

Iniciativa científica de:



## Novedades en CPNCP: Estadios iniciales

**Dra. Karla Medina**

*Hospital Universitario Nuestra Señora de  
Candelaria, Tenerife*



# Novedades en CPNCP: Estadios Iniciales

2025 ASCO®  
ANNUAL MEETING

## Overall survival with neoadjuvant nivolumab + chemotherapy in patients with resectable NSCLC in CheckMate 816

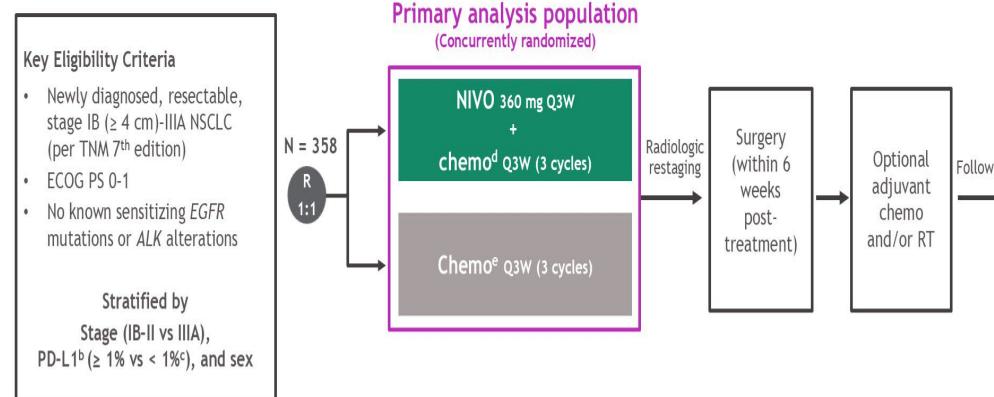
Patrick M. Forde,<sup>1</sup> Jonathan D. Spicer,<sup>2</sup> Mariano Provencio,<sup>3</sup> Tetsuya Mitsudomi,<sup>4</sup> Mark M. Awad,<sup>5</sup> Changli Wang,<sup>6</sup> Shun Lu,<sup>7</sup> Enriqueta Felip,<sup>8</sup> Stephen Broderick,<sup>9</sup> Scott J. Swanson,<sup>10</sup> Julie Brahmer,<sup>9</sup> Keith Kerr,<sup>11</sup> Tudor-Eliade Ciuleanu,<sup>12</sup> Fumihiro Tanaka,<sup>13</sup> Gene B. Saylor,<sup>14</sup> Ke-Neng Chen,<sup>15</sup> Lily Wang,<sup>16</sup> Quyen Duong,<sup>16</sup> Nicolas Girard<sup>17</sup>

<sup>1</sup>Trinity St. James's Cancer Institute, Trinity College Dublin, Dublin, Ireland; <sup>2</sup>McGill University Health Centre, Montreal, Quebec, Canada; <sup>3</sup>Hospital Universitario Puerta de Hierro, Madrid, Spain; <sup>4</sup>Kindai University Faculty of Medicine, Ohno-Higashi, Osaka-Sayama, Japan; <sup>5</sup>Memorial Sloan Kettering Cancer Center, New York, NY, USA; <sup>6</sup>Tianjin Lung Cancer Center, Tianjin Medical University Cancer Institute & Hospital, Tianjin, China; <sup>7</sup>Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiao Tong University, Shanghai, China; <sup>8</sup>Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology, Universitat Autònoma de Barcelona, Barcelona, Spain; <sup>9</sup>The Bloomberg-Kimmel Institute for Cancer Immunotherapy, The Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins Medicine, Baltimore, MD, USA; <sup>10</sup>Brigham and Women's Hospital, Boston, MA, USA; <sup>11</sup>Aberdeen Royal Infirmary, Aberdeen, United Kingdom; <sup>12</sup>Institut Oncologic Prof Dr Ion Chirică and University of Medicine and Pharmacy Iuliu Hatieganu, Cluj-Napoca, Romania; <sup>13</sup>The University of Occupational and Environmental Health, Kitakyushu, Japan; <sup>14</sup>Charleston Oncology, Charleston, SC, USA; <sup>15</sup>State Key Laboratory of Molecular Oncology, Peking University Cancer Hospital & Institute, Beijing, China; <sup>16</sup>Bristol Myers Squibb, Princeton, NJ, USA; <sup>17</sup>Institut du Thorax Curie-Montsouris, Institut Curie, Paris, France

Abstract number LBA8000

CheckMate 816: 5-y OS final analysis

## CheckMate 816 study design<sup>a</sup>



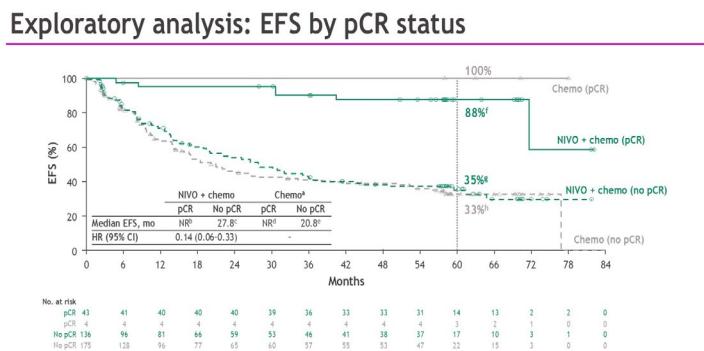
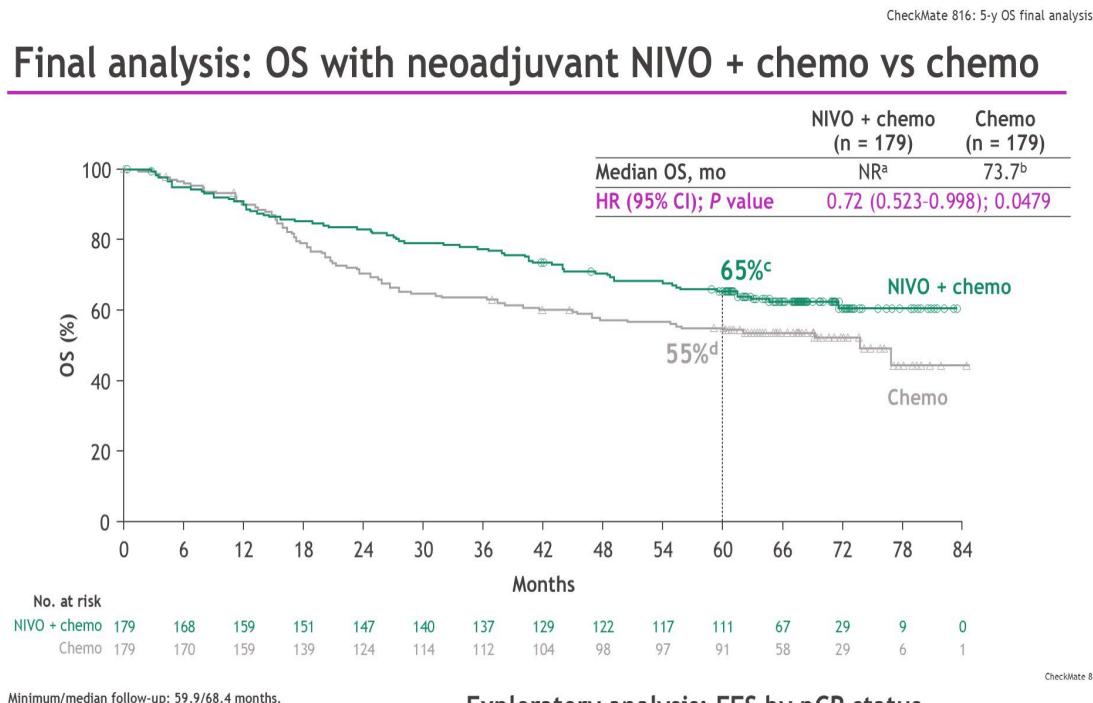
Minimum/median follow-up: 59.9/68.4 months

Primary endpoints	Key secondary endpoints	Exploratory analyses
<ul style="list-style-type: none"><li>• pCR by BIPR</li><li>• EFS by BICR</li></ul>	<ul style="list-style-type: none"><li>• OS</li><li>• MPR by BIPR</li><li>• TTDM</li></ul>	<ul style="list-style-type: none"><li>• OS by pCR, ctDNA clearance</li><li>• Lung cancer-specific survival</li></ul>

Database lock: January 23, 2025. From *The New England Journal of Medicine*, Forde PM, et al, Neoadjuvant nivolumab plus chemotherapy in resectable lung cancer, 2022;386:1973-1985. Copyright © 2022 Massachusetts Medical Society. Adapted with permission from Massachusetts Medical Society. <sup>a</sup>NCT02998528. <sup>b</sup>Determined by the PD-L1 IHC 28-8 pharmDx assay (Dako). <sup>c</sup>Included patients with PD-L1 expression status not evaluable and indeterminate. <sup>d</sup>Nonsquamous: pemetrexed + cisplatin or paclitaxel + carboplatin; squamous: gemcitabine + cisplatin or paclitaxel + carboplatin. <sup>e</sup>Vinorelbine + cisplatin, docetaxel + cisplatin, gemcitabine + cisplatin (squamous only), pemetrexed + cisplatin (nonsquamous only), or paclitaxel + carboplatin.



