

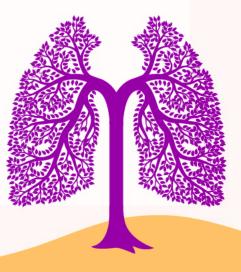
ESMO 2023 Industry Satellite Symposium

Redefining Lung Cancer Together: A New Era for Patients

> This is a non-promotional educational meeting organised and funded by F. Hoffmann-La Roche Ltd It is intended for healthcare professionals outside the United States of America (USA) Date of preparation: October 2023. M-XX-00014685

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### **Disclosures**

**Stephen V Liu:** advisory board/consultancy for AbbVie, Amgen, AstraZeneca, Boehringer-Ingelheim, Bristol Myers Squibb, Catalyst, Daiichi Sankyo, Eisai, Elevation Oncology, Genentech/Roche, Gilead, Guardant Health, Janssen, Jazz Pharmaceuticals, Merck, Merus, Mirati, Novartis, Regeneron, Sanofi, Takeda, and Turning Point Therapeutics; research grants (to institution) from AbbVie, Alkermes, Elevation Oncology, Ellipses, Genentech, Gilead, Merck, Merus, Nuvalent, RAPT, and Turning Point Therapeutics; member of Data Safety Monitoring Board for Candel Therapeutics

Nasser Altorki: research grants from AstraZeneca and Janssen; honoraria from Merck, Regeneron, and Roche

Lara Pijuan: consulting fees and honoraria from AstraZeneca, Janssen, Merck/MSD, and Roche

**Martin Reck:** honoraria from Amgen, AstraZeneca, BeiGene, Bristol Myers Squibb, Boehringer Ingelheim, Daiichi Sankyo, GlaxoSmithKline, Janssen, Lilly, Medscape, Merck Serono, Mirati Therapeutics, MSD, Novartis, Pfizer, PharmaMar, Regeron, Roche/Genentech, Sanofi and Takeda; speakers' bureau for AstraZeneca, BMS, Boehringer Ingelheim, Daiichi Sankyo, GSK, Lilly, Merck Serono, Mirati, MSD, Pfizer, Roche/Genentech, Sanofi, and Takeda; research funding (to institution) from Boehringer Ingelheim, and Bristol Myers Squibb; member of Data Safety Monitoring Board for Daiichi Sankyo, and Sanofi

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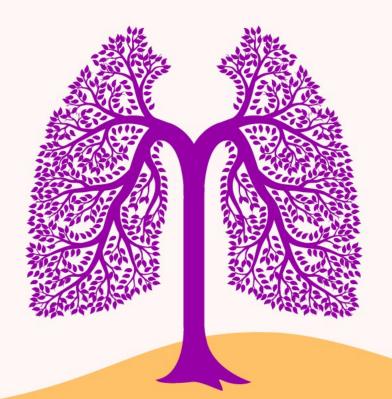




#### Meeting Chair Stephen V Liu

Georgetown University Washington DC, USA

### Welcome and introduction



### Symposium faculty



#### Stephen V Liu (Chair)

Georgetown University Washington DC, USA



Nasser Altorki Weill Cornell Medicine New York, NY, USA



Martin Reck

LungenClinic Großhansdorf, Germany



#### Lara Pijuan Hospital Universitari de Bellvitge

Barcelona, Spain



Alba Silverio Pons Vall d'Hebron Institute of Oncology (VHIO) Barcelona, Spain





#### Welcome and introduction

Stephen V Liu

#### Optimising the patient journey: from lung cancer detection to biomarker testing

Stephen V Liu, Lara Pijuan

#### **Evolving treatment decisions in resectable NSCLC**

Martin Reck, Nasser Altorki

### A look at the patient journey through the lens of the nurse

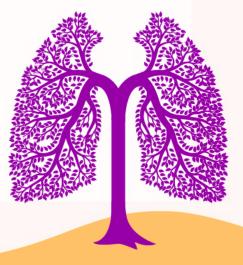
Alba Silverio Pons

#### Panel discussion and Q&A

All

#### **Closing remarks**

Stephen V Liu



# Feel free to send your questions during the symposium

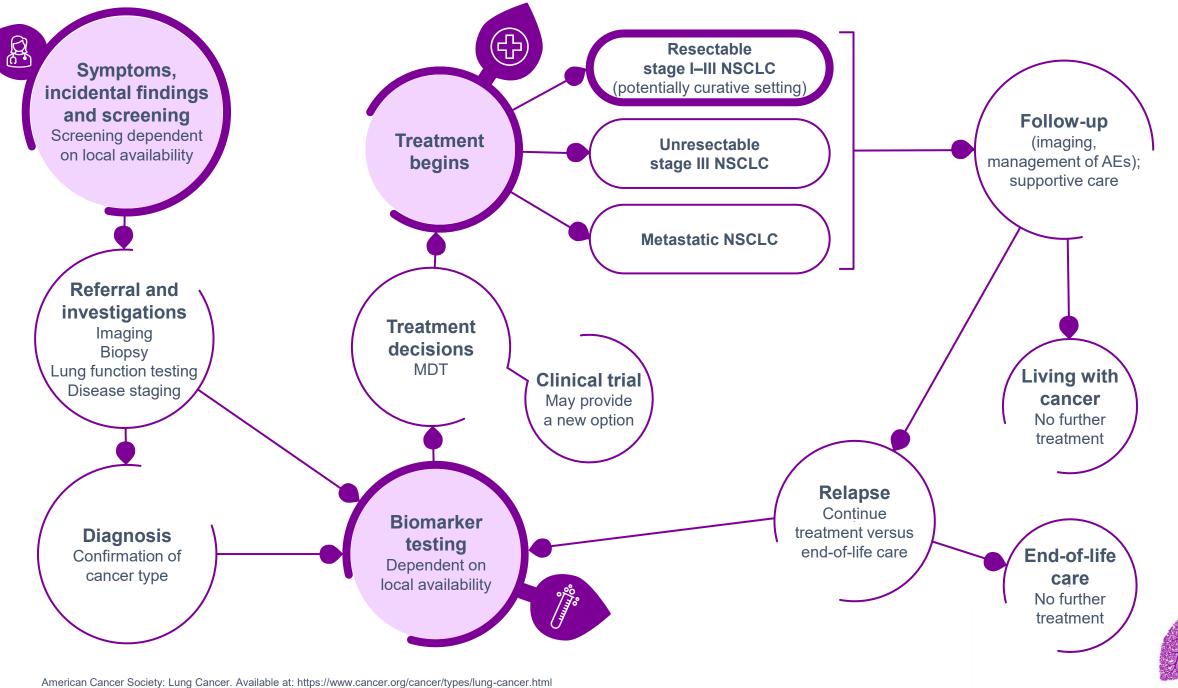
#### Live audience

Scan the QR code on the right Select the session name: REDEFINING LUNG CANCER TOGETHER: A NEW ERA FOR PATIENTS

#### **Online attendees**

Type in the chat box next to the streaming video





Cancer Research UK: Lung Cancer. Available at: https://www.cancer.org/cancer/types/lung-cancer.html



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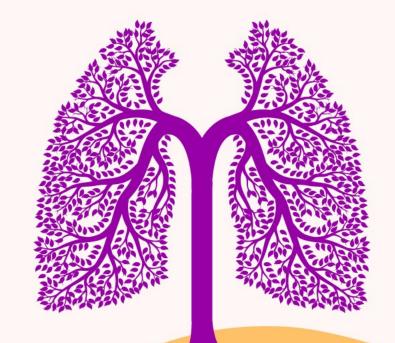
Stephen V Liu

Medical Oncologist Georgetown University, USA

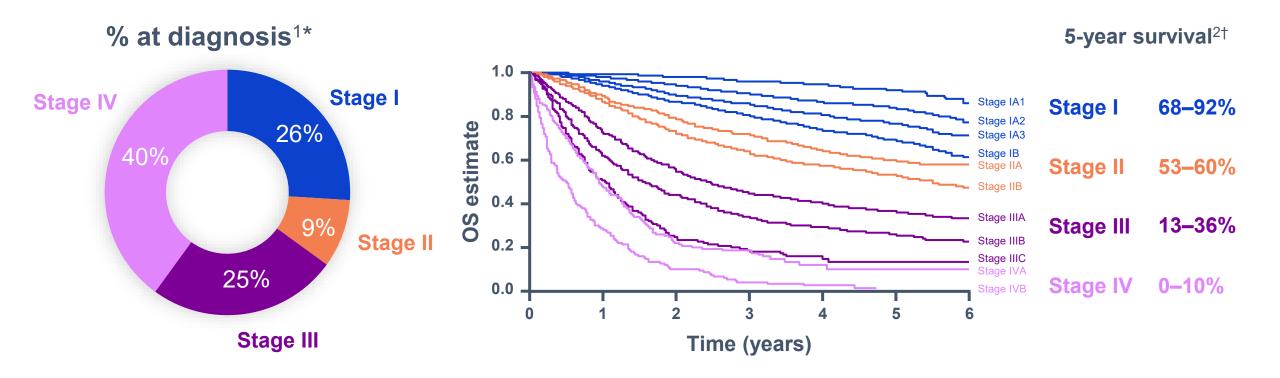
#### Lara Pijuan

Cytopathologist and Pulmonary Pathologist Hospital Universitari de Bellvitge, Spain

### Optimising the patient journey: from lung cancer detection to biomarker testing



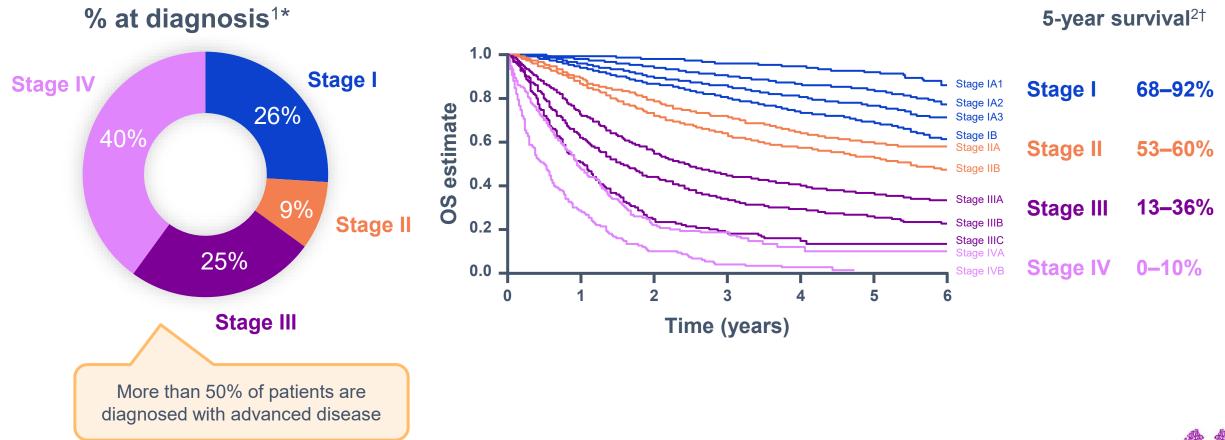
Most patients are diagnosed with advanced disease, which is associated with a poorer prognosis





\*Published data from: France, Germany, Japan, Italy, Spain, UK and US; <sup>†</sup>per AJCC 8<sup>th</sup> edition 1. EpiCast report: NSCLC Epidemiology Forecast to 2025. GlobalData. 2016; 2. Goldstraw, et al. J Thorac Oncol 2016. Figure reprinted from Journal of Thoracic Oncology, Vol 11/ issue 1, Goldstraw et al., The IASLC Lung Cancer Staging Project: Proposals for Revision of the TNM Stage Groupings in the Forthcoming (Eighth) Edition of the TNM Classification for Lung Cancer, Copyright (2016), with permission from Elsevier

