#ESMOUPDATES

Iniciativa científica de:

GECP lung cancer research

LUNG CANCER UPDATES

ESMO HIGHLIGHTS

27 SEPTIEMBRE - 1 OCTUBRE 2019

Con la colaboración de:

Bristol-Myers Squibb

illumina

Lilly

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BARCELONA

Novedades en cáncer de pulmón no microcítico localizado y localmente avanzado (III)

Dr. Fabio Franco

Con la colaboración de:
Bristol-Myers Squibb
illumina
Lilly

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Poster Discussion - Non-metastatic NSCLC and other thoracic malignancies

Con la colaboración de:

Bristol-Myers Squibb

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1440PD - JIPANG study: Randomized phase III study of PEM/Cis vs VNR/Cis for completely resected estage II-IIIA non-squamous NSCLC: Outcomes based on EGFR mutation status. Tsuboi M.

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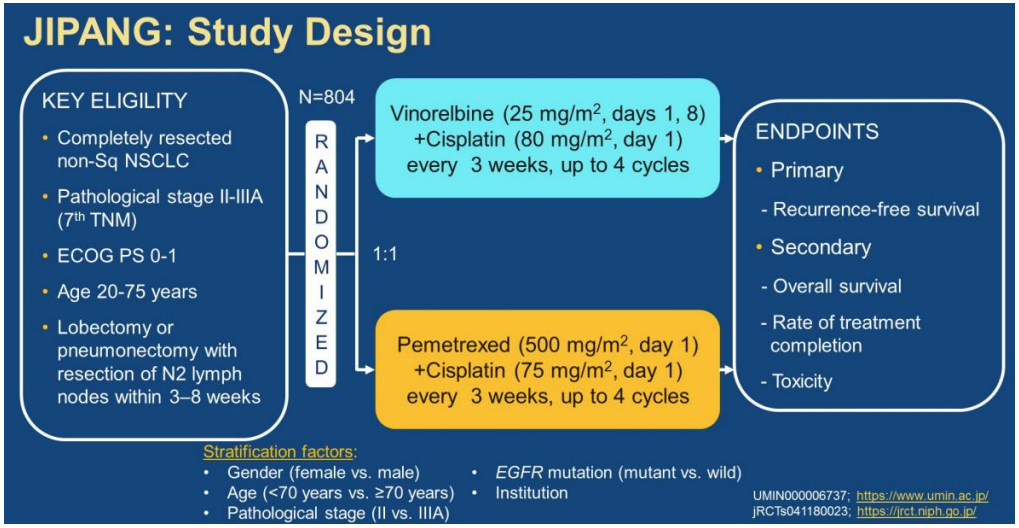