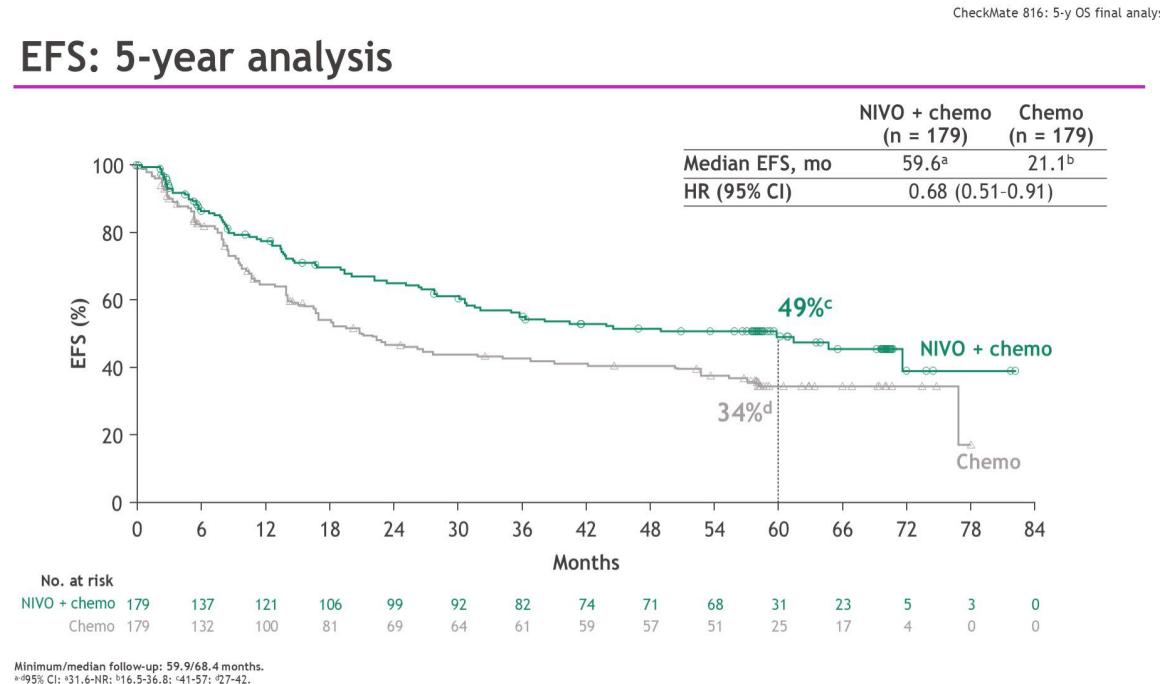
# Novedades en CPNCP: Estadios Iniciales.



In the NIVO + chemo arm:

- Among patients with pCR, 3 (7.0%) patients had disease recurrence or relapse
- Among patients with no pCR, 57 (41.9%) patients had disease recurrence or relapse

HR were IC if there was an insufficient number of events (< 10 per arm). In the chemo arm, no patients with pCR had disease recurrence or relapse; 84 (48.0%) of patients without pCR had disease recurrence or relapse.  
HR (95% CI): \*1.14(NR); <sup>g</sup>18.9(3.1-48.4); <sup>h</sup>14.8(3.1-48.4); <sup>i</sup>73.95; <sup>j</sup>25(44.3-45.4). Among the 3 patients with recurrence, 1 patient is alive at 3 years on an ALB-directed therapy, the other 2 patients had recurrence by BICR, however, they did not receive further systemic therapy and are alive at 5 years.



# Novedades en CPNCP: Estadios Iniciales

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

## Overall Survival with Neoadjuvant Nivolumab plus Chemotherapy in Lung Cancer

Patrick M. Forde, M.B., B.Ch., Ph.D.,<sup>1</sup> Jonathan D. Spicer, M.D., Ph.D.,<sup>2</sup>

Mariano Provencio, M.D., Ph.D.,<sup>3</sup> Tetsuya Mitsudomi, M.D., Ph.D.,<sup>4</sup>

Mark M. Awad, M.D., Ph.D.,<sup>5</sup> Changli Wang, M.D.,<sup>6</sup> Shun Lu, M.D., Ph.D.,<sup>7</sup>

Enriqueta Felip, M.D., Ph.D.,<sup>8</sup> Scott J. Swanson, M.D.,<sup>9</sup> Julie R. Brahmer, M.D.,<sup>10</sup>

Keith Kerr, M.B., Ch.B.,<sup>11</sup> Janis M. Taube, M.D.,<sup>12</sup>

Tudor-Eliade Ciuleanu, M.D., Ph.D.,<sup>13</sup> Fumihiro Tanaka, M.D., Ph.D.,<sup>14</sup>

Gene B. Saylor, M.D.,<sup>15</sup> Ke-Neng Chen, M.D., Ph.D.,<sup>16</sup> Hiroyuki Ito, M.D., Ph.D.,<sup>17</sup>

Moishe Liberman, M.D., Ph.D.,<sup>18</sup> Claudio Martin, M.D.,<sup>19</sup>

Stephen Broderick, M.D.,<sup>20</sup> Lily Wang, M.D.,<sup>20</sup> Junliang Cai, M.D.,<sup>20</sup>

Quyen Duong, Ph.D.,<sup>20</sup> Stephanie Meadows-Shropshire, Ph.D.,<sup>20</sup>

Joseph Fiore, Pharm.D.,<sup>20</sup> Sumeena Bhatia, Ph.D.,<sup>20</sup> and

Nicolas Girard, M.D., Ph.D.,<sup>21</sup> for the CheckMate 816 Investigators\*



# Novedades en CPNCP: Estadios Iniciales

Abstract:LBA8010

2025 ASCO®  
ANNUAL MEETING

## Perioperative nivolumab vs placebo in patients with resectable NSCLC: updated survival and biomarker analyses from CheckMate 77T

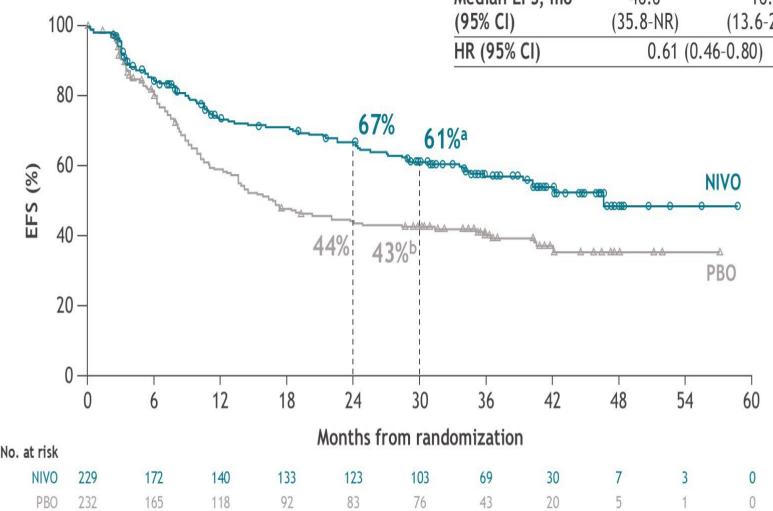
Tina Cascone,<sup>1</sup> Mark M. Awad,<sup>2</sup> Jonathan D. Spicer,<sup>3</sup> Jie He,<sup>4</sup> Shun Lu,<sup>5</sup> Fumihiro Tanaka,<sup>6</sup> Robin Cornelissen,<sup>7</sup> Lubos B. Petruzelka,<sup>8</sup> Hiroyuki Ito,<sup>9</sup> Ludmila de Oliveira Muniz Koch,<sup>10</sup> Lin Wu,<sup>11</sup> Sabine Bohnet,<sup>12</sup> Cinthya Coronado Erdmann,<sup>13</sup> Stephanie Meadows-Shropshire,<sup>14</sup> Jaclyn Neely,<sup>14</sup> Yu-Han Hung,<sup>14</sup> Padma Sathyanarayana,<sup>14</sup> Sumeena Bhatia,<sup>14</sup> Mariano Provencio<sup>15</sup>