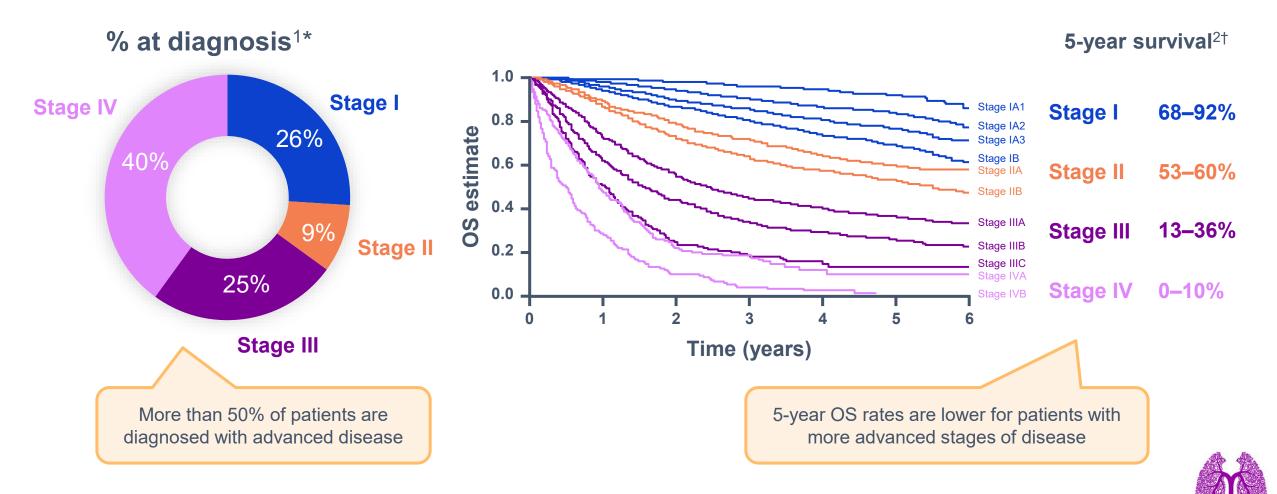
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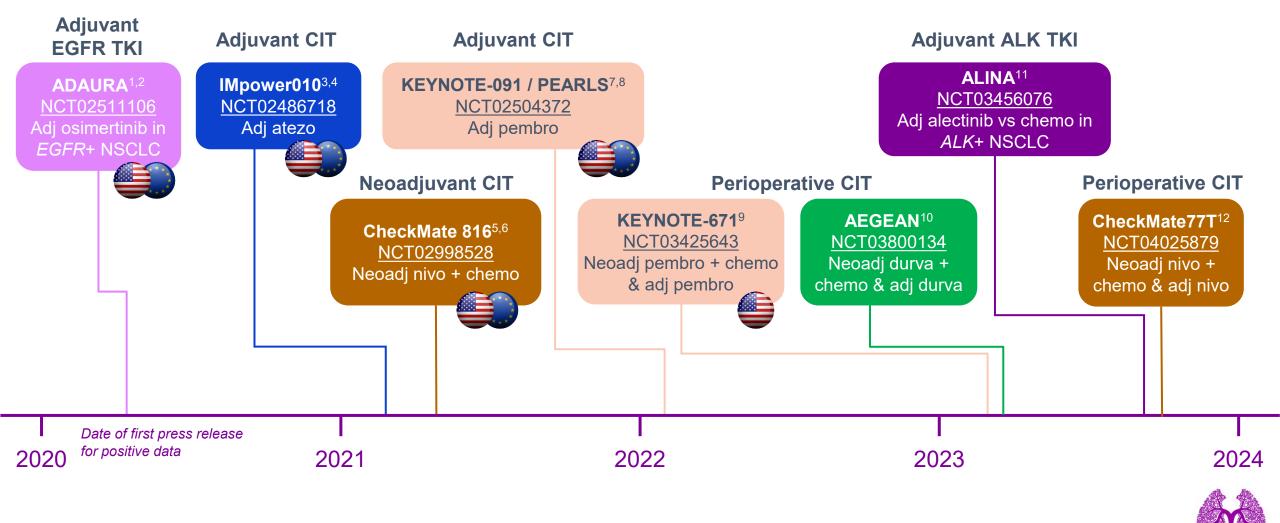
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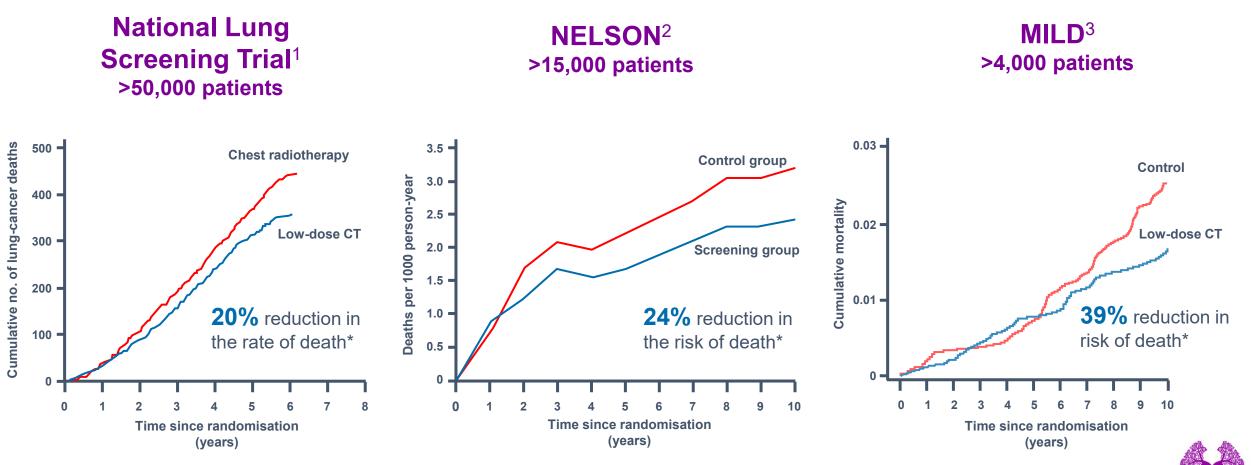
1. EpiCast report: NSCLC Epidemiology Forecast to 2025. GlobalData. 2016; 2. Goldstraw, et al. J Thorac Oncol 2016. Figure reprinted from Journal of Thoracic Oncology, Vol 11/ issue 1, Goldstraw et al., The IASLC Lung Cancer Staging Project: Proposals for Revision of the TNM Stage Groupings in the Forthcoming (Eighth) Edition of the TNM Classification for Lung Cancer, Copyright (2016), with permission from Elsevier

### Recent phase III positive trials of new therapies in early-stage disease reinforce the benefit of early diagnosis



The content of this symposium may include scientific information about experimental or investigational compounds, indications and services that are not yet approved in the EU 1. US PI TAGRISSO (osimertinib); 2. EMA SmPC TAGRISSO (osimertinib); 3. US PI TECENTRIQ (atezolizumab); 4. EMA SmPC TECENTRIQ (atezolizumab); 5. US PI OPDIVO (nivolumab) 6. EMA SmPC OPDIVO (nivolumab); 7. US PI KEYTRUDA (pembrolizumab); 8. Merck press release (16 October 2023; KEYNOTE-091); 9. Merck press release (16 October 2023; KEYNOTE-671) 10. AstraZeneca press release (09 March 2023; AEGEAN); 11. Roche press release (01 September 2023; ALINA); 12. Bristol Myers Squibb press release (22 September 2023; CheckMate 77T)

Low-dose CT screening can improve lung cancer survival by detecting cancers at an earlier stage, where outcomes are better



#### \*From lung cancer

1. From The New England Journal of Medicine, Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening, Volume 365. Copyright © (2011) Massachusetts Medical Society 2. From The New England Journal of Medicine, de Koning, et al., Reduced Lung-Cancer Mortality with Volume CT Screening in a Randomized Trial, Volume 382, Copyright © (2020) Massachusetts Medical Society; 3. Reprinted from Annals of Oncology, Vol 30/ Issue 7, Pastorino et al., Prolonged lung cancer screening reduced 10-year mortality in the MILD trial: new confirmation of lung cancer screening efficacy. Copyright (2019), with permission from Elsevier

## Current identification of individuals at increased risk of being diagnosed with lung cancer is based on a wide range of factors

#### Guidelines for lung cancer screening prioritise people with a history of smoking

#### **USPSTF recommendations:**<sup>1</sup>

- Adults aged 50 to 80 years
- A 20 pack-year smoking history
- Currently smoke or have quit within the past 15 years

#### **European evidence (NELSON study):**<sup>2</sup>

- Adults aged 50 to 74 years
- A history of >15 cigarettes/day for >25 years or >10 cigarettes/day for >30 years
- Currently smoke or have quit within the past 10 years



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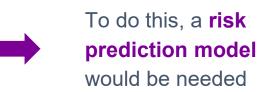
TALENT study:<sup>3</sup> screening study of 12,011 high-risk, never smokers in Taiwan High detection rate; most patients diagnosed at stage 0 or 1 **FANSS** study:<sup>4</sup> US screening study of 201 **female non-smokers of Asian descent** 

High detection rate; all patients detected had EGFR mutations

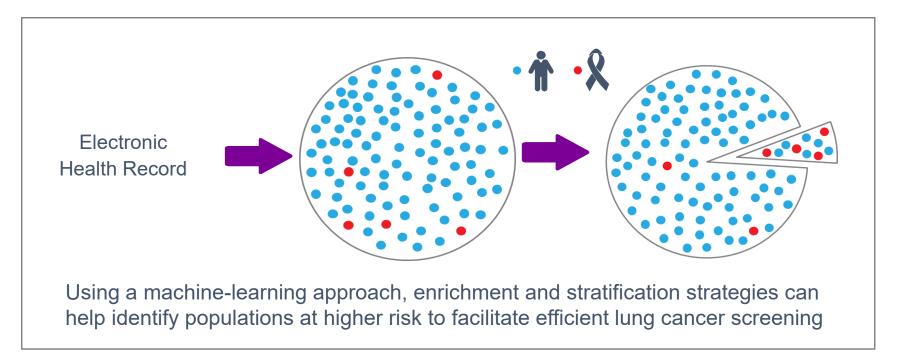


## Risk prediction models could improve the effectiveness of lung cancer screening

Lung cancer mortality could be reduced by **identifying people at higher risk of lung cancer** and **offering low dose CT screening** 

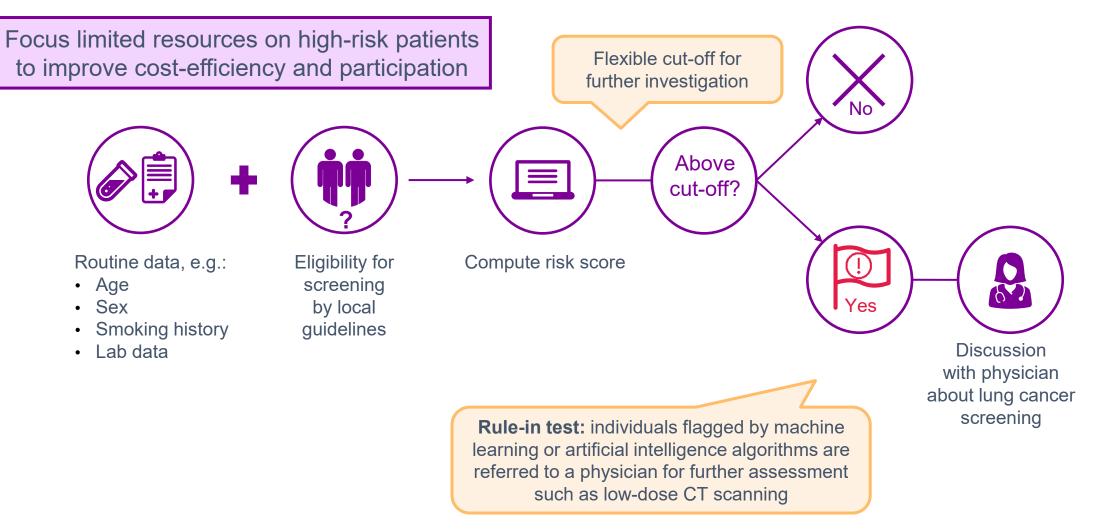


The model would then need to be **validated** to establish performance, health-economic effectiveness, and equity in different sub-populations



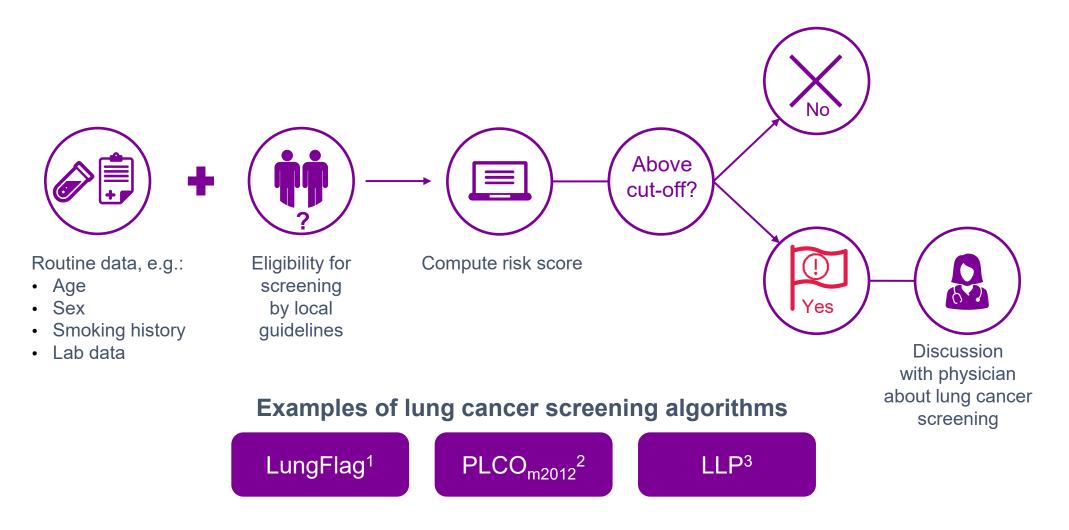


### Machine-learning tools and AI algorithms can act as 'digital biomarkers' to rule-in high-risk patients and improve the efficiency of screening





Machine-learning tools and AI algorithms can act as 'digital biomarkers' to rule-in high-risk patients and improve the efficiency of screening



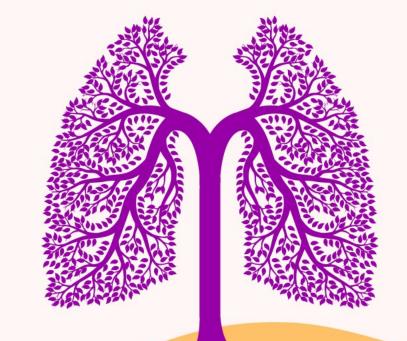
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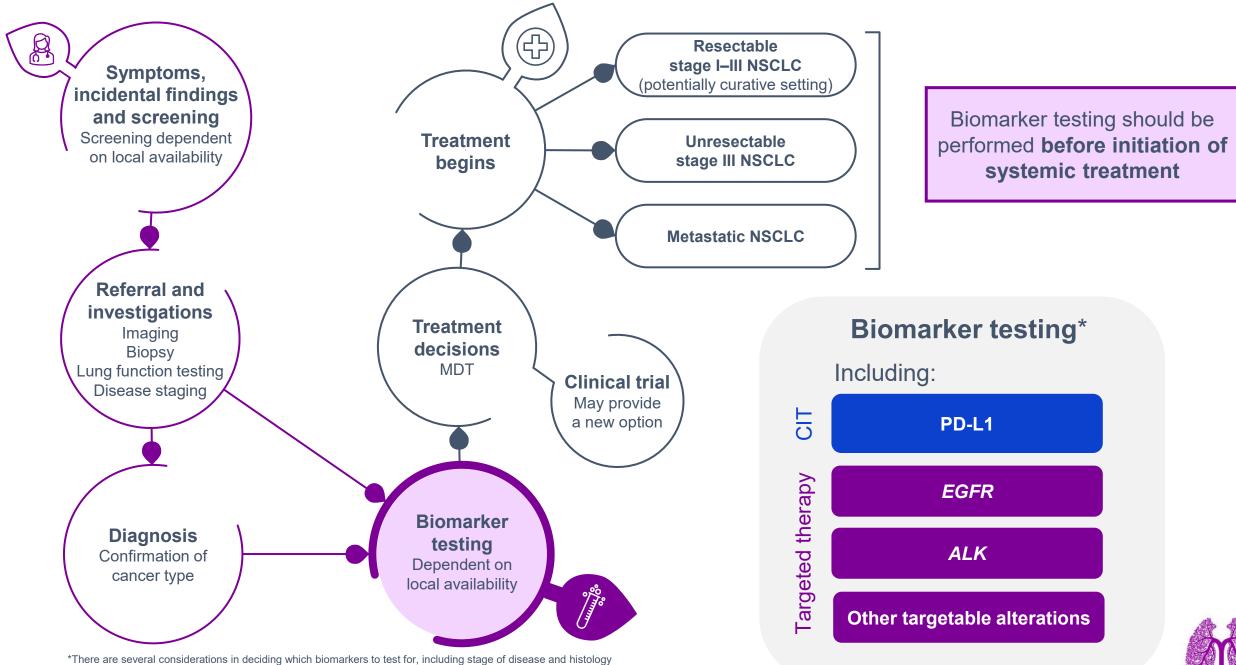
Exact parameters vary between tools

LLP, Liverpool Lung Project; PLCO, Prostate, Lung, Colorectal, and Ovarian cancer screening trial

1. Morgenstern & Choman. ASCO 2023; 2. Tammemägi, et al. N Engl J Med 2013; 3. Cassidy, et al. Br J Cancer 2008

Besides screening, what else is key to optimising the patient journey and what can we learn from the advanced disease setting?





