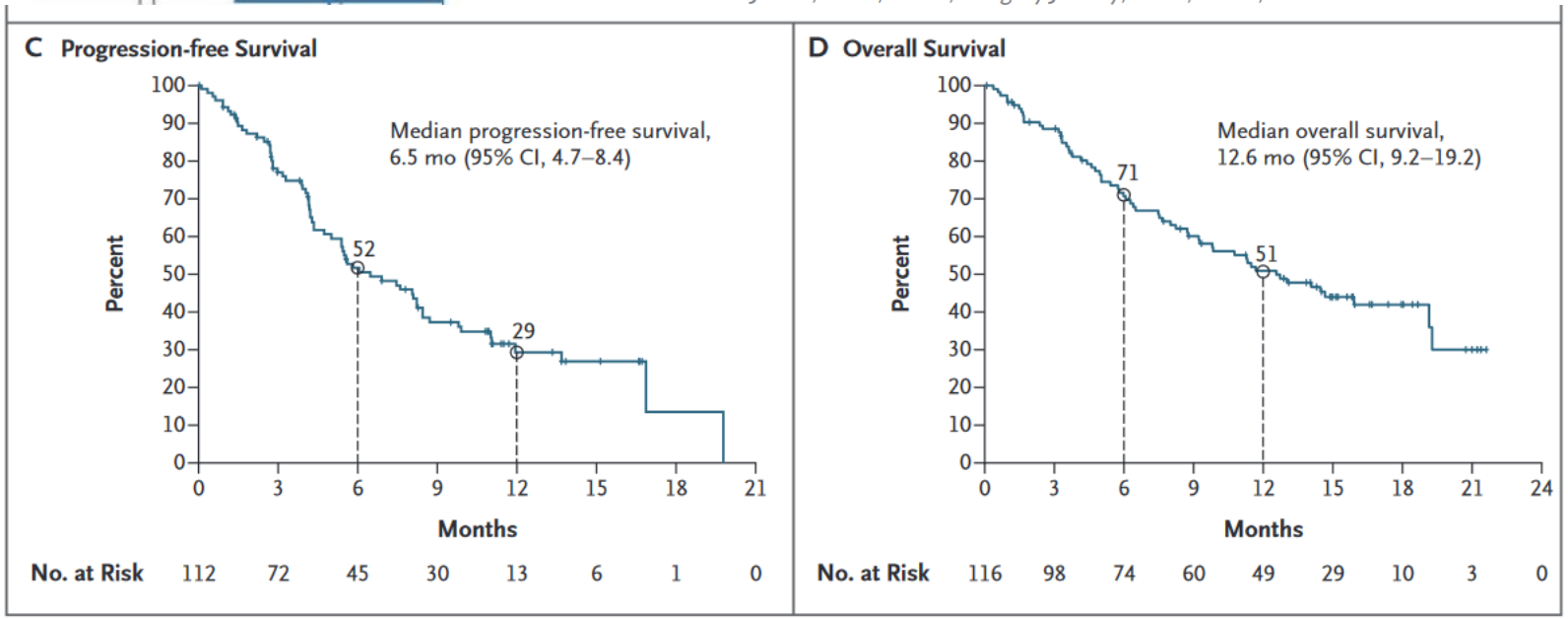
Krystal 01

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

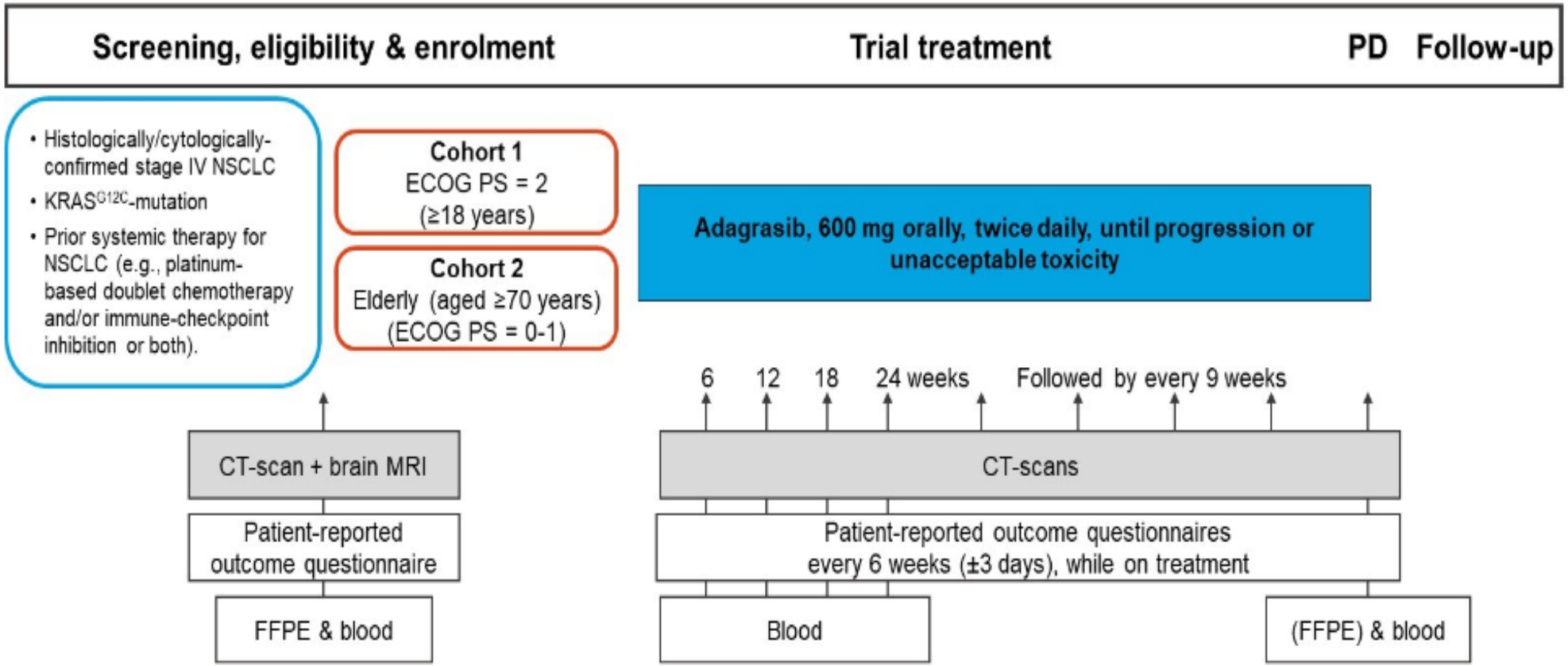
Adagrasib in Non–Small-Cell Lung Cancer Harboring a *KRAS*^{G12C} Mutation

Pasi A. Jänne, M.D., Ph.D., Gregory J. Riely, M.D., Ph.D.,



ADEPPT: A multicentre single-arm phase II trial of adagrasib in patients with KRAS G12C-mutant NSCL, including the elderly (> or = 70 years) or patients with poor performance status