<sup>1</sup>The University of Texas MD Anderson Cancer Center, Houston, TX, USA; <sup>2</sup>Memorial Sloan Kettering Cancer Center, New York, NY, USA; <sup>3</sup>McGill University Health Centre, Montreal, Quebec, Canada; <sup>4</sup>National Cancer Center/National Clinical Research Center for Cancer/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College, Beijing, China; <sup>5</sup>Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai Jiao Tong University, Shanghai, China; <sup>6</sup>University of Occupational and Environmental Health, Kitakyushu, Japan; <sup>7</sup>Erasmus MC Cancer Institute, Rotterdam, Netherlands; <sup>8</sup>Charles University, Prague, Czech Republic; <sup>9</sup>Kanagawa Cancer Center, Yokohama, Japan; <sup>10</sup>Hospital Israelita Albert Einstein, Sao Paulo, Brazil; <sup>11</sup>Hunan Cancer Hospital, Changsha, China; <sup>12</sup>University Medical Center Schleswig-Holstein, Lubeck, Germany; <sup>13</sup>Bristol Myers Squibb, Boudry, Switzerland; <sup>14</sup>Bristol Myers Squibb, Princeton, NJ, USA; <sup>15</sup>Hospital Universitario Puerta de Hierro, Madrid, Spain

Abstract number LBA8010

## EFS per BICR

	NIVO (n = 229)	PBO (n = 232)
Median EFS, mo (95% CI)	46.6 (35.8-NR)	16.9 (13.6-28.2)
HR (95% CI)	0.61 (0.46-0.80)	

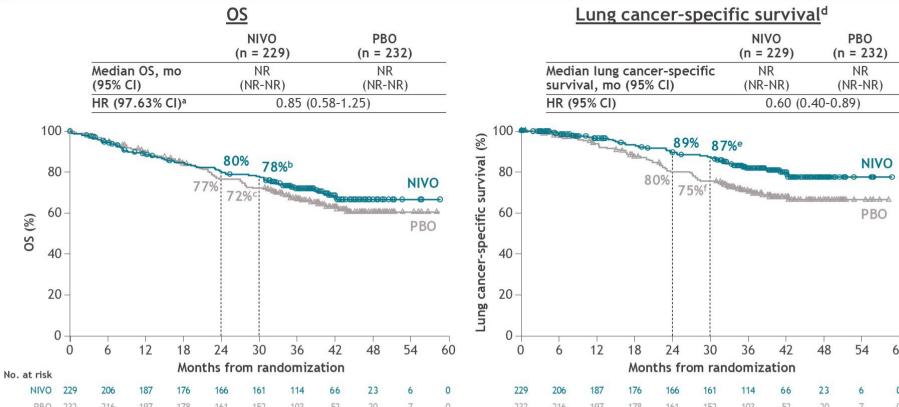


CheckMate 77T: survival and biomarker update

: 54-68; : 36-50.

base lock date: December 16, 2024; median follow-up (range): 41.0 months (31.3-59.8).

## OS and lung cancer-specific survival



Median follow-up (range): 41.0 months (31.3-59.8).  
<sup>a</sup>67 (29%) patients in the NIVO arm and 101 (44%) patients in the PBO arm received subsequent therapy of any type; 50 (22%) and 87 (38%) patients, respectively, received subsequent systemic therapy.  
<sup>b</sup>HR (95% CI), 0.85 (0.40-1.18). Significance boundary for OS was not met at this interim analysis. <sup>c</sup>-95% CI: 172-83; 166-78. <sup>d</sup>Exploratory analysis; events were deaths with noted reason of "disease" per investigator assessment. <sup>e</sup>93% CI: 82-91; 69-81.



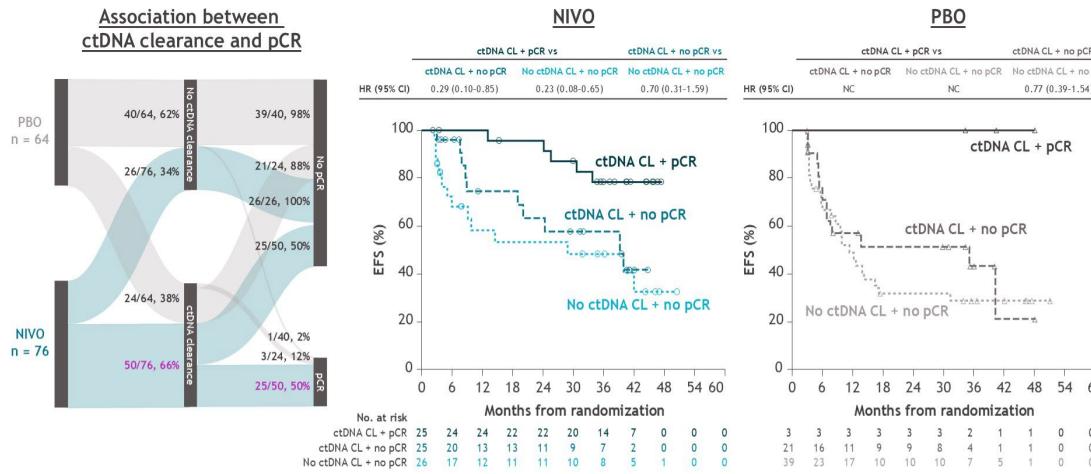
# Novedades en CPNCP: Estadios Iniciales

Abstract: LBA8010



CheckMate 77T: survival and biomarker update

## EFS by ctDNA clearance<sup>a</sup> and pCR status



<sup>a</sup>Change from detectable ctDNA at neoadjuvant treatment initiation (C1D1) to no detectable ctDNA at neoadjuvant treatment completion (end of neoadjuvant treatment or prior to definitive surgery); patients with no detectable ctDNA at neoadjuvant C1D1 were excluded from this analysis. Of randomized patients, 82 (36%) patients in the NIVO arm and 74 (32%) patients in the PBO arm had ctDNA-evaluable samples at both neoadjuvant treatment initiation and completion; 76 (33%) and 64 (28%) patients, respectively, had detectable ctDNA at neoadjuvant treatment initiation.

Landmark EFS from definitive surgery continued to favor NIVO vs PBO in patients with pCR (HR, 0.90; 95% CI, 0.19-4.15) or without pCR (HR, 0.72; 95% CI, 0.50-1.05).

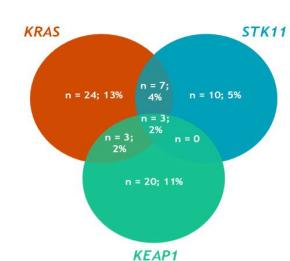
## Summary

- In this updated analysis from CheckMate 77T, perioperative NIVO continued to demonstrate EFS benefit vs PBO in patients with resectable NSCLC (HR, 0.61)
- ctDNA clearance and pCR were associated with improved EFS, regardless of treatment
- EFS favored NIVO vs PBO regardless of KRAS, KEAP1, and/or STK11 tumor mutation status
- OS showed a trend favoring perioperative NIVO over PBO
  - NIVO improved lung cancer-specific survival vs PBO
- No new safety signals were observed at this clinical update
- Results of these efficacy and biomarker analyses further support perioperative NIVO as an efficacious treatment option for patients with resectable NSCLC

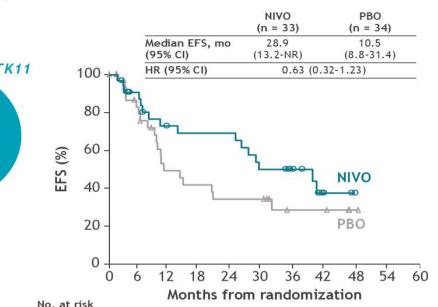
## EFS by tumor mutation status

- Of randomized patients, 190 patients had biomarker-evaluable samples (NIVO, 98 [43%]; PBO, 92 [40%])<sup>a</sup>
- Baseline characteristics were generally balanced between treatment arms, including the frequency of KRAS, KEAP1, and STK11 tumor mutations

### KRAS, KEAP1, and STK11<sup>b</sup>

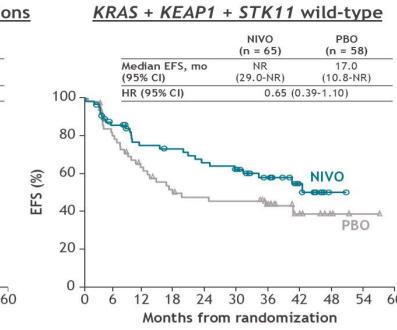


### KRAS ± KEAP1 ± STK11 tumor mutations



CheckMate 77T: survival and biomarker update

### KRAS + KEAP1 + STK11 wild-type



CheckMate 77T: survival and biomarker update



# Novedades en CPNCP: Estadios Iniciales

2025 ASCO®  
ANNUAL MEETING

GECP  
lung cancer  
research

## Neoadjuvant osimertinib ± chemotherapy vs chemotherapy alone in resectable epidermal growth factor receptor-mutated (EGFRm) NSCLC: NeoADAURA

Jamie E. Chaft<sup>1</sup>, Walter Weder, Jianxing He, Ke-Neng Chen, Maximilian J. Hochmair, Jin-Yuan Shih, Sung Yong Lee, Kang-Yun Lee, Nguyen Viet Nhung, Somcharoen Saeteng, Carlos H.A. Teixeira, Carles Escrivà, Alex Martinez-Martí, Collin M. Blakely, Yasushi Yatabe, Sanja Dacic, Xiangning Huang, Yuri Rukazenkova, Anupriya Dayal, Masahiro Tsuboi