American Cancer Society: Lung Cancer. Available at: https://www.cancer.org/cancer/types/lung-cancer.html Cancer Research UK: Lung Cancer. Available at: https://www.cancerresearchuk.org/about-cancer/lung-cancer Hendriks, et al. Ann Oncol 2023a; Hendriks, et al. Ann Oncol 2023b; Remon, et al. Ann Oncol 2023

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### In advanced NSCLC, the development of multiple targeted therapies has revolutionised the treatment landscape

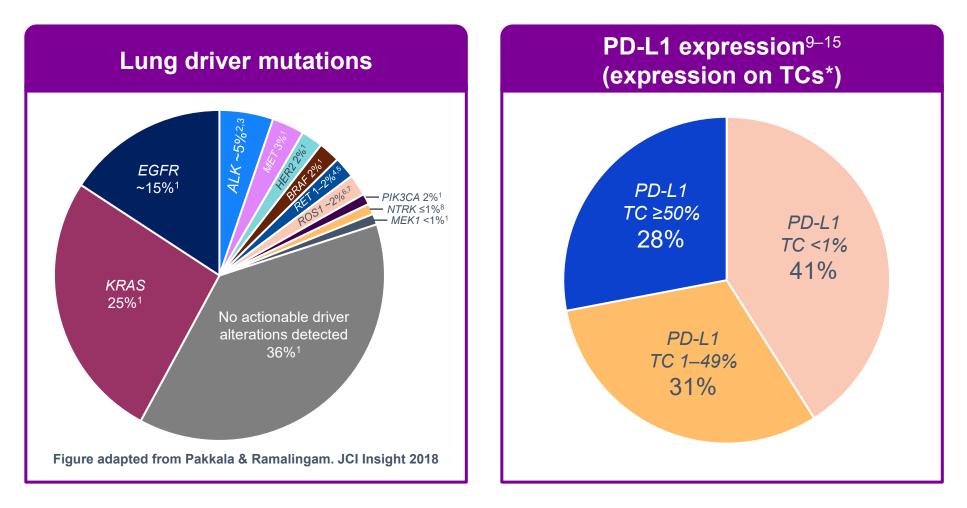
#### EGFR ALK Erlotinib Alectinib ~5% Afatinib Brigatinib Ceritinib Dacomitinib • • ALK EGFR Crizotinib Gefitinib • ~15%1 Osimertinib PIK3CA 2%1 Lorlatinib NTRK ≤1%<sup>8</sup> Erlotinib + bevacizumab • MFK1 <1%<sup>1</sup> NTRK Erlotinib + ramucirumab Entrectinib▼ ROS1 KRAS Larotrectinib 25%<sup>1</sup> Entrectinib▼ No actionable driver BRAF V600E alterations detected Crizotinib 36%<sup>1</sup> Dabrafenib + trametinib RET KRAS G12C Targeting actionable Pralsetinib▼ driver alterations Sotorasib Selpercatinib Adagrasib ٠ Figure adapted from Pakkala & Ramalingam. JCI Insight 2018 MET HER2 Capmatinib Trastuzumab deruxtecan Tepotinib The content of this symposium may include scientific information about experimental or investigational compounds, indications and services that are not vet approved in the EU This medicinal product is subject to additional monitoring. This will allow guick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions Please report suspected adverse reactions to the National Health Authority in your country and/or Roche Safety contact in your country (www.roche.com and select your country)

Approved drugs for each biomarker<sup>9</sup>

**Oncogenic drivers in lung cancer** 

1. Pakkala & Ramalingam. JCI Insight 2018; 2. Barlesi, et al. Lancet 2016; 3. Ťian, et al. Lung Cancer 2017; 4. Qiu, et al. Sci Rep 2020; 5. Gainor & Shaw. Oncologist 2013 6. Bergethon, et al. J Člin Oncol 2012; 7. Dugay, et al. Oncotarget 2017; 8. Farago, et al. JCO Precis Oncol 2018, 9. US PIs and/or EMA SmPCs for individual drugs

### NSCLC has important genomic and immunological biomarkers that directly affect treatment decisions

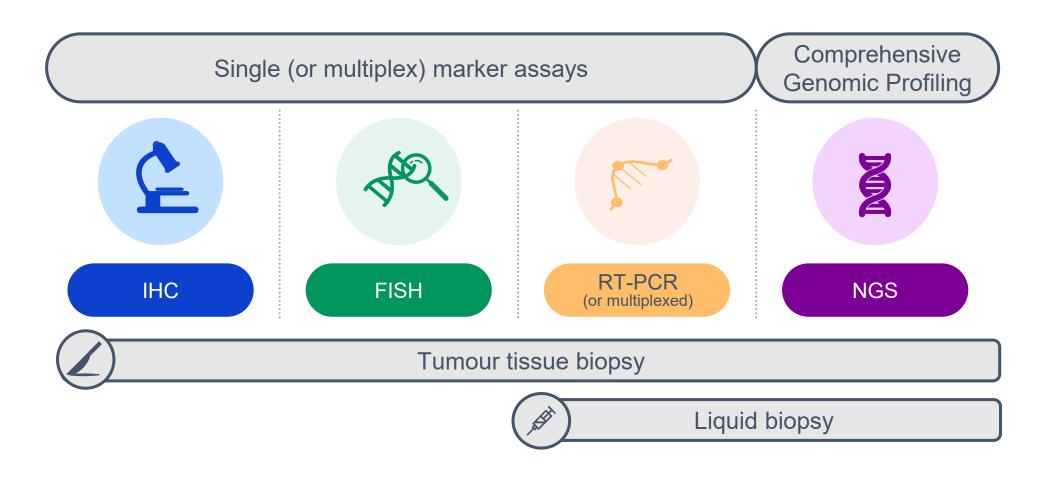


The content of this symposium may include scientific information about experimental or investigational compounds, indications and services that are not yet approved in the EU \*PD-L1 high is TC/TPS ≥50%, PD-L1 low is TC/TPS 1–49%, PD-L1 negative is TC/TPS <1%

Pakkala & Ramalingam. JCI Insight 2018; 2. Barlesi, et al. Lancet 2016; 3. Tian, et al. Lung Cancer 2017; 4. Qiu, et al. Sci Rep 2020; 5. Gainor & Shaw. Oncologist 2013
Bergethon, et al. J Clin Oncol 2012; 7. Dugay, et al. Oncotarget 2017; 8. Farago, et al. JCO Precis Oncol 2018; 9. Felip, et al. Lancet 2021; 10. Carbone, et al. WCLC 2020
Forde, et al. N Engl J Med 2022; 12. Kowanetz, et al. AACR 2018; 13. Gandhi, et al. N Engl J Med 2018; 14. Paz-Ares, et al. N Engl J Med 2018; 15. Paz-Ares, et al. Lancet Oncol 2021

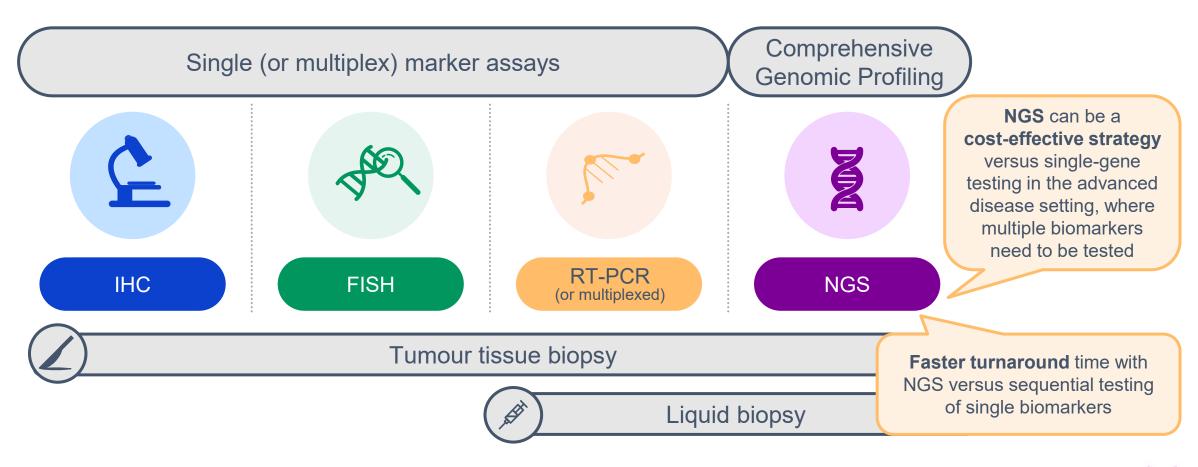


### Tissue biomarker testing is the gold standard, but liquid biopsies are also an option in advanced NSCLC





### Tissue biomarker testing is the gold standard, but liquid biopsies are also an option in advanced NSCLC





## Blood-based NGS has advantages and disadvantages compared with tissue biopsy testing



**Less invasive** than tissue biopsy procedures<sup>1</sup>



Clinical utility in **patients** who are unfit for biopsy or with insufficient tissue sample<sup>1</sup> Risk of missed biomarker, due to **lower sensitivity** than tissue-based testing and reliance on ctDNA shedding into the blood<sup>4–7</sup>

Cannot be used for initial histologic diagnosis or PD-L1 testing<sup>7,8</sup>

Faster turnaround time<sup>2</sup>

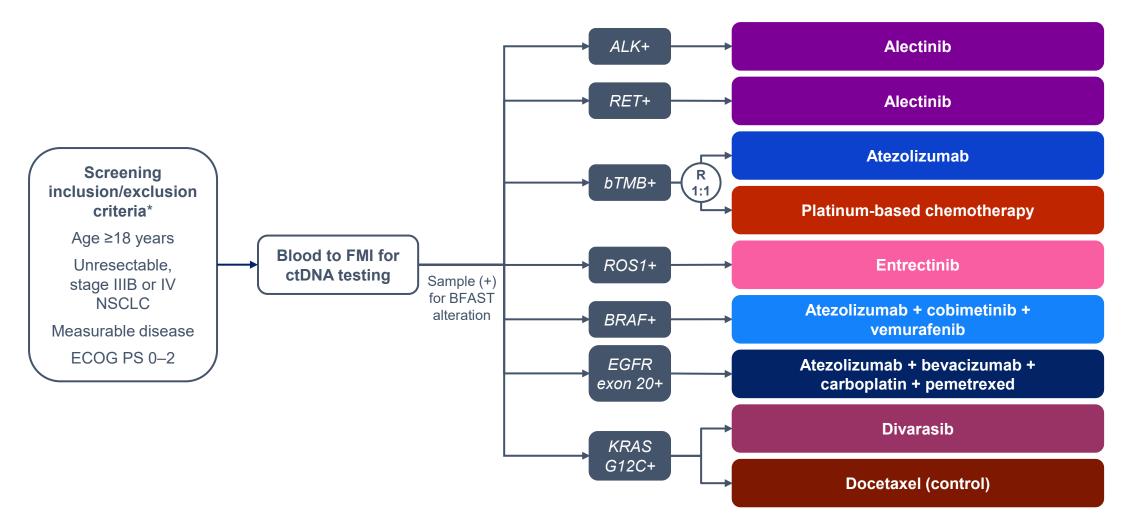
Potential tool for **early diagnosis**, **monitoring** of treatment response and **resistance**<sup>1,3</sup> Blood-based NGS is more optimal in advanced disease; disease burden is associated with the amount of tumour DNA shed into the blood, which is lower in early-stage NSCLC, and may be below the detection limit of liquid assays<sup>4–7</sup>

M

ctDNA, circulating tumour DNA

1. Diaz Jr, et al. J Clin Oncol 2014; 2. Raez, et al. Clin Lung Cancer 2023; 3. Martins, et al. Genes (Basel) 2021; 4. Singh. J Mol Diagn 2020; 5. Chen & Zhao. Human Genomics 2019 6. Xie, et al. BMC Cancer 2023; 7. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for **Non-Small Cell Lung Cancer V.3.2023**.<sup>®</sup> National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed 17 October 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way; 8. Hita-Millan, et al. J Pers Med 2021

## The BFAST trial is investigating multiple therapies in 1L metastatic NSCLC based on blood-based NGS testing



The content of this symposium may include scientific information about experimental or investigational compounds, indications and services that are not yet approved in the EU \*All cohorts have additional, treatment-specific inclusion/exclusion criteria Gadgeel, et al. ESMO 2019; Dziadziuszko, et al. J Thorac Oncol 2021; https://clinicaltrials.gov/study/NCT03178552

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## The data from the *ALK*+ cohort of the BFAST study were consistent with those from the tissue-based ALEX trial