Trial schema:



Study population
Patients with stage IV NSCLC with mutation of KRASG12C

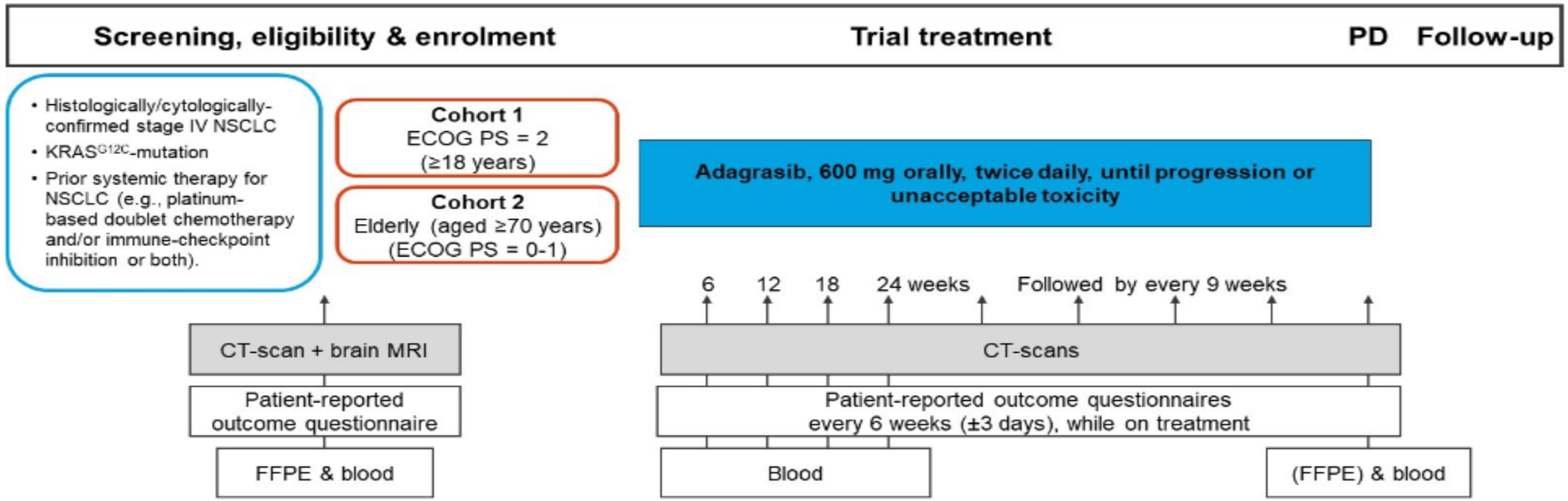
- Cohort 1: ECOG=2

- Cohort 2: elderly patients (≥ 70 years) and ECOG=0-1

Fecha Apertura: 26/04/2023**, Promoter:** ETOP IBSCG Partners**. Coordinating Researchers**: Dr Naidoo, Dr Lindsay, Dr. Massuti, Dr. Peters