<sup>1</sup>Thoracic Oncology Service, Memorial Sloan Kettering Cancer Center, New York, NY, USA; Department of Medicine, Weill Cornell Medical College, New York, NY, USA

2025 ASCO®  
ANNUAL MEETING

#ASCO25

PRESENTED BY: Dr Jamie E. Chaft  
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

ASCO® AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER

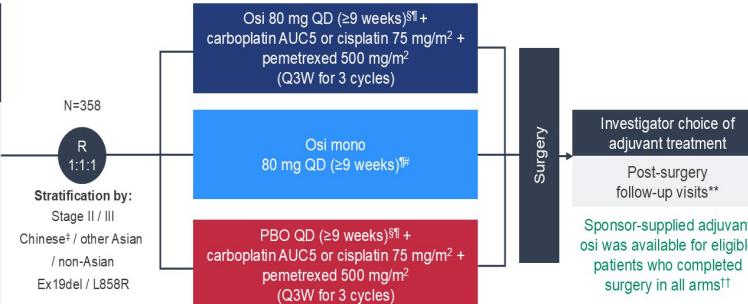
Key inclusion criteria:

- Aged ≥18 years
- Histologically / cytologically confirmed non-squamous NSCLC
- Ex19del / L858R†
- WHO PS 0 / 1

Patients with completely  
resectable EGFRm  
stage II–IIIB NSCLC\*

Stratification by:

N=358  
R  
1:1:1  
Stage II / III  
Chinese‡ / other Asian  
/ non-Asian  
Ex19del / L858R



### Endpoints:

- Primary: major pathological response (MPR; by blinded central pathology review)
- Secondary: event-free survival, pathological complete response, nodal downstaging and safety

NCT04351555. Figure borrowed from 'Neoadjuvant osimertinib with/without chemotherapy versus chemotherapy alone for EGFR-mutated resectable non-small-cell lung cancer: NeoADAURA'. Tsuboi M et al. Published online July 19, 2021 in Future Oncology and reprinted by permission of the publisher Informa UK Limited trading as Taylor & Francis Ltd <http://www.tandfonline.com>. The figure was adapted with permission from the authors.  
\*AJCC Staging Manual 8th edition. †Confirmed by sponsor pre-approved local or central tissue testing. ‡Chinese living in mainland China. †Double-blind. ††Or PBO could be continued up to the date of surgery, at the discretion of the investigator. \*Open-label, sponsor-blinded. ††With cycles 12 and 24 post-surgery, then every 24 weeks until disease recurrence or death, or until discontinuation of therapy due to adverse events, whichever comes first. ‡‡With cycles 12 and 24 post-surgery, then every 24 weeks until disease recurrence or death, or until discontinuation of therapy due to adverse events, whichever comes first. AJCC, American Joint Committee on Cancer; AUC, area under the curve; CTx, chemotherapy; d/t, deletion; EGFR, epidermal growth factor receptor; m, mutated; Ex19del, Exon 19 deletion; mono, monotherapy; NSCLC, non-small cell lung cancer; osi, osimertinib; PBO, placebo; Q3W, once every 3 weeks; QD, once daily; R, randomization; WHO PS, World Health Organisation performance status.

2025 ASCO®  
ANNUAL MEETING

ASCO®  
#ASCO25

PRESENTED BY: Dr Jamie E. Chaft

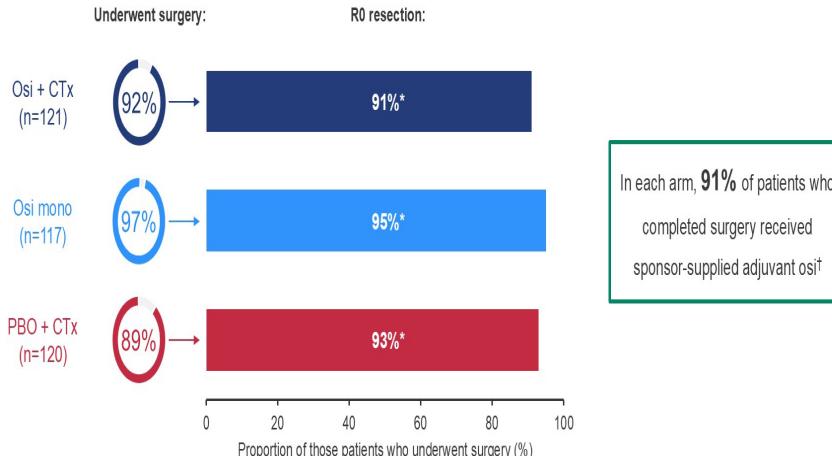
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

ASCO® AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER



# Novedades en CPNCP: Estadios Iniciales

## Surgery summary



- SAEs causally related to surgery occurred in 10%, 5% and 7% of patients
- No patients died within 30 days post-surgery

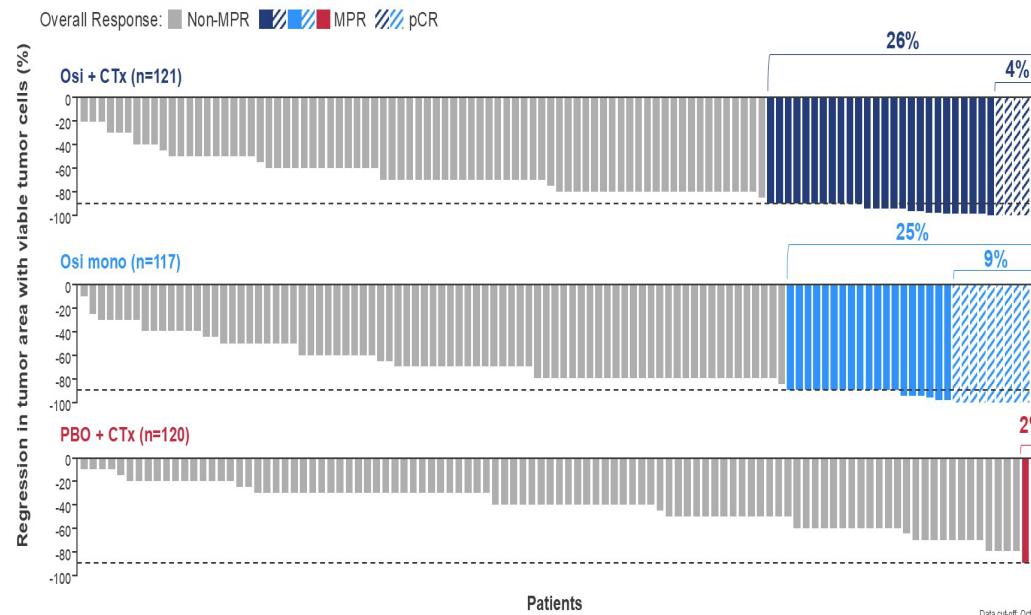
\*One patient in the osi + CTx arm, two patients in the osi mono arm and one patient in the PBO + CTx arm had missing R status data. One patient in the osi + CTx arm and one patient in the PBO + CTx arm had an R2 resection. In addition to patients who received sponsor-supplied adjuvant osi, two patients in the osi + CTx arm, one patient in the osi mono arm and two patients in the PBO + CTx arm received commercial supplied osi.  
†Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

2025 ASCO®  
ANNUAL MEETING #ASCO25

Data cut-off: October 15, 2024.  
CTx, chemotherapy; mono, monotherapy; osi, osimertinib; PBO, placebo  
ASCO® AMERICAN SOCIETY OF CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER

## Depth of pathological response

### Depth of pathological response was greater with the osi-containing regimens



2025 ASCO®  
ANNUAL MEETING #ASCO25

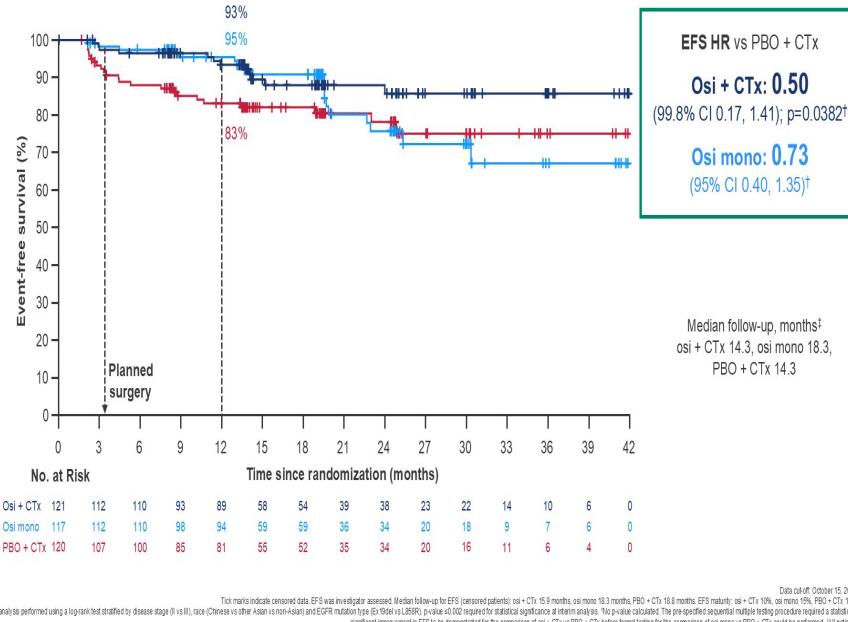
PRESNTED BY: Dr Jamie E. Chaff  
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