- BFAST identified a cohort of 119 patients with advanced NSCLC who had *ALK*+ disease based on blood-based NGS testing only
- Patients received standard-of-care 1L treatment with alectinib
- Primary endpoint: investigator-assessed ORR

#### **Efficacy results in the BFAST** *ALK***+ cohort (N=87)**:

**89.7%** investigator-assessed objective response rate

**33.0 months** median

progression-free survival

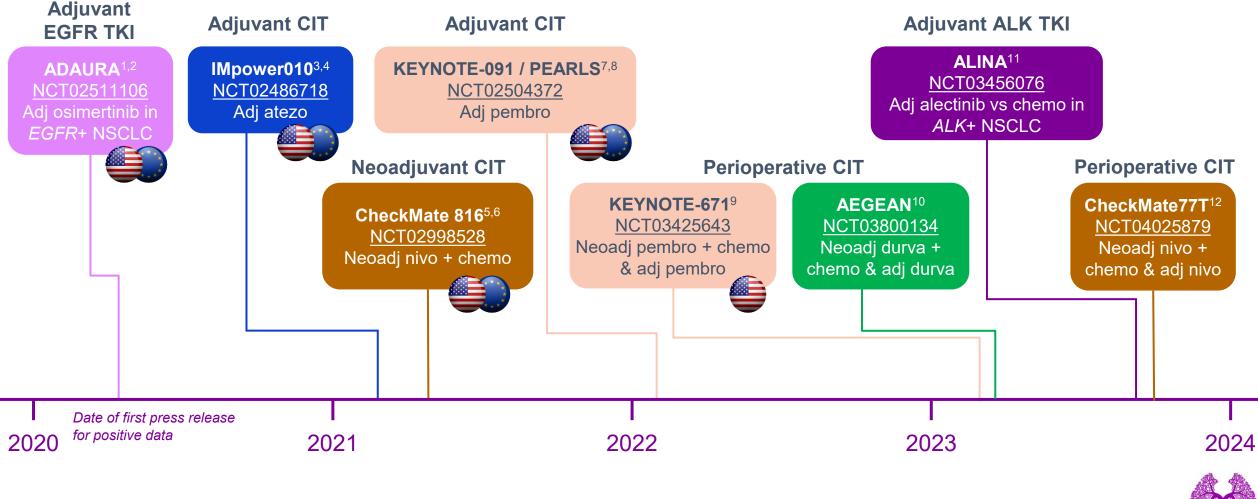
#### 35.1 months

median duration of response

Data were consistent with those seen in the ALEX study,<sup>3</sup> in which patients were identified using tissue-based testing



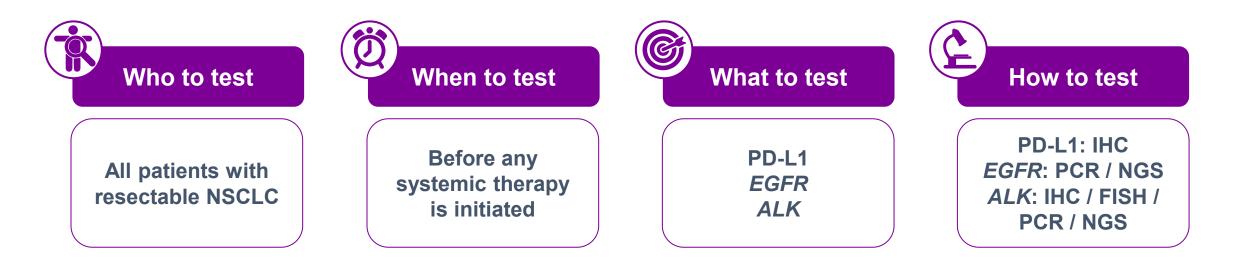
## The evolution of the treatment landscape in the early-stage setting means that biomarker testing is now needed



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Biomarker testing should be performed before initiation of systemic therapy in early-stage NSCLC



- A good collaboration between pulmonologists and pathologists would be key to optimising biopsy procedures to ensure a large enough sample with enough good-quality tumour tissue
  - Biomarker testing can be performed on the diagnostic biopsy and/or the surgical resection sample, although the small sample size of the diagnostic biopsy can impact the feasibility and quality of testing
- Patients with EGFR+ or ALK+ NSCLC are less likely to benefit from immunotherapy

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- Early diagnosis of lung cancer correlates with better prognosis;<sup>1</sup> machine learning and AI tools are being developed to identify high-risk patients and improve screening<sup>2,3</sup>
- Biomarker testing is a key stage in the patient journey and helps inform treatment decisions; it should be performed before initiation of systemic therapy in early-stage NSCLC<sup>4–6</sup>
  - Advanced disease: guidelines recommend screening for multiple biomarkers; blood-based NGS is a good option in this setting<sup>5,6</sup>
  - > Early-stage disease: recommended testing for PD-L1, EGFR and ALK, using tissue-based testing<sup>6</sup>
- Blood-based NGS is more optimal in advanced disease as tumour DNA shedding is lower in early-stage disease, and may be below the detection limit of liquid assays<sup>7,8</sup>

1. Goldstraw, et al. J Thorac Oncol 2016; 2. Kerpel-Fronius, et al. J Thorac Oncol 2022; 3. Morgenstern & Choman. J Clin Oncol 2023; 4. Pakkala & Ramalingam. JCl Insight 2018 5. Planchard, et al. Ann Oncol 2018; 6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for **Non-Small Cell Lung Cancer V.3.2023**.<sup>©</sup> National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed 17 October 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way 7. Chen & Zhao. Human Genomics 2019; 8. Singh. J Mol Diagn 2020





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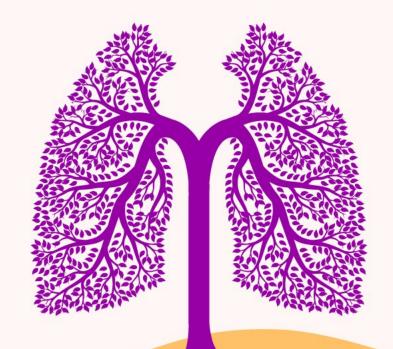
#### Martin Reck

Pulmonologist LungenClinic Großhansdorf, Germany

#### Nasser Altorki

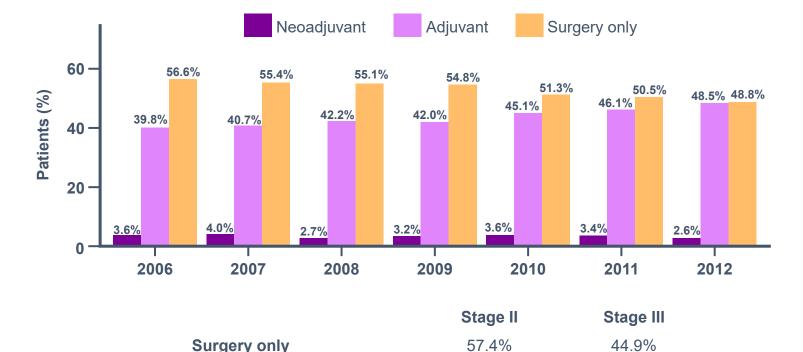
Thoracic Surgeon Weill Cornell Medicine New York, NY, USA

## Evolving treatment decisions in resectable NSCLC



Real-world data: not all patients receive systemic therapy and adjuvant chemotherapy used to be more commonly used

#### Systemic therapy amongst patients undergoing surgery National Cancer Database 2006–2012 (US patients)<sup>1</sup>



2.4%

40.2%

5.0%

50.1%

Many patients undergoing surgery have received no systemic therapy<sup>1,2</sup>

Historically adjuvant chemotherapy has been more extensively used, than neoadjuvant chemotherapy<sup>1,2</sup>

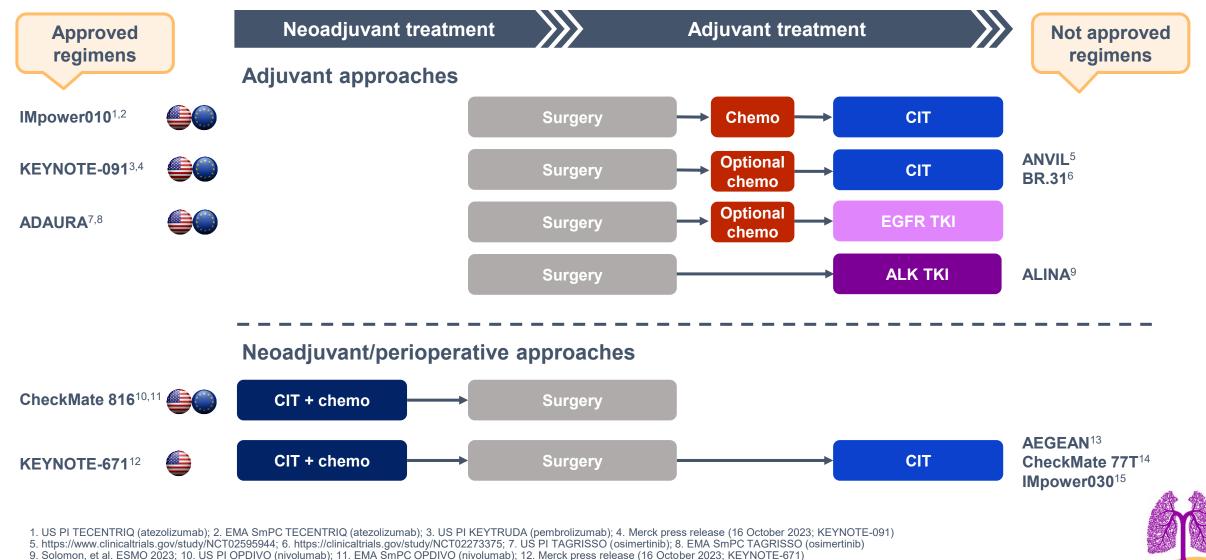


1. MacLean, et al. Oncotarget 2018; 2. Lee, et al. ESMO 2021

Neoadjuvant chemotherapy

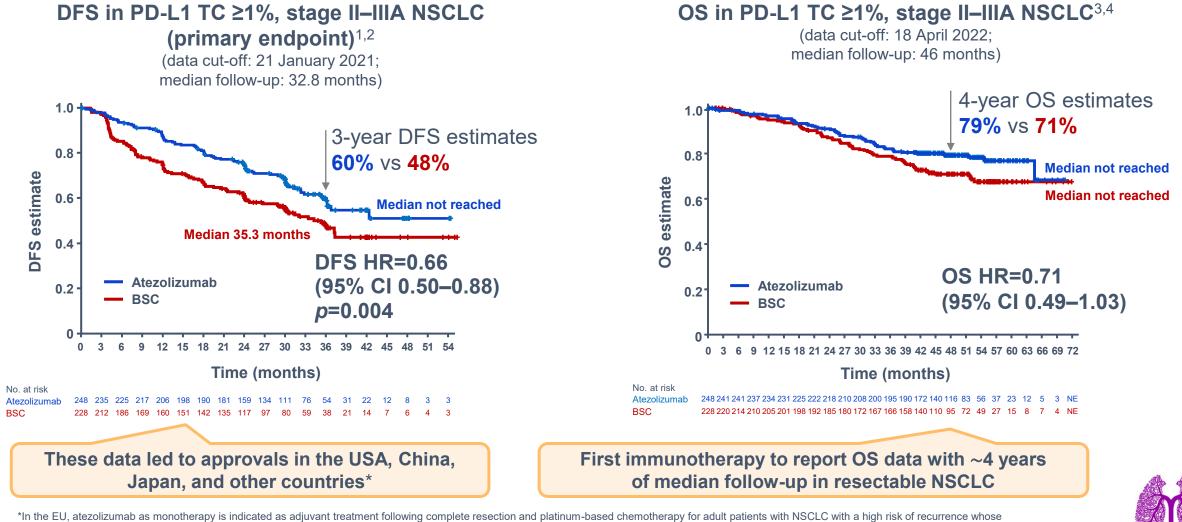
Adjuvant chemotherapy

## Various treatment strategies are under investigation in early-stage NSCLC



13. AstraZeneca press release (09 March 2023; AEGEAN); 14. Bristol Myers Squibb press release (22 September 2023; CheckMate 77T); 15. https://www.clinicaltrials.gov/study/NCT03456063

# **IMpower010:** DFS benefit and a positive OS trend observed with atezolizumab in the PD-L1 TC ≥1%, stage II–IIIA population



tumours have PD-L1 expression on ≥50% of tumour cells and who do not have EGFR mutant or ALK-positive NSCLC<sup>5</sup>

The first pre-specified OS interim analysis is considered exploratory; stratified HRs

1. Wakelee, et al. ASCO 2021; 2. Felip, et al. Lancet 2021; 3. Felip, et al. WCLC 2022; 4. Felip, et al. Ann Oncol 2023; 5. EMA SmPC TECENTRIQ (atezolizumab)

#### Adjuvant CIT

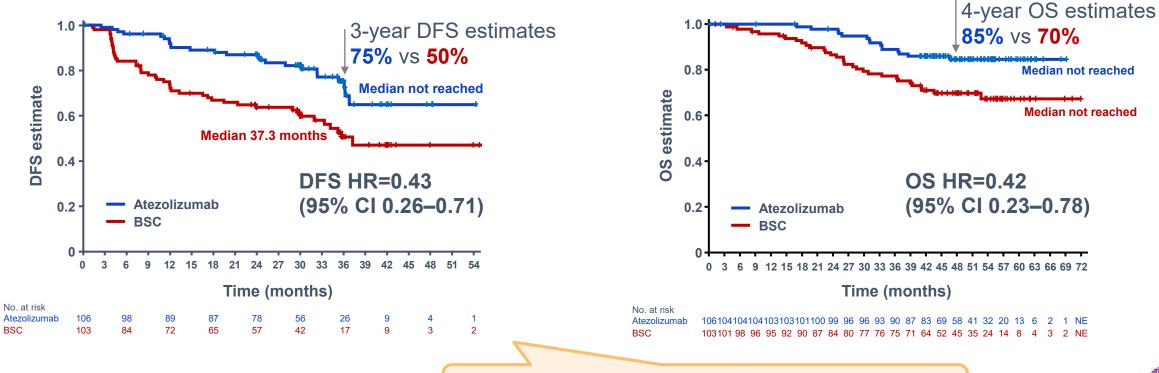
# **IMpower010:** DFS benefit and clinically meaningful OS trend in the PD-L1 ≥50%, stage II–IIIA population