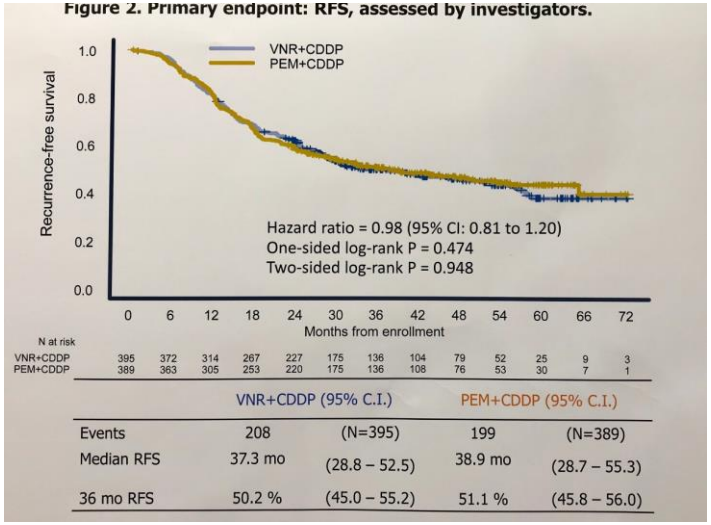

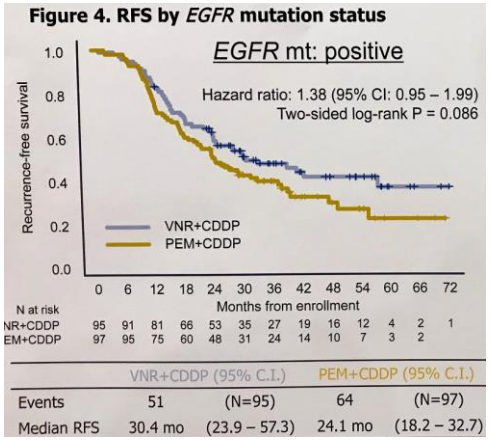

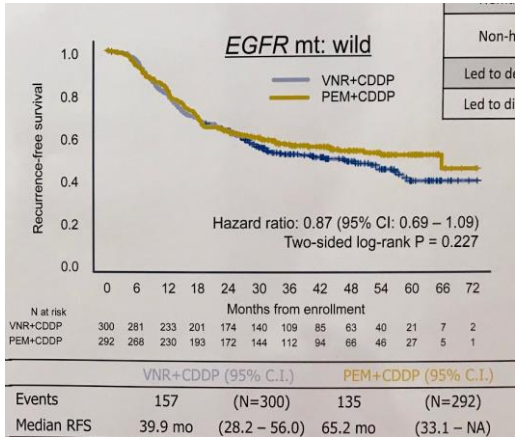

Total: 804 (65 años), E-IIIA el 52%.
EGFR: 24/24.9%.
Seguimiento: 45 meses.
RFS: 38.9 m (Pem/Cis) vs 37.3 m (VNR/Cis)
RFS EGFR-wt: 65.2 m vs 39.9 m.
OS-3y: 83.5% vs 87.2% HR 0.98.
Tto compl: 87.9% vs 72.7%.

Conclusiones: Estudio negativo, end point primario no alcanzado.
Similar eficacia en ambos regímenes pero mejor tolerancia con PEM/CDDP.
En pacientes EGFR-wt, PEM/CDDP podría ser una opción como QT adyuvante.

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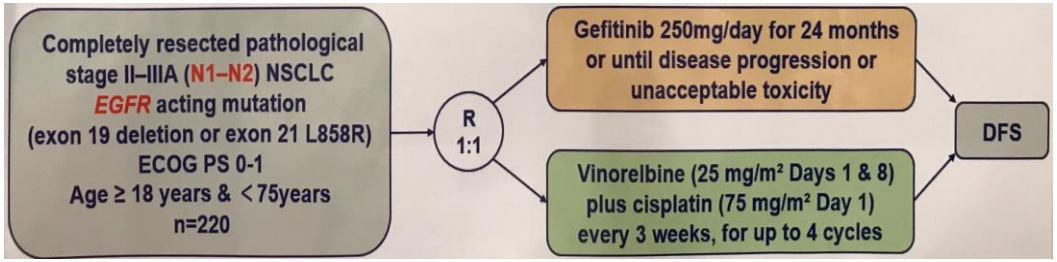
1441PD – A comprehensive model of genetic-features predicts outcome of personalized adjuvant treatment in resected EGFRm stage II-IIIA NSCLC: Results from a phase III trial (CTONG 1104-ADJUVANT). Wu YL.



Modelo predictivo MEDUSA para determinar el beneficio de la terapia adyuvante en pacientes EGFRm operados.

171 muestras analizadas (95 grupo Gefitinib y 76 CDDP/VNR).

Panel de genes: Geneseeq 422.

Los biomarcadores que favorecen el gefitinib incluyen mutaciones TP53 exon4 / 5, la ganancia de número de copias de NKX2-1 y MYC.

Alteraciones de RB1 favorecieron fuertemente la VP (HR 4.07, IC 95% 1.56-10.53, p = 0.004).

El grupo que favorece fuertemente el uso de TKI mostró un beneficio significativo de la SG.

Conclusiones: La incorporación del score MEDUSA podría ayudar a seleccionar la terapia adyuvante personalizada para pacientes con NSCLCmen estadio II-IIIA resecado.

Table 1. Interaction Anal… dentify Predictive Biomarkers

Biomarker	No. of Patients	Interactive HR (95% CI)	*p* Value
RB1 alterations	33	4.07 (1.56-10.58)	0.004
NKX2-1 gain	34	0.26 (0.098-0.68)	0.006
CDK4 gain	12	0.14 (0.025-0.77)	0.024
TP53 exon4/5 mut	29	0.33 (0.12-0.93)	0.035
MYC gain	15	0.10 (0.011-0.98)	0.048