CTx, chemotherapy; mono, monotherapy; IASLC, International Association for the Study of Lung Cancer; MPR, major pathological response; osi, osimertinib; PBO, placebo  
ASCO® AMERICAN SOCIETY OF CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER



# Novedades en CPNCP: Estadios Iniciales

## Interim EFS analysis (15% maturity)



## Conclusions

- Neoadjuvant osi, with or without CTx, demonstrated statistically significant improvement in MPR rates vs CTx alone (26% or 25% vs 2%) in resectable EGFRm stage II–IIIB NSCLC
- Interim EFS trends favored the osi-containing arms (osi + CTx HR 0.50; 99.8% CI 0.17, 1.41; osi mono HR 0.73; 95% CI 0.40, 1.35)
- Fewer patients with an MPR had an EFS event vs patients without an MPR (2% vs 18%)
- Over 50% of patients with baseline N2 disease were down-staged at surgery with osi-containing arms vs 21% with CTx alone
- Safety findings were consistent with the known profiles of the individual agents

**Neoadjuvant osi, with or without CTx, should be considered when planning treatment for patients with resectable EGFRm stage II–IIIB NSCLC**

# Novedades en CPNCP: Estadios Iniciales Reordenamiento ALK

Abstract:8015



2025 ASCO®  
ANNUAL MEETING



## Alectinib as Neoadjuvant Treatment in Potentially Resectable Stage III ALK-positive NSCLC: Final Analysis of ALNEO Phase II Trial (GOIRC-01-2020-ML42316)

Alessandro Leonetti<sup>1</sup>, Luca Boni<sup>2</sup>, Letizia Gnetti<sup>3</sup>, Diego Luigi Cortinovis<sup>4</sup>, Giulia Pasello<sup>5</sup>, Francesca Mazzoni<sup>6</sup>, Alessandra Bearz<sup>7</sup>, Francesco Gelsomino<sup>8</sup>, Francesco Passiglia<sup>9</sup>, Sara Pilotti<sup>10</sup>, Giulio Metro<sup>11</sup>, Angelo Delmonte<sup>12</sup>, Fabiano Letizia Cecere<sup>13</sup>, Federica Bertolini<sup>14</sup>, Luca Toschi<sup>15</sup>, Hector Soto Parra<sup>16</sup>, Serena Riccardi<sup>17</sup>, Emilio Bria<sup>18</sup>, Michele Tognetto<sup>19</sup>, **Marcello Tiseo<sup>20</sup>**

<sup>1</sup>Medical Oncology Unit, University Hospital of Parma, Parma, Italy; <sup>2</sup>Spiromedics Unit, IRCCS Ospedale Policlinico San Martino, Genova, Italy; <sup>3</sup>Pneumocrit Unit, University Hospital of Parma, Parma, Italy; <sup>4</sup>GOIRCneoplasie, Fondazione IRCCS San Camillo de' Besta, Monza, Italy; <sup>5</sup>Department of Surgery, Oncology, and Radiotherapy, University of Padova Medical School, Medical Oncology 2 Division, Institute of Oncology IRCCS, Padua, Italy; <sup>6</sup>Medical Oncology Unit, Careggi University Hospital, Florence, Italy; <sup>7</sup>Medical Oncology Unit, CRO-IRCCS Istituto Nazionale Tumori "Dino Avolio", IRCCS, Catania, Italy; <sup>8</sup>Medical Oncology Unit, Department of Oncology, University of Turin, San Luigi Hospital, Orbassano, Italy; <sup>9</sup>Section of Oncology, Department of Engineering for Innovative Medicine, University of Verona, Verona, Italy; <sup>10</sup>Division of Medical Oncology, Azienda Ospedaliera di Perugia, Santa Maria della Misericordia Hospital, Perugia, Italy; <sup>11</sup>Thoracic Oncology Unit, IRCCS Istituto Romagnolo per lo Studio dei Tumori "Dino Arzuffi", IRCCS, Lecce, Italy; <sup>12</sup>Medical Oncology Unit, Department of Oncology, University of Palermo, Palermo, Italy; <sup>13</sup>Medical Oncology Unit, IRCCS Istituto Humanitas Gippa, Rozzano, Italy; <sup>14</sup>Medical Oncology, Policlinico Vittorio Emanuele, Catania, Italy; <sup>15</sup>Pneumo-Oncology Unit, San Camillo-Forlanini Hospital, Rome, Italy; <sup>16</sup>USSD Oncologia Toraco-Pettorale, Comprehensive Cancer Center, Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Medical Oncology, Department of Translational Medicine and Surgery, Università Cattolica del Sacro Cuore, Rome, Italy; <sup>17</sup>Gruppo Oncologico Italiano di Ricerca Clinica, GOIRC, Parma, Italy; <sup>20</sup>Department of Medicine and Surgery, University of Parma, Medical Oncology Unit, University Hospital of Parma, Gruppo Oncologico Italiano di Ricerca Clinica, GOIRC, Parma, Italy

2025 ASCO  
ANNUAL MEETING

#ASCO25

PRESENTED BY: Marcello Tiseo, MD, PhD  
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

ASCO AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER

## Study Design

- Resectable locally advanced stage III NSCLC
- Candidate for surgical resection after multidisciplinary discussion
- ALK-positive (IHC/FISH/NGS)
- No Previous treatment
- ECOG PS 0-1



**Primary Endpoint:** MPR ( $\leq 10\%$  viable tumor) by BICR

**Secondary Endpoints:** pCR by BICR, ORR, EFS, DFS, OS, AEs

**Ancillary biological study<sup>a</sup>:** correlation of tissue and cell-free biomarkers with MPR and DFS

According to the Simon's two-stage mini-max design, the null hypothesis that the MPR is  $\leq 20\%$  will be tested and will be rejected if 11 or more MPR are observed in 33 patients at the final analysis. This design yields a one-sided type I error rate of 0.05 and power of 0.80 when the true MPR is 40%

Abbreviations: AEs, Adverse Events; BICR, Blinded Independent Central Review; DFS, Disease-Free Survival; EFS, Event-Free Survival; MPR, Major Pathologic Response; ORR, Objective Response Rate; OS, Overall Survival; pCR, Pathologic Complete Response; PD, Progressive Disease

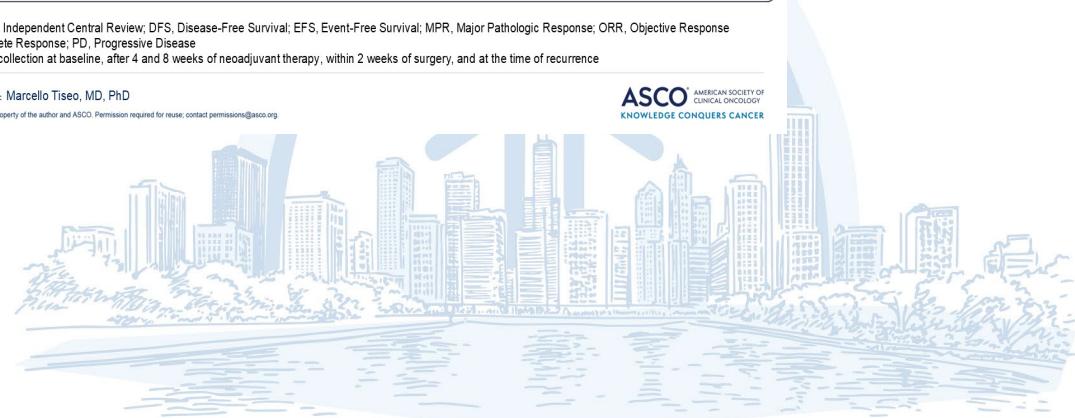
<sup>a</sup>tissue collection at diagnosis and surgery; plasma collection at baseline, after 4 and 8 weeks of neoadjuvant therapy, within 2 weeks of surgery, and at the time of recurrence

2025 ASCO  
ANNUAL MEETING

#ASCO25

PRESENTED BY: Marcello Tiseo, MD, PhD  
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org.