### DFS in PD-L1 TC ≥50%, stage II–IIIA NSCLC<sup>1,2</sup>

Excluding *EGFR*+/*ALK*+ (data cut-off: 21 January 2021; median follow-up in stage II–IIIA population: 32.2 months)

#### OS in PD-L1 TC ≥50%, stage II–IIIA NSCLC<sup>3,4</sup>

Excluding EGFR+/ALK+ (data cut-off: 18 April 2022; median follow-up in stage II–IIIA population: 45.1 months)



These data led to approvals in the EU and other countries including Canada, the UK, and Switzerland\*

Unstratified HRs; the first pre-specified OS interim analysis is considered exploratory

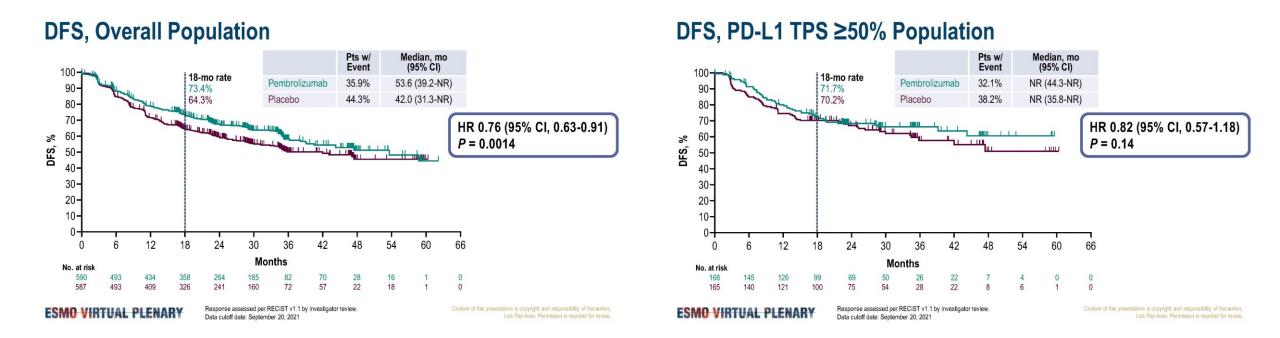
\*EGFR+/ALK+ NSCLC not excluded in Switzerland

1. Felip, et al. ELCC 2022; 2. Felip, et al. Lancet 2021; 3. Felip, et al. WCLC 2022; 4. Felip, et al. Ann Oncol 2023

#### Adjuvant CIT

# **KEYNOTE-091:** adjuvant pembrolizumab improved DFS versus placebo in the overall study population





DFS HR in patients who received prior chemotherapy: **all patients = 0.73; PD-L1 TPS ≥50% = 0.89** Approval for adjuvant pembrolizumab: following resection and platinum-based chemotherapy for patients at high risk of recurrence, irrespective of PD-L1 status



Paz-Ares, et al. ESMO Plenary 2022; O'Brien, et al. Lancet 2022; Oselin, et al. ASCO 2023; Merck press release (16 October 2023; KEYNOTE-091)

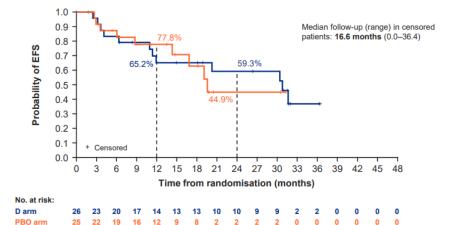
#### **Perioperative CIT**

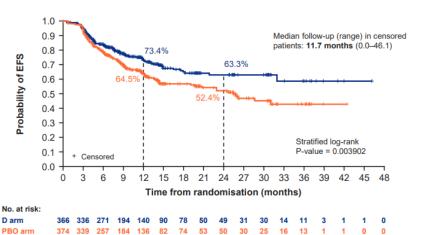
# Analysis of outcomes by *EGFR* status highlights the importance of biomarker testing in resectable NSCLC: AEGEAN study

### EFS using RECIST v1.1 (BICR) (EGFRm and mITT)\*

EGFRm subgroup	Durvalumab arm	Placebo arm
No. events / no. patients (%)	12/26 (46.2)	9/25 (36.0)
mEFS, months (95% CI)	30.8 (11.4, NR)	19.6 (14.3, NR)
Unstratified HR <sup>+</sup> (95% CI)	0.86 (0.35, 2.19)	

mITT population <sup>1</sup>	Durvalumab arm	Placebo arm
No. events / no. patients (%)	98/366 (26.8)	138/374 (36.9)
mEFS, months (95% CI)	NR (31.9, NR)	25.9 (18.9, NR)
Stratified HR <sup>†</sup> (95% CI)	0.68 (0.53, 0.88)	







<sup>1</sup>Heymach JV, et al. Cancer Res 2023;83 (8 Supplement):CT005

David Harpole, Department of Surgery, Duke University Medical Center, Durham, North Carolina, USA

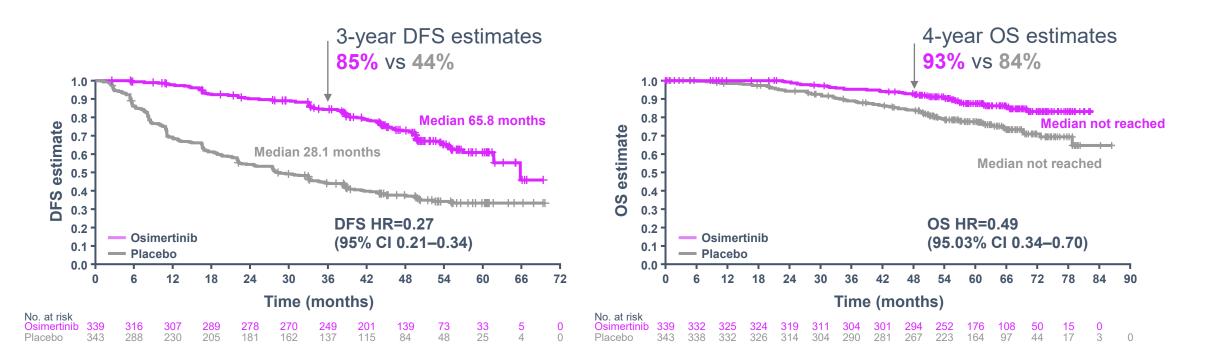
DC0 = Nov 10, 2022. \*Pre-planned analysis. EFS is defined as time from randomisation to the earliest of: (A) progressive disease (PD) that precludes surgery; (B) PD discovered and reported by the investigator upon attempting surgery that prevents completion of surgery; (C) local/distant recurrence using BICR per RECIST v1.1; or (D) death from any cause. HR <1 favours the D arm versus the PBO arm. Median and landmark EFS estimates calculated using the Kaplan-Meier method. <sup>1</sup>HR for the *EGFR*m subgroup calculated from an unstratified Cox proportional hazards model; HR for the mITT population calculated using a stratified Cox proportional hazards model. C) confidence interval; D, durvalumab; HR, hazard ratio; mEFS, median EFS; NR, not reached; PBO, placebo.

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# **ADAURA:** improved DFS and OS with adjuvant osimertinib versus placebo in patients with *EGFR*+, stage II–IIIA NSCLC

DFS in stage IB–IIIA<sup>1</sup>

OS in stage IB–IIIA<sup>2,3</sup>



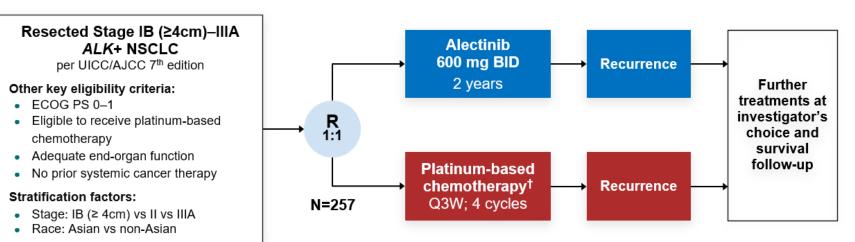


1. Herbst, et al. J Clin Oncol 2023. Herbst et al., Adjuvant Osimertinib for Resected EGFR-Mutated Stage IB-IIIA Non–Small-Cell Lung Cancer: Updated Results From the Phase III Randomized ADAURA Trial, Journal of Clinical Oncology, volume 41, issue 10, https://ascopubs.org/doi/10.1200/JCO.22.02186; 2. Herbst, et al. ASCO 2023; 3. Tsuboi, et al. N Engl J Med 2023

#### Adjuvant ALK TKI

# **ALINA:** adjuvant alectinib versus chemotherapy in patients with resected *ALK*+ NSCLC

### ALINA study design\*





#### **Primary endpoint**

- DFS per investigator,<sup>‡</sup> tested hierarchically:
  - Stage II–IIIA  $\rightarrow$  ITT (Stage IB–IIIA)

#### • OS

Other endpoints

CNS disease-free survival

Safety

Disease assessments (including brain MRI)<sup>§</sup> were conducted: at baseline, every 12 weeks for year 1–2, every 24 weeks for year 3–5, then annually



Data cut-off: 26 June 2023; CNS, central nervous system; DFS, disease-free survival; ITT, intention to treat \*Superiority trial; †Cisplatin + pemetrexed, cisplatin + vinorelbine or cisplatin + gemcitabine; cisplatin could be switched to carboplatin in case of intolerability; ‡DFS defined as the time from randomisation to the first documented recurrence of disease or new primary NSCLC as determined by the investigator, or death from any cause, whichever occurs first; §Assessment by CT scan where MRI not available; NCT03456076



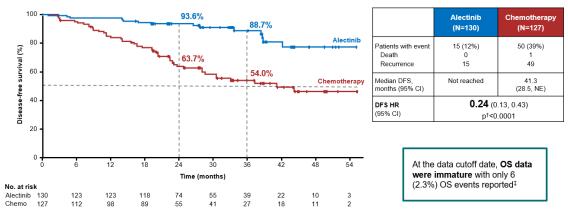
#### Adjuvant ALK TKI

ESMO

# **ALINA:** adjuvant alectinib improved DFS and CNS-DFS versus chemotherapy in patients with resected *ALK*+ NSCLC



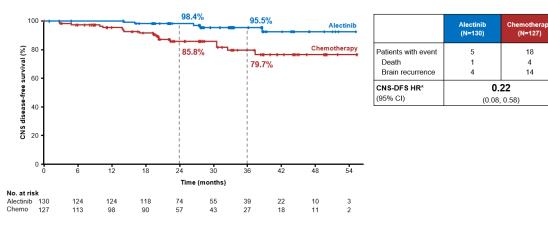
#### Disease-free survival: ITT (stage IB–IIIA)\*



#### Median survival follow up: alectinib, 27.8 months; chemotherapy, 28.4 months



#### CNS disease-free survival in the ITT population



#### Median survival follow up: alectinib, 27.8 months; chemotherapy, 28.4 months



Data cut-off: 26 June 2023 "Stratified analysis with race and stage as stratification factors CNS-DFS defined as time from randomisation to the first documented recurrence of disease in the CNS or death from any cause



# ALINA: DFS benefit with alectinib versus chemotherapy was seen across all subgroups

#### DFS HR (95% CI) Subgroup No. of events / patients 65 / 257 0.24 (0.14-0.43) All patients 0.26 (0.13-0.52) <65 43 / 196 Age ≥65 22 / 61 0.24 (0.08-0.71) 0.26 (0.11-0.60) 35 / 123 Male Sex 30 / 134 0.22 (0.10-0.50) Female 0.36 (0.17-0.79) Asian Race 31 / 143 0.16 (0.06-0.38) Non-Asian 34 / 114 ECOG PS at 0.20 (0.09-0.46) 32 / 137 0 baseline 33 / 120 0.31 (0.14-0.69) 1 Never 37 / 154 0.27 (0.13-0.55) Tobacco use 0 / 8 NE Current history 28 / 95 Previous 0.22 (0.08-0.57) Stage IB 6 / 26 0.21 (0.02-1.84) Stage\* 22 / 92 0.24 (0.09-0.65) Stage II Stage IIIA 37 / 139 0.25 (0.12-0.53) Regional lymph N0 11 / 39 0.19 (0.04-0.88) node status N1 20 / 88 0.34 (0.13-0.89) 0.21 (0.09-0.47) N2 34 / 130 0.3 0.1 1.0 3.0 Alectinib better Chemotherapy better

Disease-free survival subgroup analysis (ITT)



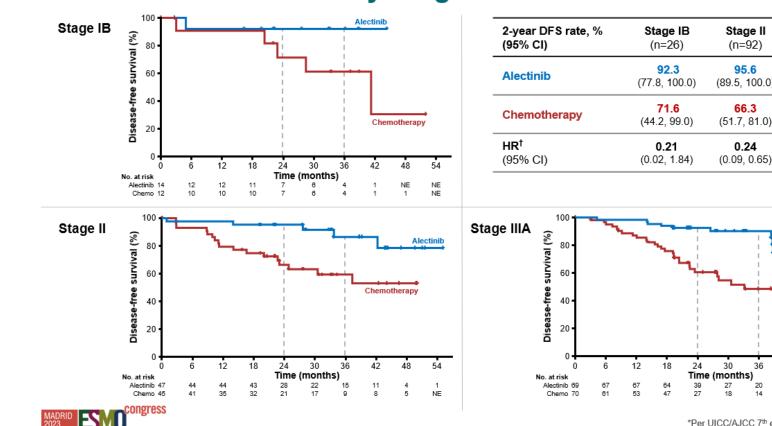


Data cut-off: 26 June 2023 Arrows indicate lower bound of the CI<0.1; \*Per UICC/AJCC 7<sup>th</sup> edition