ADEPPT: A multicentre single-arm phase II trial of adagrasib in patients with KRAS G12C-mutant NSCL, including the elderly (> 70 years) or patients with poor performance status

Trial schema:



- ✓ **Primary endpoint** (ORR) per RECIST v1.1, assessed at 12 weeks
- ✓ **Secondary enpoints** Durable clinical benefit, Time to progression, PFS, OS, Patient-related outcomes
- ✓ **Exploratory endpoint:** Blood-and tissue-based biomarkers (circulating genomic, immunologic parameters

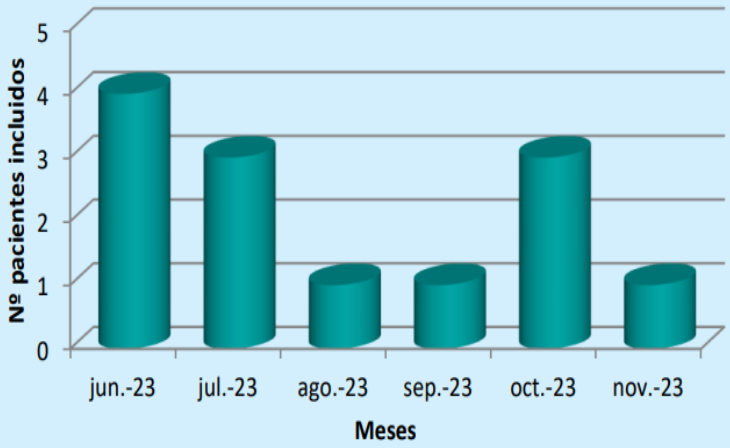
Fecha Apertura: 26/04/2023**, Promoter:** ETOP IBSCG Partners**. Coordinating Researchers**: Dr Naidoo, Dr Lindsay, Dr. Massuti, Dr. Peters

ADEPPT

Expected patients: 68

Number of participating centers: **8 centers** in Spain

ESTADO DEL ESTUDIO EN ESPAÑA:



Pacientes incluidos: 13
(3 pacientes en screening)

Total centros: 8 Centros abiertos: 8

RECLUTAMIENTO Y ESTADO DE CENTROS

Nº	HOSPITAL	IP	FECHA APERTURA	INCLUIDOS	VÁLIDOS	NO VÁLIDOS
ESP058	ICO BADALONA	Dra. Teresa Moran	*16/05/2023*	*6*	*6*	*0*
ESP248	H. DE BASURTO	Dra. María Ángeles Sala	*26/04/2023*	*3*	*3*	*0*
ESP059	ICO HOSPITALET	Dr. Ernest Nadal	*26/04/2023*	*2*	*2*	*0*
ESP001	H. GRAL. UNIV. VALENCIA	Dra. Ana Blasco	*01/06/2023*	*1*	*1*	*0*
ESP216	H. PUERTA DEL HIERRO	Dr. Mariano Provencio	*22/08/2023*	*1*	*1*	*0*
ESP055	H. GRAL ALICANTE Dr. BALMIS	Dr. Bartomeu Massutí	*01/05/2023*	-	-	-
ESP185	C. H. U. A CORUÑA	Dra. Rosario García	*04/07/2023*	-	-	-
ESP240	FUNDACIÓN JIMÉNEZ DÍAZ	Dr. Manuel Dómine	*10/07/2023*	-	-	-
			TOTAL	***13***	***13***	***0***

MÁXIMOS RECLUTADORES Y ESTADO INTERNACIONAL

Total pacientes Cohorte 1: 13

Total pacientes Cohorte 2: 8

HOSPITAL	PAÍS	INCLUIDOS
ICO Badalona	España	*6*
Sta. Maria della Misericodia	Italia	*5*
H. de Basurto	España	*3*
Institut Jules Bordet	Bélgica	*2*
ICO Hospitalet	España	*2*

PAÍS	CENTROS	ESTADO
Bélgica	1	*Activado*
Francia	4	*1 pdte. contrato + 1 pdte activación + 2 activados*
Italia	4	*2 pdte. contratos + 2 activados*
Irlanda	5	*5 pdte activación*
Gran Bretaña	4	*Pdte. Submission*


15th
MADRID
CONGRESS
on Lung CANCER
23&24
November 2023
#15CongressGECP
Fundación
GECP
lung cancer
research
Thank you patients and families, thanks to the researchers and coordinators of the studies
esais@iconcologia.net
Salut/ ICO Institut Català d'Oncologia
Hospital Universitari de Girona Doctor Josep Trueta
InstitutCatalàdelaSalut
Universitat de Girona
Facultat de Medicina
IdIBGi
Institut d'Investigació Biomèdica de Girona Dr. Josep Trueta