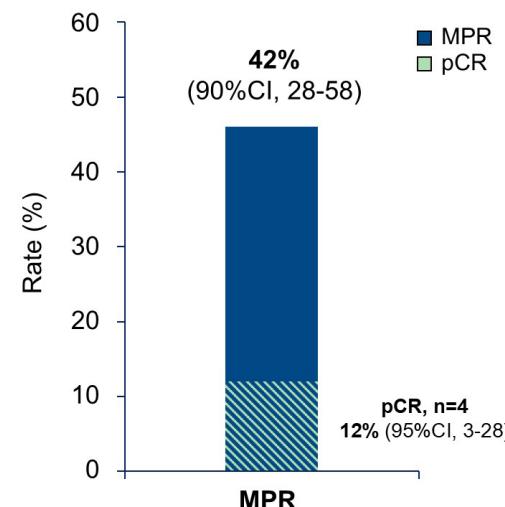
ASCO AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER



## Results – Primary Endpoint: MPR by BICR

Pathologic Response	N=33
MPR ( $\leq 10\%$ viable tumor), n (%)	14 (42)
Non-MPR ( $>10\%$ viable tumor), n (%)	13 (40)
Not assessed, n (%)	6 (18) <sup>a</sup>

<sup>a</sup>5 patients did not undergo surgery, 1 patient underwent explorative thoracotomy



Abbreviations: CI, Confidence Interval; MPR, Major Pathologic Response; pCR, Pathologic Complete Response

2025 ASCO  
ANNUAL MEETING

#ASCO25

PRESNTED BY: Marcello Tiseo, MD, PhD  
Presentation is property of the author and ASCO. Permission required for reuse; contact permissions@asco.org

ASCO<sup>®</sup> AMERICAN SOCIETY OF  
CLINICAL ONCOLOGY  
KNOWLEDGE CONQUERS CANCER

## Conclusions

- ALNEO phase II trial met its primary endpoint with neoadjuvant alectinib in potentially resectable stage III ALK-positive NSCLC patients
  - **MPR 42% (90%CI, 28-58); pCR 12% (95%CI, 3-28)**
- The treatment was well-tolerated and the safety profile was consistent with previous alectinib studies
- With the limitation of a small phase II non-randomized trial, ALNEO study suggests alectinib as an active and feasible peri-operative option in resectable stage III ALK-positive NSCLC patients
- Molecular sub-study on tissue and liquid biopsies is ongoing

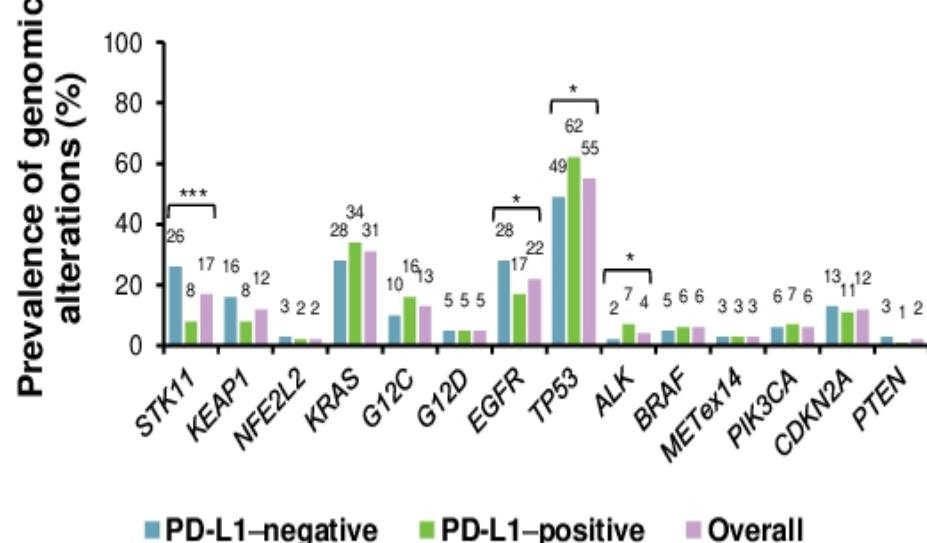


# Novedades en CPNCP: Estadios Iniciales

## Genomic alterations associated with PD-L1 TC SP263 status by histology

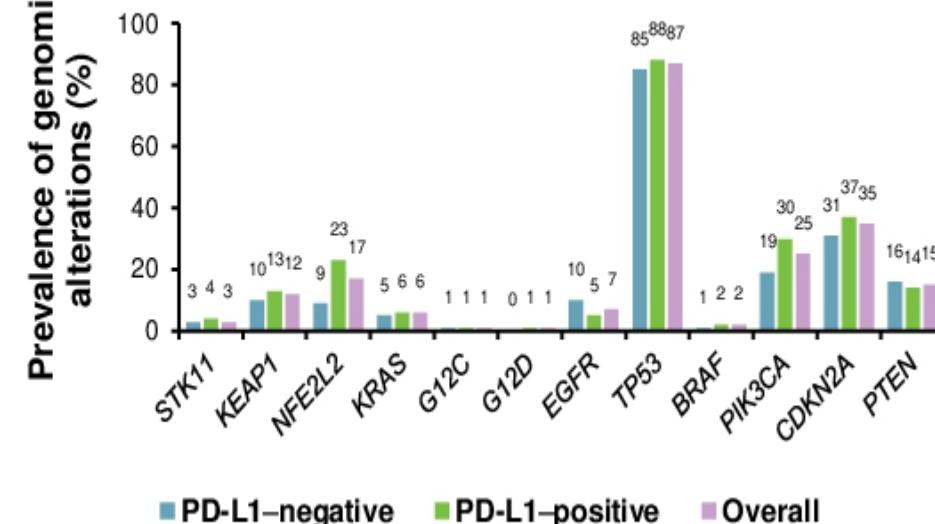
A

Non-squamous (n=413)



B

Squamous (n=210)



## CONCLUSIONS

- This analysis represents the largest dataset evaluating the genomic profile of patients with eNSCLC who were treated with cancer immunotherapy
- The prevalences of *STK11* and *KEAP1* genomic alterations were lower than in mNSCLC and were enriched for PD-L1-negative TCs in non-squamous NSCLC
- Unlike in mNSCLC, patients with tumors that harbored *KEAP1* genomic alterations did not have poor prognosis in IMpower010
- These data are hypothesis-generating and require validation in independent eNSCLC datasets with larger numbers



# Novedades en CPNCP: Estadios Iniciales

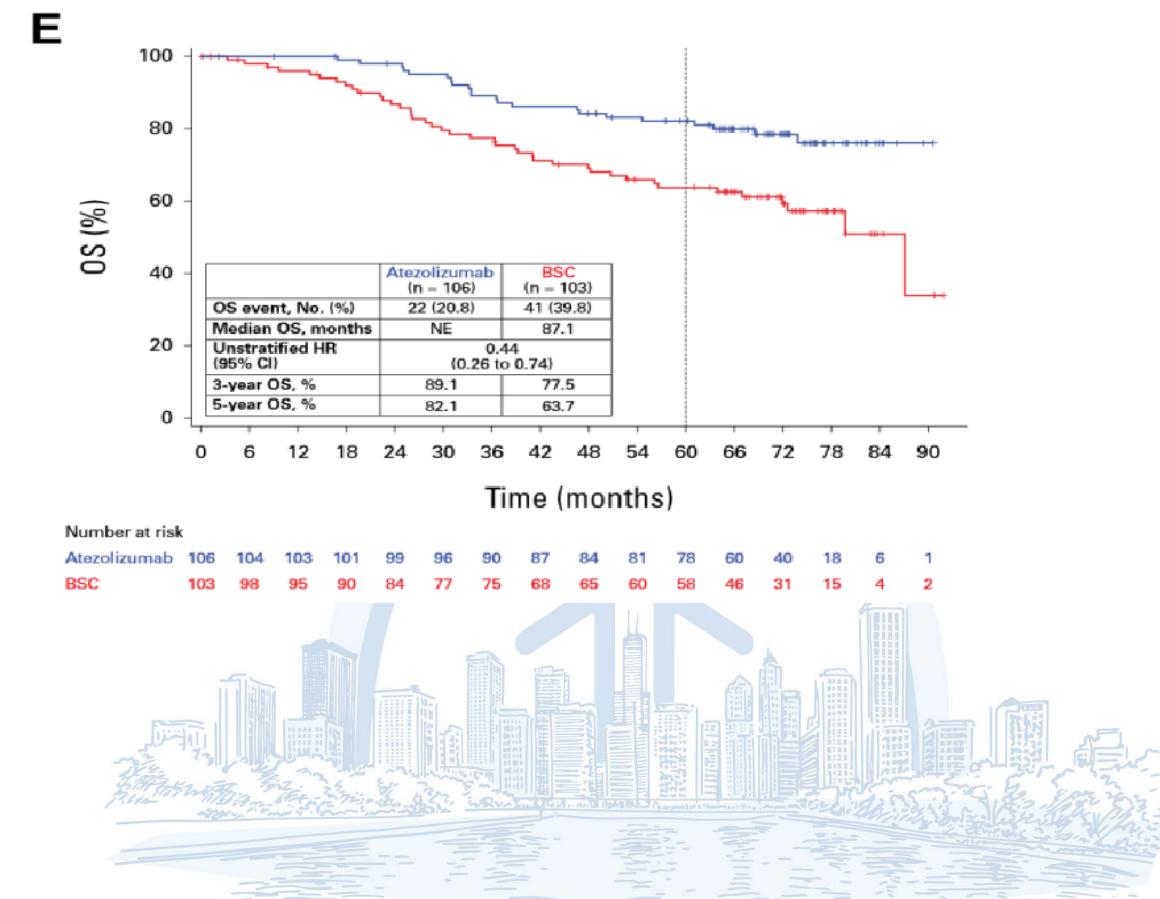
ASCO® Journal of Clinical Oncology\*

## Five-Year Survival Outcomes With Atezolizumab After Chemotherapy in Resected Stage IB- IIIA Non-Small Cell Lung Cancer (IMpower010): An Open-Label, Randomized, Phase III Trial