#### **Adjuvant ALK TKI**

### ALINA: DFS benefit with alectinib versus chemotherapy was seen across all disease stages included in the study

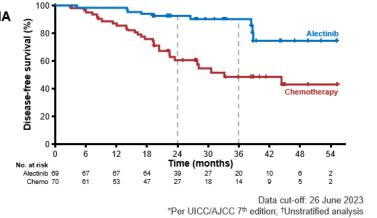


### **Disease-free survival by stage\***

<b>tage IB</b>	Stage II	Stage IIIA
(n=26)	(n=92)	(n=139)
<b>92.3</b>	<b>95.6</b>	<b>92.7</b>
.8, 100.0)	(89.5, 100.0)	(86.4, 98.9)
<b>71.6</b>	<b>66.3</b>	<b>60.7</b>
I.2, 99.0)	(51.7, 81.0)	(47.9, 73.5)
0.21	0.24	0.25

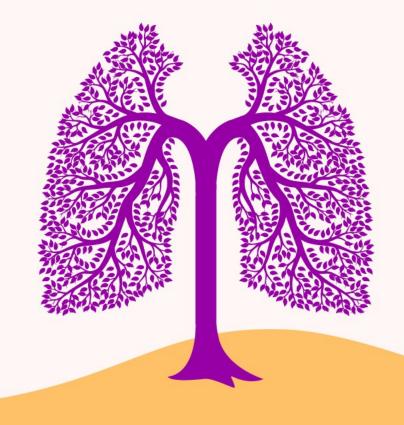
(0.12, 0.53)



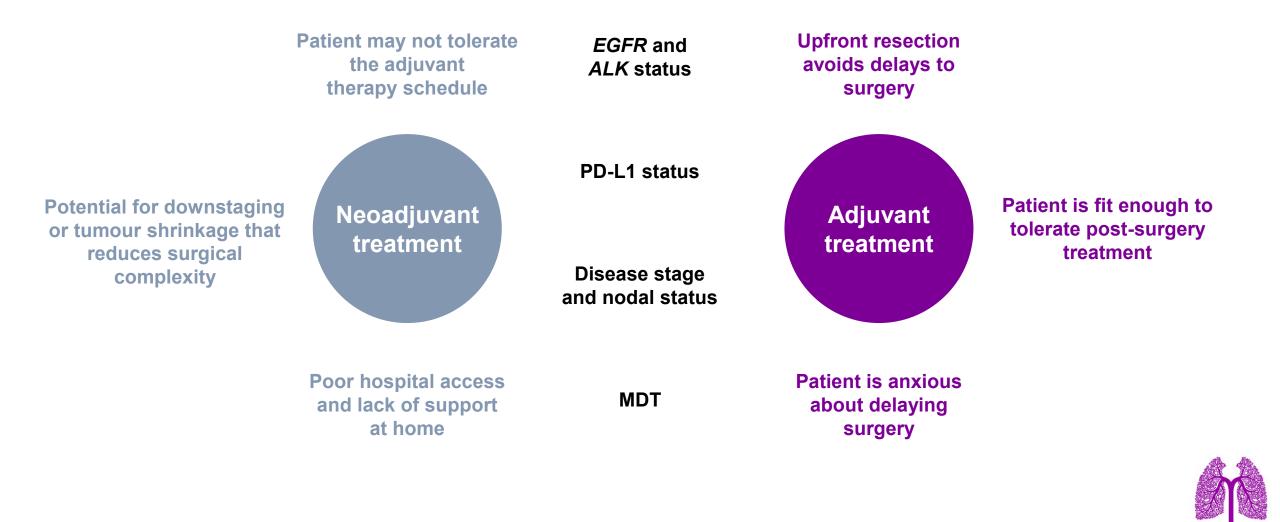


Unauthorised product/indication, experimental use Solomon, et al. ESMO 2023

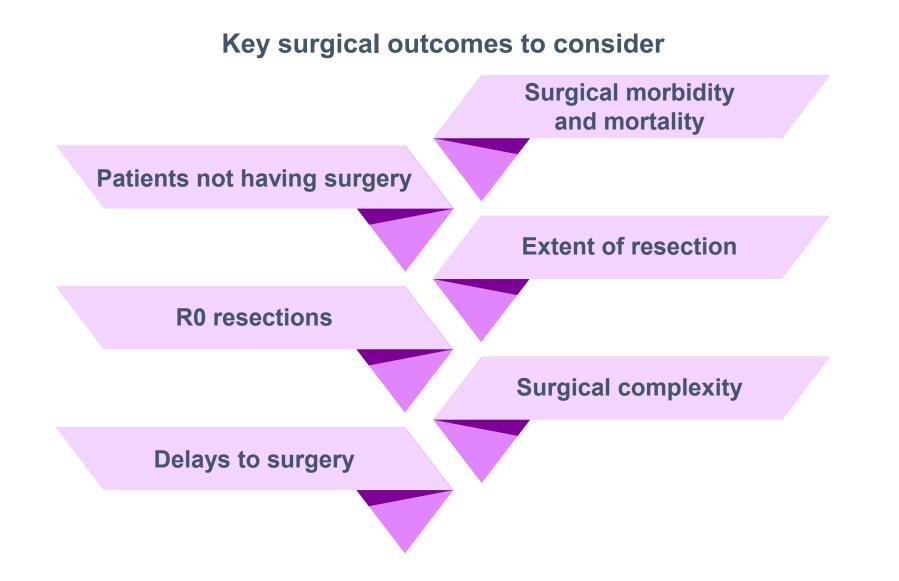
### The surgeon's perspective



### A wide range of factors inform treatment decisions around adjuvant and neoadjuvant therapy



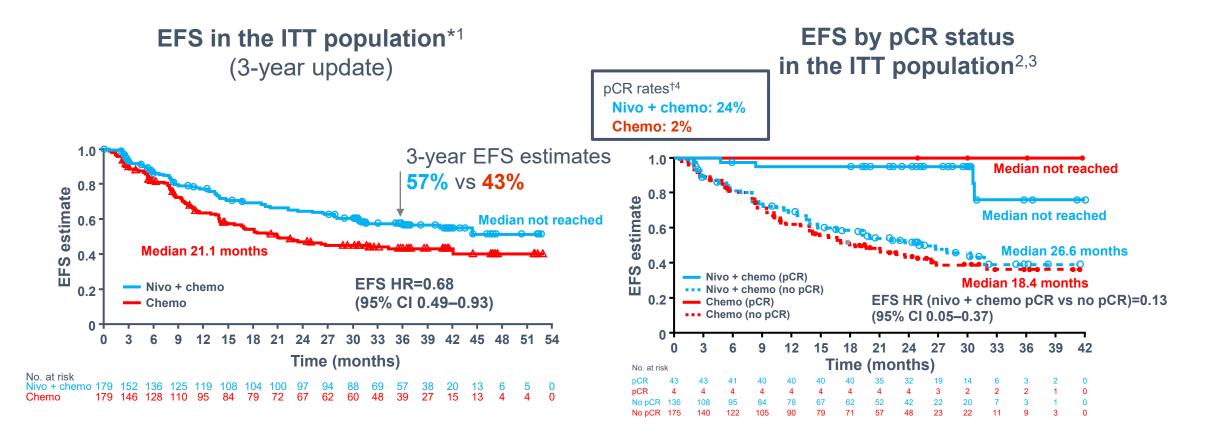
### How neoadjuvant therapy impacts surgical decision making?



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#### **Neoadjuvant CIT**

# **CheckMate 816:** neoadjuvant nivolumab + chemotherapy improved EFS versus chemotherapy alone



OS HR (3-year update): 0.62 (99.34% CI 0.36-1.05)<sup>1</sup>



In the EU, nivolumab is indicated in combination with chemotherapy as neoadjuvant treatment for adult patients with NSCLC with a high risk of recurrence whose tumours have PD-L1 expression on ≥1% of tumour cells;<sup>5</sup> minimum follow-up for 3-year EFS update: 32.9 months (median follow-up, 41.4 months); minimum follow-up: for EFS by pCR analysis: 21 months (median follow-up: 29.5 months) \*Exploratory analysis; <sup>†</sup>pCR: 0% residual viable tumour cells in both primary tumour (lung) and sampled lymph nodes

1. Girard, et al. ELCC 2023; 2. Girard, et al. AACR 2022; 3. Forde, et al. N Eng J Med 2022; 4. Forde, et al. AACR 2021; 5. EMA SmPC OPDIVO (nivolumab)

# **CheckMate 816:** the addition of neoadjuvant nivolumab to chemotherapy did not have a negative impact on surgical outcomes

ITT population	Nivolumab + chemotherapy (N=179)	Chemotherapy (N=179)	
Patients with definitive surgery	83%	75%	~20% of patients
Patients with delayed surgery*†	21%	18%	do not undergo surgery
Type of surgery <sup>*‡</sup>			
Pneumonectomy	17%	25%	
Lobectomy	77%	61%	
Resection rate*			
R0	83%	78%	
R1 / R2	11% / 3%	16% / 3%	
Surgery-related AEs <sup>§</sup>			
Any grade	41%	47%	
Grade 3–4	11%	15%	

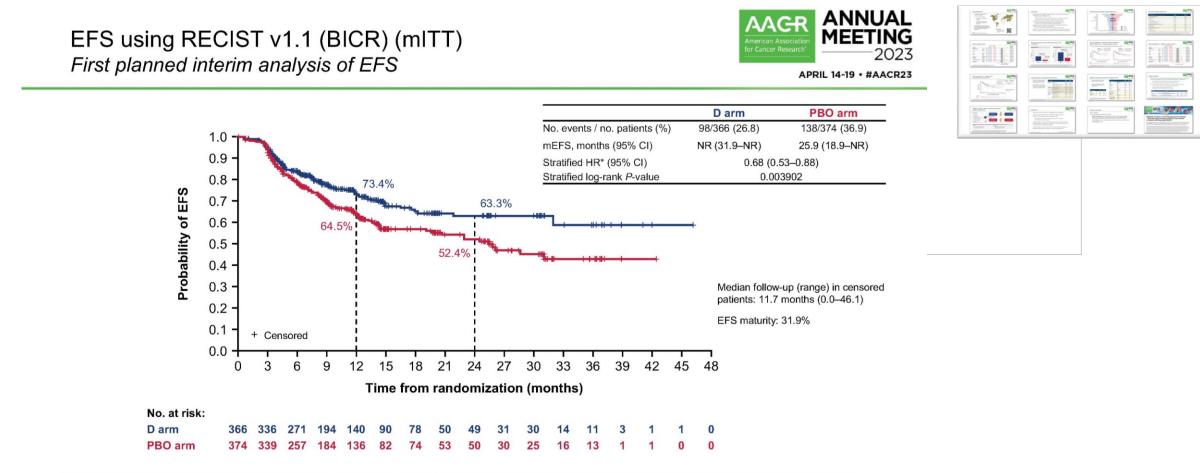
**Grade 5 surgery-related AEs<sup>¶</sup> were reported in 2 patients in the nivolumab + chemotherapy arm** (pulmonary embolism n=1; aortic rupture n=1) and were deemed unrelated to study drug per investigator

\*Denominator based on patients with definitive surgery; <sup>†</sup>delayed surgery defined as time from last neoadjuvant dose to surgery >6 weeks; <sup>‡</sup>patients may have had more than one surgery type <sup>§</sup>includes events reported up to 90 days after definitive surgery; <sup>¶</sup>defined as events that led to death within 24 hours of AE onset Spicer, et al. ASCO 2021; Forde, et al. N Engl J Med 2022; Forde, et al. AACR 2021



#### **Neoadjuvant CIT**

# **AEGEAN:** perioperative durvalumab + neoadjuvant chemotherapy improved EFS versus placebo + neoadjuvant chemotherapy

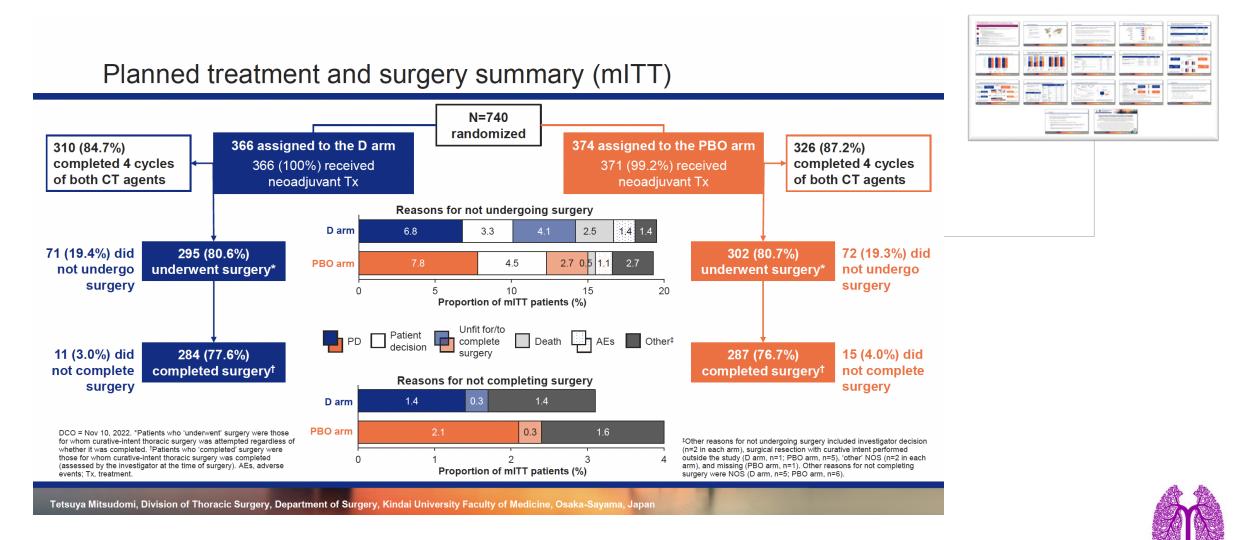


DCO = Nov 10, 2022. EFS is defined as time from randomization to the earliest of: (A) progressive disease (PD) that precludes surgery; (B) PD discovered and reported by the investigator upon attempting surgery that prevents completion of surgery; (C) local/distant recurrence using BICR per RECIST v1.1; or (D) death from any cause. \*HR <1 favors the D arm versus the PBO arm. Median and landmark estimates calculated using the Kaplan–Meier method; HR calculated using a stratified log rank test. Stratification factors: disease stage (III vs III) and PD-L1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5% alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (based on total 5%) alpha), calculated using a Lan–DeMets alpha spending function with OPL1 expression status (<1%) vs 21%). Significance boundary = 0.003899 (