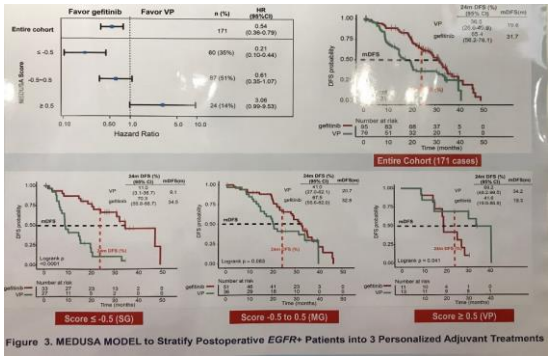
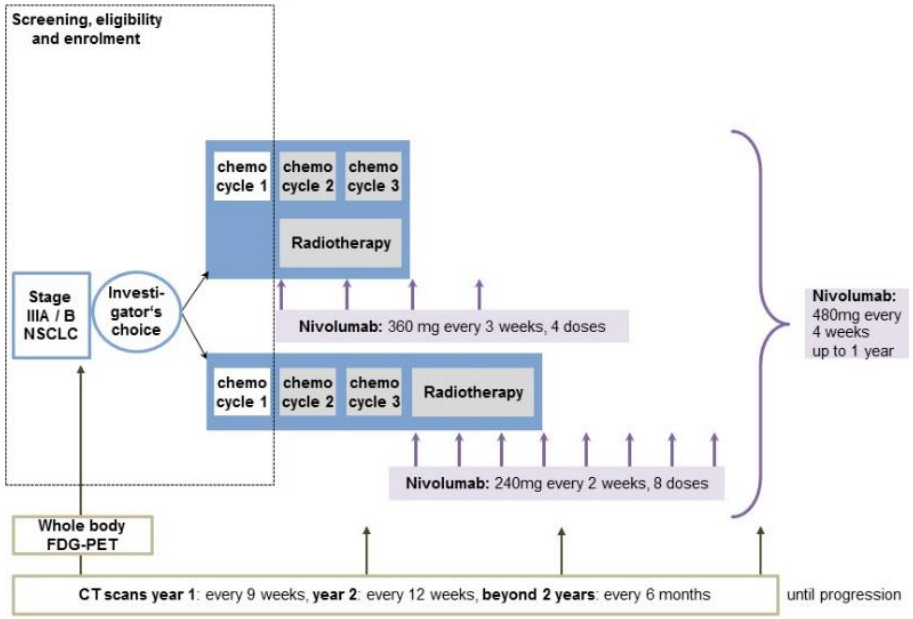
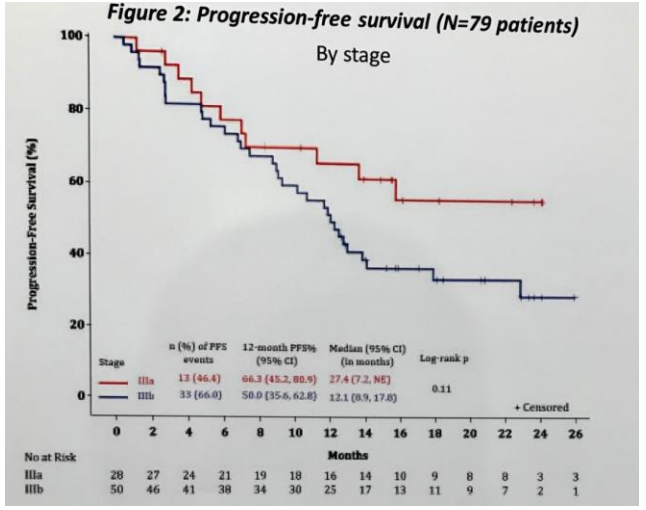
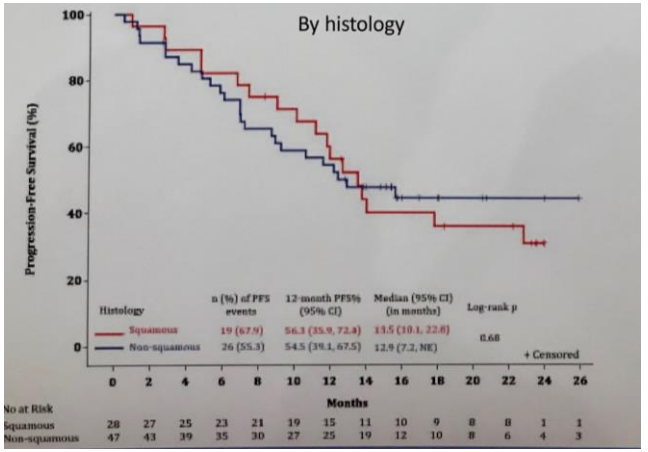


Figure 3. MEDUSA MODEL to Stratify Postoperative *EGFR*+ Patients into 3 Personalized Adjuvant Treatments

1457PD - Efficacy evaluation of concurrent nivolumab addition to a first-line, concurrent C-RT regimen in unresectable NSCLC: Results from the ETOP 6-14 - NICOLAS phase II trial. Peters S.