Enriqueta Felip<sup>1</sup>, Nasser Altorki<sup>2</sup>, Caicun Zhou<sup>3</sup>, Eric Vallières<sup>4</sup>, Tibor Csozzi<sup>5</sup>, Ihor O Vynnychenko<sup>6</sup>, Oleksandr Goloborodko<sup>7</sup>, Achim Rittmeyer<sup>8</sup>, Martin Reck<sup>9</sup>, Alex Martinez-Martí<sup>1</sup>, Hirotugu Kenmotsu<sup>10</sup>, Yuh-Min Chen<sup>11</sup>, Antonio Chella<sup>12</sup>, Shunichi Sugawara<sup>13</sup>, Chengqi Fu<sup>14</sup>, Marcus Ballinger<sup>14</sup>, Yu Deng<sup>14</sup>, Minu K Srivastava<sup>14</sup>, Elizabeth Bennett<sup>14</sup>, Barbara J Gitlitz<sup>14</sup>, Heather A Wakelee<sup>15</sup>; IMpower010 Study Investigators

	SLE	SG
ITT	0.85 (95% CI, 0.71 to 1.01; $P = .07$ )	0.97 (95% CI, 0.78 to 1.22)
Estadio II-III-A	HR: 0.83 (95% CI, 0.69 to 1.00)	0.94 (95% CI, 0.75 to 1.19)
Estadio II-III-A PD-L1 $\geq 1\%$	HR: 0.70 (95% CI, 0.55 to 0.91)	0.77 (95% CI, 0.56 to 1.06)
Estadio II-III-A PD-L1 $\geq 50\%$ (EGFR/ALK wt)	HR: 0.49 (95% CI, 0.32 to 0.75)	HR: 0.44 (95% CI, 0.26 to 0.74).

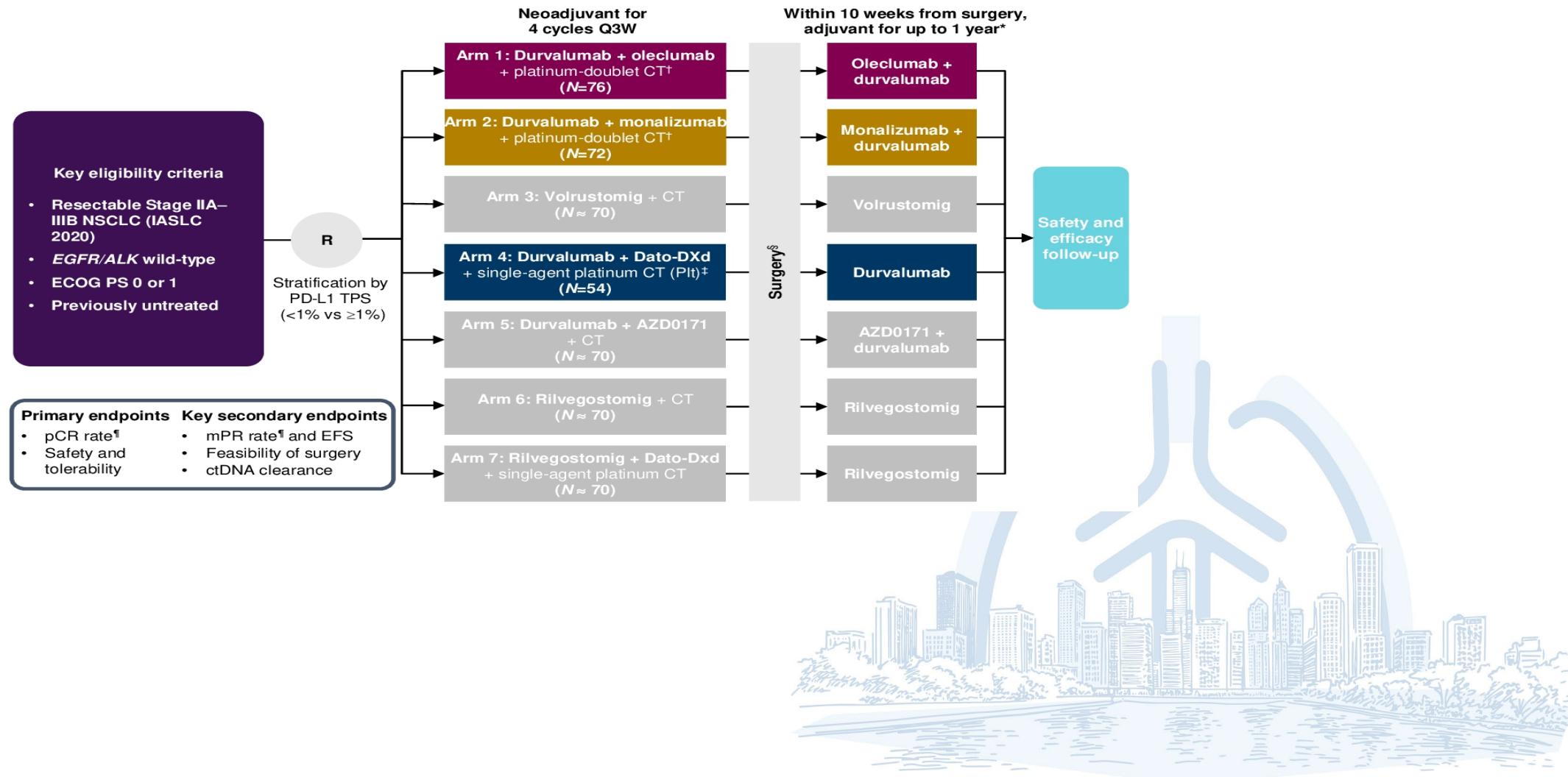
In conclusion, after a 5-year follow-up, atezolizumab did not show a statistically significant improvement in DFS in the ITT population. No improvement in OS was observed in the ITT population at this interim analysis; follow-up is continuing for another OS analysis. Results from the DFS final analysis and second OS interim analysis further support the use of adjuvant atezolizumab in PD-L1-selected patient populations.



# Novedades en CPNCP: Estadios Iniciales

## NeoCOAST-2 study design

Abstract: 8043. Poster Bd: #167

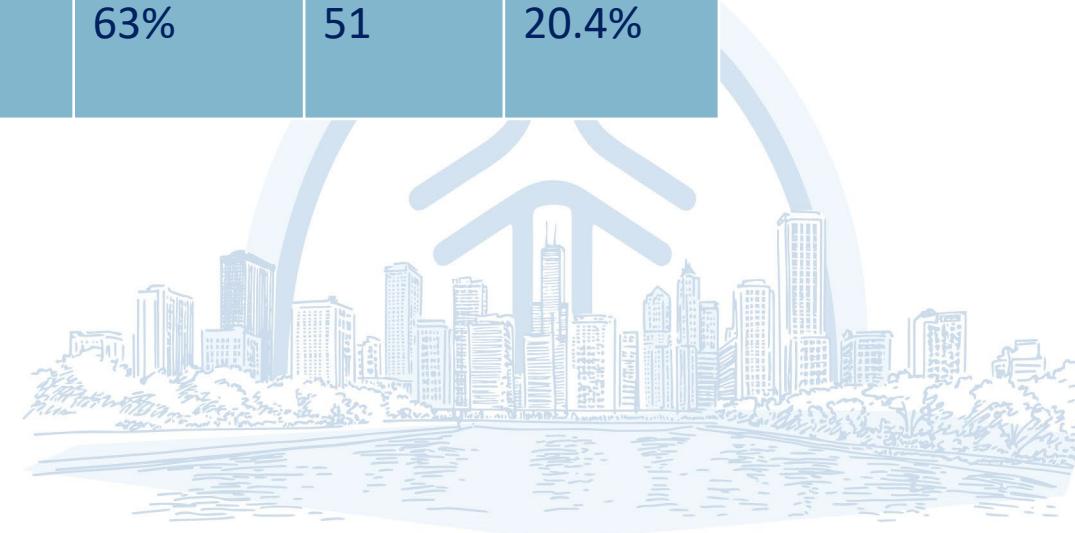


# Novedades en CPNCP: Estadios Iniciales

Abstract: 8043. Poster Bd: #167



NeoCOAST 2	Fármacos	Mecanismo de acción (nuevo agente)	cPR	mPR	Operados	Seguridad $\geq 3$
ARM 1 <i>n: 74</i>	N. Durvalumab+Oleclumab+ QT (2 agentes) A. D + O	Inhibidor de CD73	20.3%	41.9%	69	36.5%
ARM 2 <i>n: 70</i>	N. Durvalumab+Monalizumab+ QT (2 agentes) A. D +M	Inhibidor de NKG2A	25.7%	50%	66	40.8%
ARM 4 <i>n: 54</i>	N.Durvalumab+Datopotamab-Dxt + Platino A. D	ADC (TROP-2)	35.2%	63%	51	20.4%