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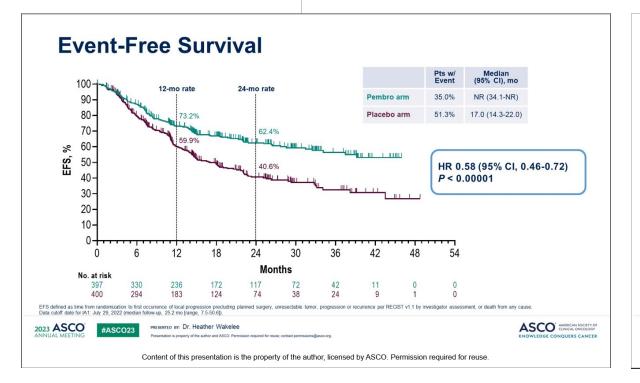
# **AEGEAN:** the addition of neoadjuvant durvalumab to chemotherapy did not have a negative impact on surgical outcomes



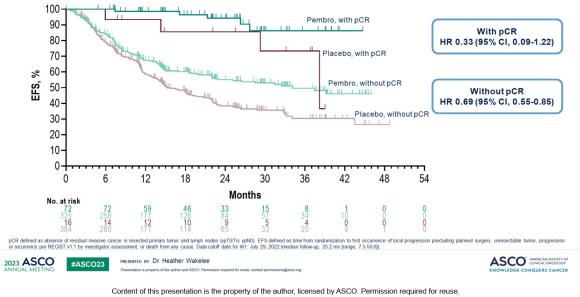
#### Perioperative CIT

# **KEYNOTE-671:** EFS benefit was seen with perioperative pembrolizumab + chemotherapy versus placebo





#### **Exploratory Analysis of EFS by pCR Status**





#### **Perioperative CIT**

# **KEYNOTE-671:** addition of neoadjuvant pembrolizumab to chemotherapy did not have a negative impact on surgical outcomes

### **Surgical Details**

	Pembro Arm N = 325	Placebo Arm N = 317
In-Study Surgery <sup>a</sup>		
Resected	320 (98.5%)	302 (95.3%)
Complete - R0	299 (92.0%)	267 (84.2%)
Incomplete - R1	17 (5.2%)	31 (9.8%)
Incomplete - R2	4 (1.2%)	4 (1.3%)
Unresected	5 (1.5%)	15 (4.7%)
Surgical procedure		
Lobectomy	256 (78.8%)	238 (75.1%)
Pneumonectomy	37 (11.4%)	39 (12.3%)
Bilobectomy	26 (8.0%)	26 (8.2%)
Exploratory thoracotomy	4 (1.2%)	13 (4.1%)
Other	2 (0.6%) <sup>b</sup>	1 (0.3%) <sup>c</sup>
30-day all-cause mortality	6 (1.8%) <sup>d</sup>	2 (0.6%) <sup>e</sup>



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\*An additional 8 participants in the pembro arm and 7 participants in the placebo arm underwent off-study surgery. <sup>b</sup>Lung segmentectomy (n=1), lung wedge resection (n=1). <sup>c</sup>Lymph node dissection only (planned surgery was lung lobectomy; need for more extensive surgery discovered during surgery, but consent was not granted). <sup>d</sup>Pulmonary embolism (n=2), pulmonary hemorrhage due to arterial injury during surgery (n=1), pulmonary sepsis (n=1), respiratory failure (n=1), and septic shock (n=1).



PRESENTED BY: Dr. Heather Wakelee

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# Recent data are changing our approach to treatment decision-making in resectable NSCLC

- **Cancer immunotherapy** and **targeted therapies** in the adjuvant and neoadjuvant setting have emerged as new efficacious treatment options in resectable NSCLC and some are available in clinical practice<sup>1–7</sup>
  - > The full potential of perioperative regimens is still emerging
  - > Further development of targeted therapies against 'new' biomarkers is key to optimising treatment<sup>8</sup>
- Multidisciplinary shared decision making and a wide range of factors should inform when to initiate systemic treatment, i.e. before or after surgery:
  - Disease characteristics (e.g. disease stage, biomarker status); assessment of resectability and operability for definitive surgery; patient characteristics and preference<sup>9,10</sup>
- The evolving treatment landscape requires that all patients with resectable NSCLC undergo PD-L1, *EGFR* and *ALK* biomarker testing **before systemic treatment decisions are made**<sup>9</sup>

1. US PI TECENTRIQ (atezolizumab); 2. EMA SmPC TECENTRIQ (atezolizumab); 3. US PI KEYTRUDA (pembrolizumab); 4. US PI TAGRISSO (osimertinib); 5. EMA SmPC TAGRISSO (osimertinib); 6. US PI OPDIVO (nivolumab); 7. EMA SmPC OPDIVO (nivolumab); 8. Pakkala & Ramalingam. JCI Insight 2018; 9. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for **Non-Small Cell Lung Cancer V.3.2023**.<sup>©</sup> National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed 17 October 2023. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way; 10. Postmus, et al. Ann Oncol 2017





ESMO 2023 Industry Satellite Symposium

Redefining Lung Cancer Together: A New Era for Patients

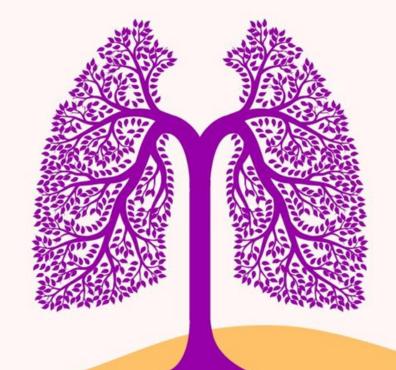
> This is a non-promotional educational meeting organised and funded by F. Hoffmann-La Roche Ltd It is intended for healthcare professionals outside the United States of America (USA) Date of preparation: October 2023. M-XX-00014685



### Alba Silverio Pons

Operational Research Nurse Vall d'Hebron Institute of Oncology (VHIO) Barcelona, Spain

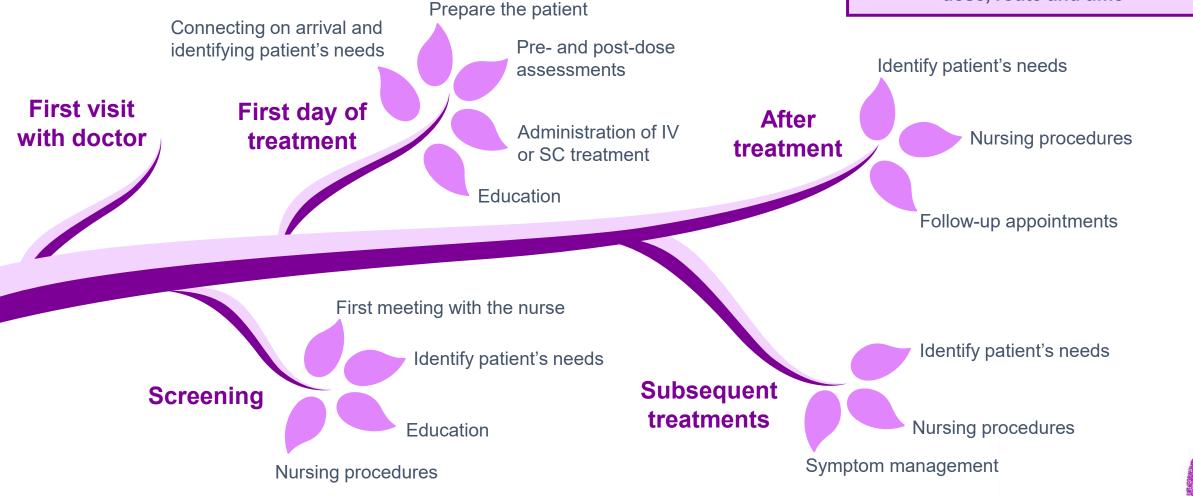
### A look at the patient journey through the lens of the nurse



# Nurses carry out an essential role throughout the patient journey<sup>1–3</sup>

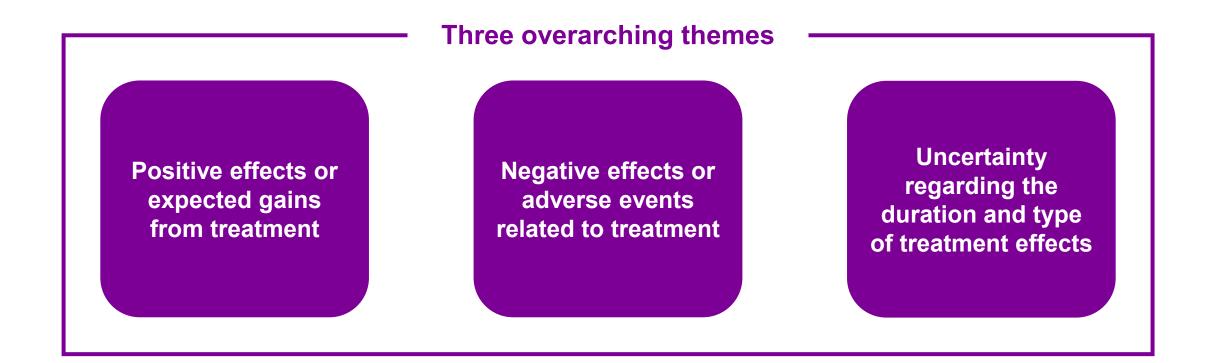
Nurse insights on a patient's needs can help optimise care

The right patient, medication, dose, route and time



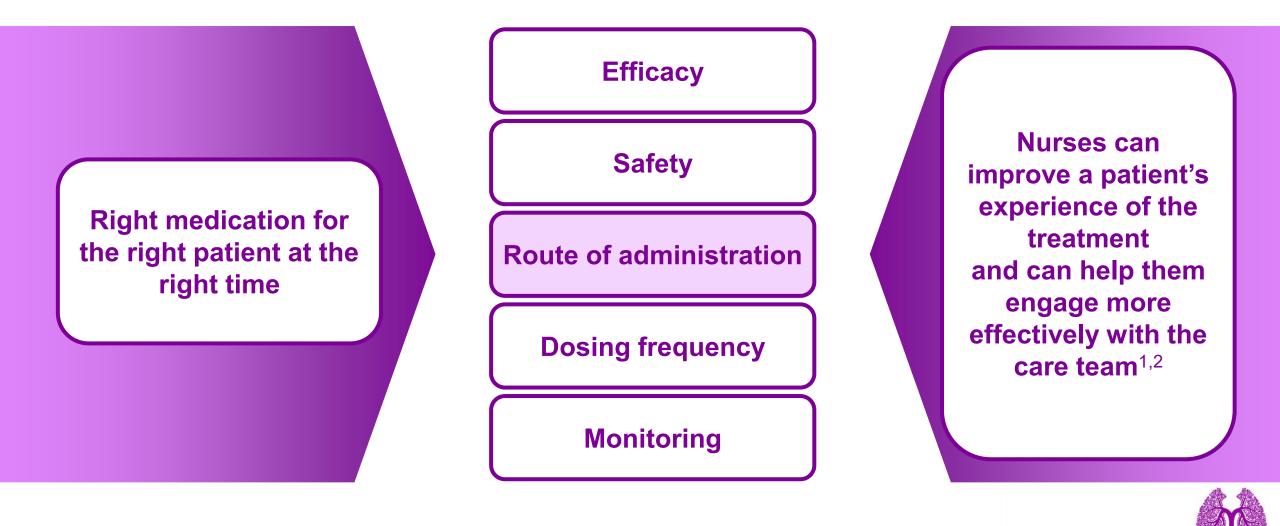
1. Young, et al. Lancet Oncol 2020; 2. Role of the oncology nurse, from Holland-Frei Cancer Medicine. 6th edition; 3. Olsen, et al. J Comp Eff Res 2018