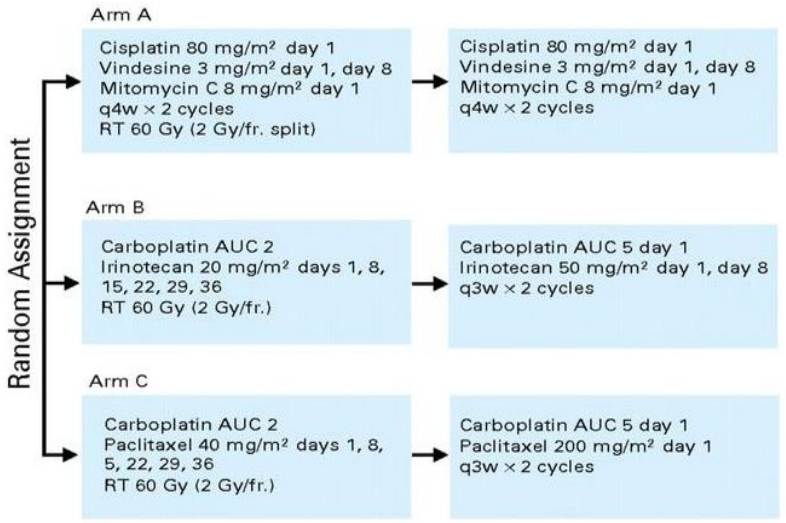


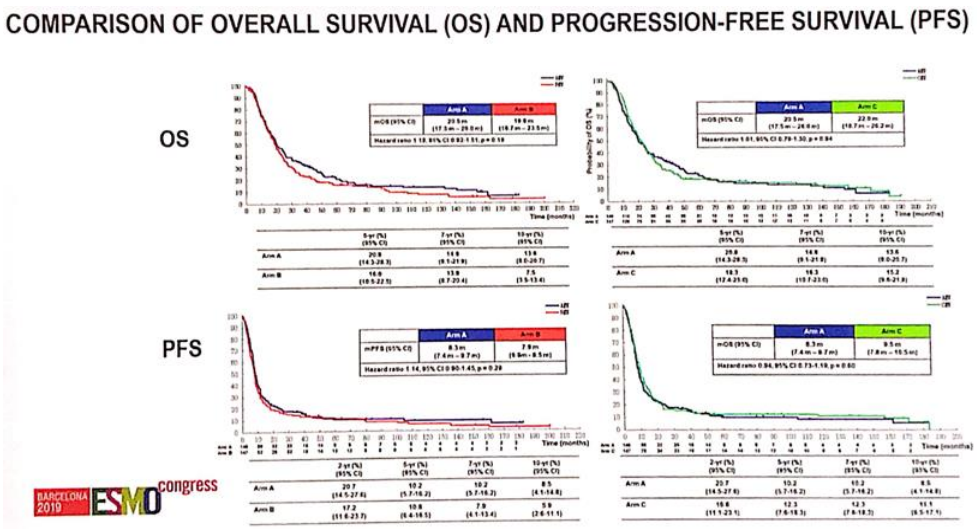




Objetivo primario: 1y-PFS (mejora de al menos 15%).
Pacientes evaluados: 79.
Mediana de seguimiento: 16,4 meses.
Resultados: 1y-PFS del 50% (IC95%: 39,9-61%) con una mediana de 12,7 meses.
El nº de 41 pacientes sin PR no fue alcanzado.
AEs más frecuentes: anemia, fatiga y neumonitis.
Neumonitis G3 (7) y G5 (1).

1458PD - Phase III study comparing 2º and 3ª third-generation regimens with C-RT in unresectable stage III NSCLC: 10-y follow-up of West Japan thoracic oncology group WJTOG0105. Zenke Y.





Pacientes: 440 (A = 146; B brazo = 147; brazo C = 147).
OS: 20.5, 19.8 y 22.0 meses.
Probabilidad de supervivencia: 5 años 20.9%, 16.0% y 18.2% y 10 años de 13.6%, 7.5% y 15.2%.
No hubo diferencias significativas en la SG entre los brazos de tratamiento.
No se observaron casos adicionales de toxicidad tardía (Grado 3/4).

Conclusiones:
El brazo C muestra perfiles de eficacia y toxicidad similares en comparación con el brazo A, incluso 10 años después de comenzar el tratamiento.
La probabilidad de SLP a 10 años fue solo del 11%.

1459PD - Efficacy of durvalumab in patients with stage III NSCLC who experience pneumonitis (PACIFIC). Vansteenkiste J.