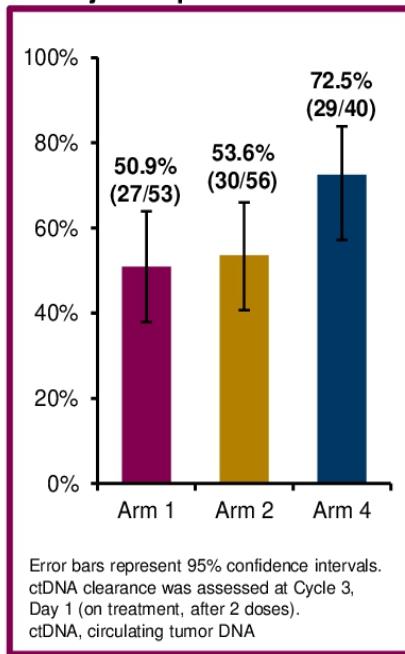


# Novedades en CPNCP: Estadios Iniciales

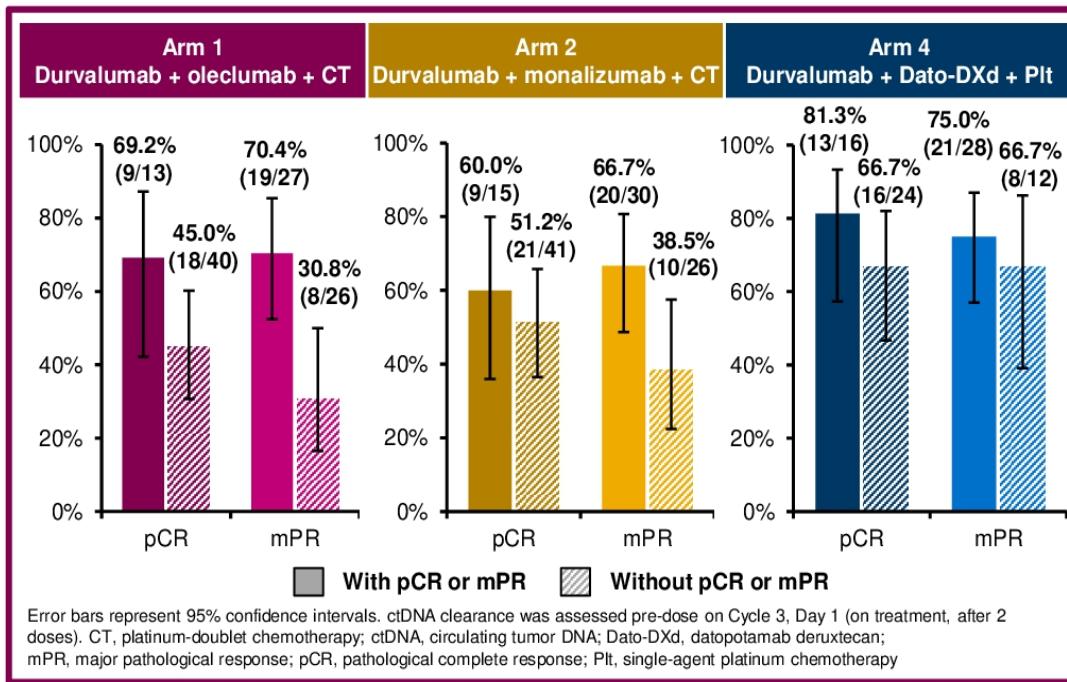
## ctDNA clearance

- Rates of ctDNA clearance in the neoadjuvant period were numerically higher in Arm 4 vs Arms 1 and 2 (**Figure 9**).
- ctDNA clearance was numerically higher in patients with pCR vs without pCR and with mPR vs without mPR across arms (**Figure 10**).

**Figure 9: Proportions of patients with ctDNA clearance in the neoadjuvant period**



**Figure 10: Proportions of patients with ctDNA clearance for patients with pCR vs without pCR and with mPR vs without mPR**



- Presurgical ctDNA clearance was associated with pathological responses in all arms, with the numerically highest rate of ctDNA clearance observed in Arm 4.
- NeoCOAST-2 is ongoing, including newly added arms assessing (1) neoadjuvant rilvecostomig + CT and adjuvant rilvecostomig, and (2) neoadjuvant Dato-DXd + rilvecostomig + Plt and adjuvant rilvecostomig.

# Novedades en CPNCP: Estadios localmente avanzados

NeoCOAST 2	Fármacos	Mecanismo de acción (nuevo agente)	cRP	mPR	Operados	Seguridad $\geq 3$	Aclaramiento de ctDNA (d+1 C3)
ARM 1 <i>n: 74</i>	Durvalumab+Oleclumab+QT (2 agentes) <b>A. D+O</b>	Inhibidor de CD73	20.3%	41.9%	69	36.5%	50.9%
ARM 2 <i>n: 70</i>	Durvalumab+Monalizumab + QT (2 agentes) <b>A. D+M</b>	Inhibidor de NKG2A	25.7%	50%	66	40.8%	53.6%
ARM 4 <i>n: 54</i>	Durvalumab+Datopotamab-Dxt+ <b>Platino</b> <b>A. D</b>	ADC (TROP-2)	35.2%	63%	51	20.4%	72.5%

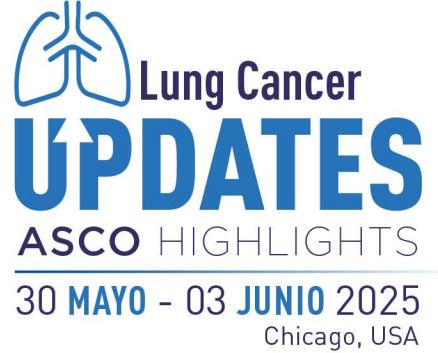


# Novedades en CPNCP: Estadios Iniciales

En resumen:

- Claro beneficio de la IO en Neoadyuvancia: CM 816 (HR, 0.72)
- Perioperatorio CM 77T: Impacta en SLE (HR, 0.61).  
Aclaramiento de ct DNA/Respuesta patológica: impacto en SLE.
- NeoADAURA: Osimertinib en neoadyuvancia: datos inmaduros en cuenta a supervivencia, pero mejoría en mPR
- ALNEO: Fase II: Perioperatorio con Alectinib, mejoría en mRP
- IMpower 010: Datos a 5 años, no se alcanzan el número de eventos, beneficio para Atezolizumab adyuvante.
- NeoCOAST-2: ADC: Datopotamab/Deruxtecan + Durvalumab + Platino: Mejora la mPR, pCR, esquema seguro, mayor aclaramiento de ctDNA y respuesta patológica.





Iniciativa científica de:



¡GRACIAS !!



# Novedades en CPNCP: Estadios Iniciales

Abstract:8009

Todos los pts	Estadio II	Estadio III	Escamoso	No escamoso	PD-L1 < 1%	PD-L1 ≥ 1%	
<b>NIVO</b> (N = 229) vs PBO(N = 232)	<b>NIVO</b> (n = 80) vs PBO (n = 81)	<b>NIVO</b> (n = 149) vs PBO ( n = 149)	<b>NIVO</b> (n = 116) vs PBO (n = 118)	<b>NIVO</b> (n = 113) vs PBO (n = 114)	<b>NIVO</b> (n = 93) vs PBO (n = 93)	<b>NIVO</b> (n = 128) vs PBO (n = 128)	
<b>Mediana de EFS,</b> <b>meses</b>	46.6 frente a 16.9	NR vs NR	42.1 frente a 13.4	NR vs 16.4	40,1 frente a 16,9	40,1 frente a 19,8	46,6 frente a 15,1
<b>HR</b> <b>(IC 95%)</b>	0,61 (0,46–0,80)	0,77 (0,46–1,30)	0,54 (0,39–0,74)	0,53 (0,35–0,80)	0,69 (0,48–1,00)	0,79 (0,52–1,21)	0,53 (0,36–0,76)