### What matters most to patients with lung cancer?





### Drug-related factors that can influence cancer treatment decisions



1. Yackzan, et al. Clin J Oncol Nurs 2019; 2. Tolotti, et al. Int J Environ Res Public Health 2022

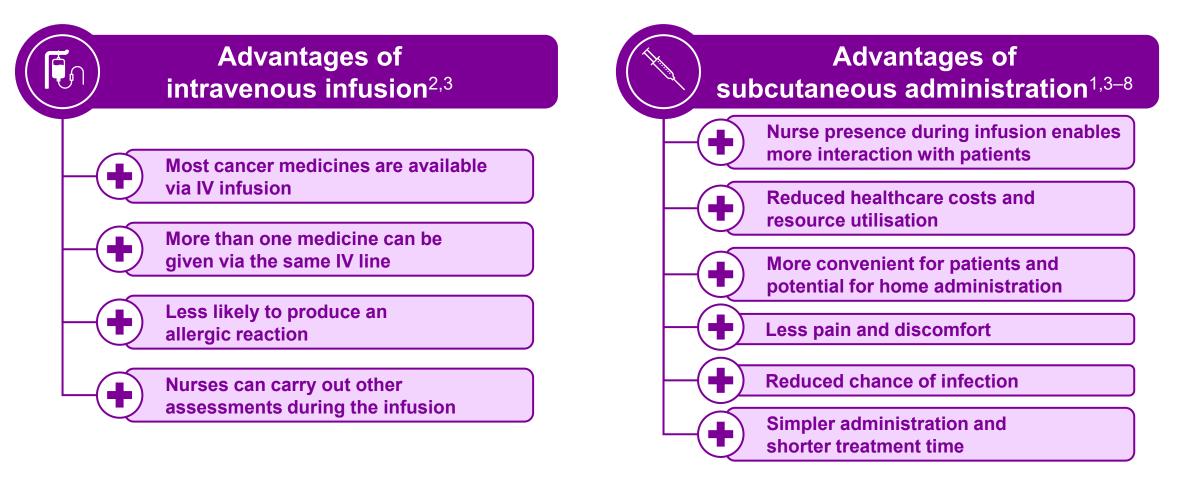
Delivering cancer medicines in different ways can help make cancer care systems more economically sustainable<sup>1</sup>



assessments during the infusion



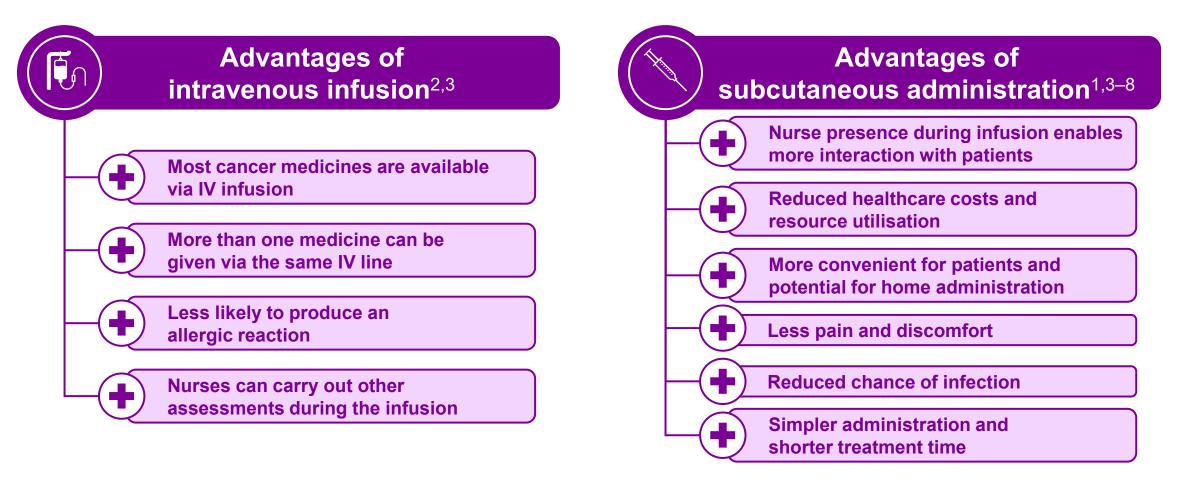
1. Stoner, et al. Patient 2015; 2. Healthline, Intravenous Medication Administration: What to Know. July 2021. Available at: https://www.healthline.com/health/intravenous-medication-administration-what-to-know 3. Leveque. Anticancer Res 2014; 4. Bittner, et al. BioDrugs 2018; 5. Anderson, et al. Future Oncol 2019; 6. Lin, et al. BMJ Open 2023; 7. De Cock, et al. Value Health 2014 8. Olsen, et al. J Comp Eff Res 2018; 9. Denys, et al. Breast Cancer Res Treat 2020; 10. O'Shaughnessy, et al. Eur J Cancer 2021; 11. Jackish, et al. Geburtshilfe Frauenheilkd 2014 Delivering cancer medicines in different ways can help make cancer care systems more economically sustainable<sup>1</sup>





1. Stoner, et al. Patient 2015; 2. Healthline, Intravenous Medication Administration: What to Know. July 2021. Available at: https://www.healthline.com/health/intravenous-medication-administration-what-to-know 3. Leveque. Anticancer Res 2014; 4. Bittner, et al. BioDrugs 2018; 5. Anderson, et al. Future Oncol 2019; 6. Lin, et al. BMJ Open 2023; 7. De Cock, et al. Value Health 2014 8. Olsen, et al. J Comp Eff Res 2018; 9. Denys, et al. Breast Cancer Res Treat 2020; 10. O'Shaughnessy, et al. Eur J Cancer 2021; 11. Jackish, et al. Geburtshilfe Frauenheilkd 2014

Delivering cancer medicines in different ways can help make cancer care systems more economically sustainable<sup>1</sup>



### Many patients and healthcare professionals prefer an SC administration route<sup>1,3–5,8–11</sup>



1. Stoner, et al. Patient 2015; 2. Healthline, Intravenous Medication Administration: What to Know. July 2021. Available at: https://www.healthline.com/health/intravenous-medication-administration-what-to-know 3. Leveque. Anticancer Res 2014; 4. Bittner, et al. BioDrugs 2018; 5. Anderson, et al. Future Oncol 2019; 6. Lin, et al. BMJ Open 2023; 7. De Cock, et al. Value Health 2014 8. Olsen, et al. J Comp Eff Res 2018; 9. Denys, et al. Breast Cancer Res Treat 2020; 10. O'Shaughnessy, et al. Eur J Cancer 2021; 11. Jackish, et al. Geburtshilfe Frauenheilkd 2014 The nurse perspective: my personal experience

**Relationship with patients** 

**Education** 

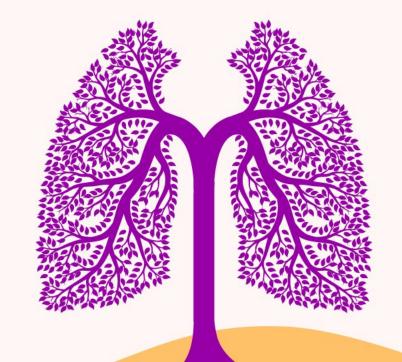
**Administration route** 

**Patient's perception / needs** 

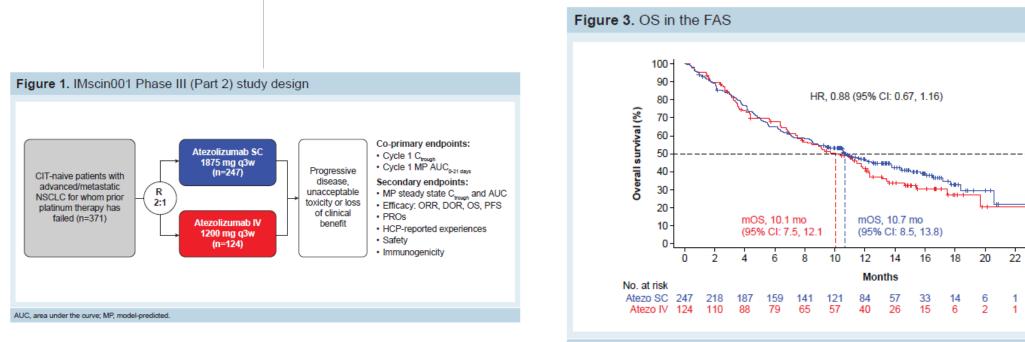
**Cancer care in the future** 



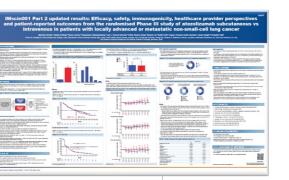
# Are there any data to support subcutaneous drug administration in NSCLC?



# IMscin001: similar OS data with atezolizumab, regardless of the mode of drug administration



mOS, median overall survival; NE, not evaluable



24

26

NE

NE



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> This is a non-promotional educational meeting organised and funded by F. Hoffmann-La Roche Ltd It is intended for healthcare professionals outside the United States of America (USA) Date of preparation: October 2023. M-XX-00014685

### Panel discussion Q&A

Stephen V Liu (Chair)

Georgetown University Washington DC, USA

Lara Pijuan Hospital Universitari de Bellvitge Barcelona, Spain

Martin Reck

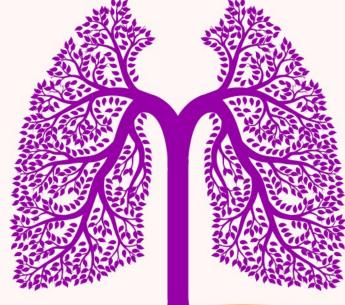
LungenClinic Großhansdorf, Germany Nasser Altorki Weill Cornell Medicine New York, NY, USA

### Alba Silverio Pons

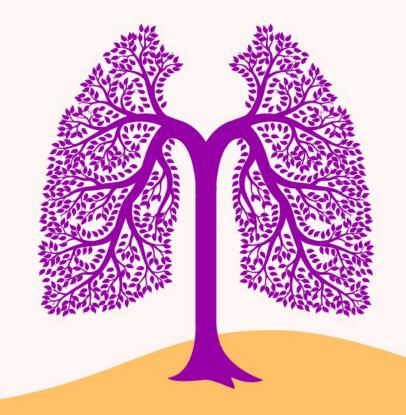
Vall d'Hebron University Hospital Barcelona, Spain



Please submit your **questions** to the panel



# What's new in immunotherapy in advanced NSCLC?



Phase III studies exploring new immunotherapy combinations to enhance the anti-tumour activity of anti-PD-(L)1 agents

New immunotherapy combinations to enhance the anti-tumour activity of anti-PD-(L)1 agents

### Anti-PD-(L)1 + Anti-TIGIT

- First phase II data with this MoA: encouraging efficacy of atezolizumab + tiragolumab in CITYSCAPE<sup>1</sup>
- Phase III SKYSCRAPER-01 trial is ongoing<sup>2</sup>
- The atezolizumab + tiragolumab combination is being investigated across lung cancer settings<sup>2–5</sup>

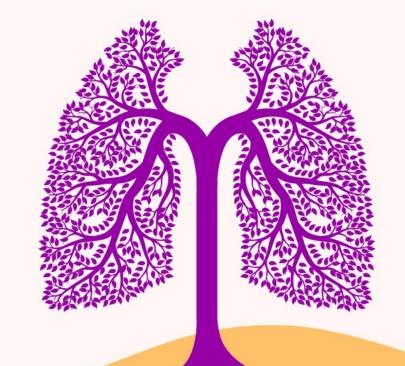
SKYSCRAPER-01 (phase III) Previously treated, locally advanced unresectable or metastatic NSCLC with high PD-L1 expression (N=660) SKYSCRAPER-06 (phase II/III) Previously untreated advanced non-squamous NSCLC in combination with chemotherapy (N=540) SKYSCRAPER-03 (phase III) Unresectable stage III NSCLC with no PD after concurrent platinum-based chemoradiation (N=829)

- Other anti-PD-(L)1 + anti-TIGIT trials are ongoing in advanced NSCLC, including:
  - KEYVIBE-003 / -007 / -006: pembrolizumab + vibostolimab +/- chemotherapy or chemoradiation<sup>6-8</sup>
  - ARC-10 / STAR-121: zimberelimab + domvanalimab +/- chemotherapy<sup>9,10</sup>
  - AdvanTIG-302: tislelizumab + ociperlimab<sup>11</sup>
  - PACIFIC-8: durvalumab + domvanalimab<sup>12</sup>

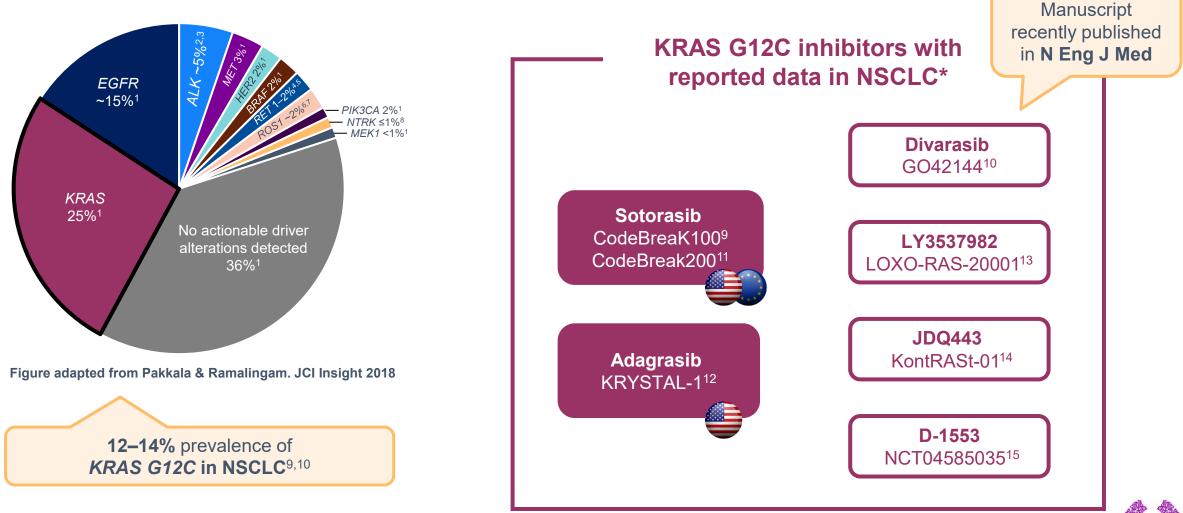
The content of this symposium may include scientific information about experimental or investigational compounds, indications and services that are not yet approved in the EU 1. Cho, et al. ESMO IO 2021; 2. https://clinicaltrials.gov/ct2/show/NCT04294810; 3. https://clinicaltrials.gov/ct2/show/NCT04619797; 4.https://clinicaltrials.gov/ct2/show/NCT04513925 5. https://clinicaltrials.gov/ct2/show/NCT04832854; 6. https://clinicaltrials.gov/ct2/show/NCT04738487; 7. https://clinicaltrials.gov/study/NCT05226598; 8. https://clinicaltrials.gov/study/NCT05298423 9. https://www.clinicaltrials.gov/study/NCT04736173; 10. https://clinicaltrials.gov/study/NCT05502237; 11. https://www.clinicaltrials.gov/study/NCT04746924; 12. https://clinicaltrials.gov/study/NCT0521895



# What new developments are there in targeted therapies?



### KRAS G12C inhibitors with reported data in NSCLC



\*Only molecules with data from global studies are reported

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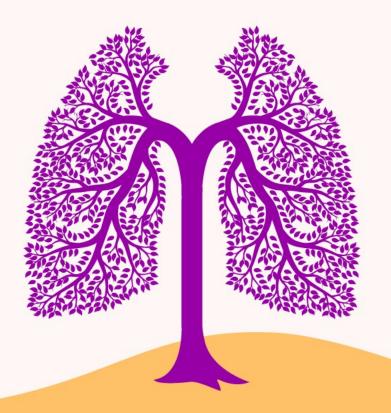
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### Meeting Chair Stephen V Liu

Georgetown University Washington DC, USA

### **Closing remarks**



### Thank you for attending!



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