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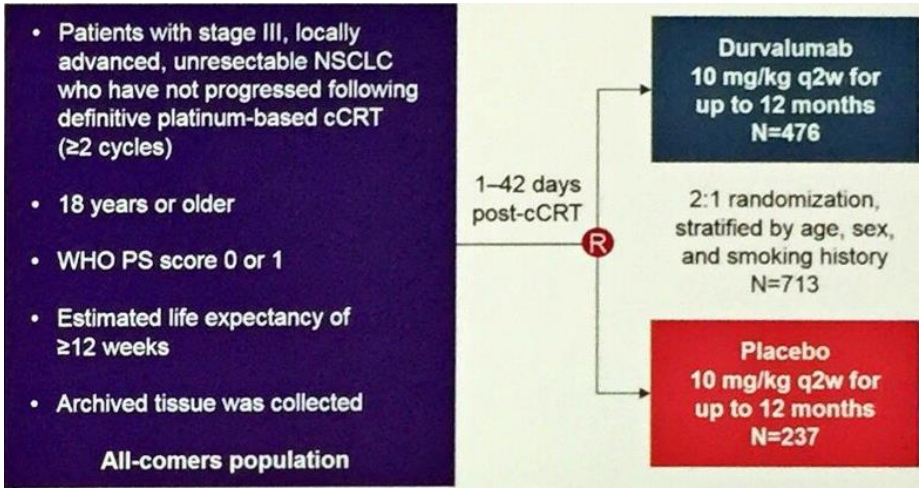

709 pacientes tratados con evaluación de la neumonitis y análisis de OS, PFS y TTDM.

Conclusiones:

El beneficio del tratamiento con durvalumab vs placebo se mantuvo independientemente de la aparición de neumonitis, siendo la mayoría leves.

MANAGEMENT AND OUTCOMES OF PNEUMONITIS CASES

	No. of durvalumab-treated patients								
	On-study pneumonitis	Management/intervention of pneumonitis					Clinical outcome of pneumonitis		
Highest CTCAE grade of pneumonitis	Any AE	Treatment interrupted	Treatment discontinued	Systemic corticosteroid	High-dose corticosteroid*	Other treatment†	Resolved	Not resolved	Outcome of death
1	67	11	2	17	3	0	20	47	0
2	72	45	12	63	37	0	47	25	0
3	17	4	11	16	11	0	12	5	0
4	0	0	0	0	0	0	0	0	0
5	5	0	5	5	5	2	0	0	5
Total, n (%)	161 (100)	60 (37.3)	30 (18.6)	101 (62.7)	56 (34.8)	2 (1.2)	79 (49.1)	77 (47.8)	5 (3.1)

Data are according to electronic case report form. No statistical analyses were performed to test for between-arm differences. *A dose that equates to at least 40 mg prednisone daily. †Other immunosuppressive treatment. CTCAE, Common Terminology Criteria for Adverse Events

- Among durvalumab-treated patients who developed on-study pneumonitis, the most common interventions were administration of systemic corticosteroids and treatment interruption, with similar rates among placebo-treated patients (data not shown)
  - Intervention included permanent discontinuation in 30/161 (18.6%) durvalumab-treated patients and 10/58 (17.2%) placebo-treated patients
- Death due to on-study pneumonitis was numerically lower with durvalumab relative to placebo (5/161 [3.1%] and 5/58 [8.6%]) and a numerically higher proportion of pneumonitis cases resolved in durvalumab-treated patients (79/161 [49.1%] and 21/58 [36.2%]), including most grade ≥2 cases

OS, PFS, AND TTDM ADJUSTED FOR THE TIME-DEPENDENT OCCURRENCE OF PNEUMONITIS

	No. of events/no. of patients (%)		HR (95% CI) for durvalumab vs placebo	
	Durvalumab	Placebo	Adjusted for the time-dependent occurrence of pneumonitis	ITT population[1,2]
OS	183/476 (38.4)	116/237 (48.9)		
Model 1 (base model)			0.70 (0.55–0.88)	0.68 (0.53–0.87)
Model 2			0.65 (0.51–0.83)	–
PFS	243/476 (51.1)	173/237 (73.0)		
Model 1 (base model)			0.54 (0.45–0.66)	0.51 (0.41–0.63)
Model 2			0.52 (0.42–0.64)	–
TTDM	182/476 (38.2)	126/237 (53.2)		
Model 1 (base model)			0.57 (0.45–0.71)	0.53 (0.41–0.68)
Model 2			0.53 (0.41–0.67)	–

Model 1 (base model) accounts for stratification factors at randomisation: age, sex, and smoking history, as used for the ITT population

Model 2 is the base model plus additional baseline prognostic factors: stage of disease at study entry, histology, best response to prior anticancer therapy, WHO PS, region and race

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