What I Tell My Patients:
New Treatments and Clinical Trial Options

An NCPD Hybrid Symposium Series
Held During the 47th Annual ONS Congress

Small Cell Lung Cancer

Friday, April 29, 2022
6:00 AM – 7:30 AM PT

Faculty

Marianne J Davies, DNP, MSN, RN, APRN
Matthew Gubens, MD, MS
Lowell L Hart, MD
Chaely J Medley, MSN, AGNP

Moderator

Neil Love, MD

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Faculty

Marianne J Davies, DNP, MSN, RN, APRN, CNS-BC, ACNP-BC, AOCNP, FAAN
Nurse Practitioner
Smilow Cancer Hospital at Yale New Haven
Yale Comprehensive Cancer Center
Associate Professor
Yale University School of Nursing
New Haven, Connecticut

Matthew Gubens, MD, MS
Associate Professor, Thoracic Medical Oncology
University of California, San Francisco
San Francisco, California

Lowell L Hart, MD
Scientific Director of Clinical Research
Florida Cancer Specialists and
Research Institute
Fort Myers, Florida
Associate Professor of Internal Medicine,
Hematology and Oncology
Wake Forest University School of Medicine
Winston-Salem, North Carolina

Chaely J Medley, MSN, AGNP
Oncology Nurse Practitioner
Department of Thoracic Oncology
UNC Lineberger Comprehensive
Cancer Center
Chapel Hill, North Carolina

Moderator

Neil Love, MD
Research To Practice
Miami, Florida

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Ms Davies — Disclosures

No relevant conflicts of interest to disclose

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Ms Medley — Disclosures

No relevant conflicts of interest to disclose

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Dr Gubens — Disclosures

Advisory Committee	AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Company, Inivata, iTeos Therapeutics, Sanofi Genzyme
Contracted Research	Amgen Inc, Celgene Corporation, Johnson & Johnson Pharmaceuticals, Merck, Novartis, OncoMed Pharmaceuticals Inc, Roche Laboratories Inc, Trizell

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Dr Hart — Disclosures

Advisory Committee	Boehringer Ingelheim Pharmaceuticals Inc, G1 Therapeutics Inc, Novartis
Speakers Bureau	Circulogene

Commercial Support

This activity is supported by educational grants from G1 Therapeutics Inc and Jazz Pharmaceuticals Inc.

Research To Practice CME Planning Committee Members, Staff and Reviewers

Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Clinicians in the Meeting Room

Networked iPads are available.

Review Program Slides: Tap the Program Slides button to review speaker presentations and other program content.

Answer Survey Questions: Complete the premeeting survey before the meeting. Survey results will be presented and discussed throughout the meeting.

Ask a Question: Tap Ask a Question to submit a challenging case or question for discussion. We will aim to address as many questions as possible during the program.

Complete Your Evaluation: Tap the CME Evaluation button to complete your evaluation electronically to receive credit for your participation.

For assistance, please raise your hand. Devices will be collected at the conclusion of the activity.

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Clinicians Attending via Zoom

Review Program Slides: A link to the program slides will be posted in the chat room at the start of the program.

Answer Survey Questions: Complete the premeeting survey before the meeting. Survey results will be presented and discussed throughout the meeting.

Ask a Question: Submit a challenging case or question for discussion using the Zoom chat room.

Get CME Credit: A CME credit link will be provided in the chat room at the conclusion of the program.

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About the Enduring Program

- The live meeting is being video and audio recorded.
- The proceedings from today will be edited and developed into an enduring web-based video/PowerPoint program.
  An email will be sent to all attendees when the activity is available.
- To learn more about our education programs, visit our website, **www.ResearchToPractice.com**

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"What I Tell My Patients"
14th Annual RTP-ONS NCPD Symposium Series
ONS Congress, Anaheim, California — April 27 - May 1, 2022

Thursday April 28	**Prostate Cancer** 6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)
	Ovarian Cancer 12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)
	Non–Small Cell Lung Cancer 6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)
	Hepatobiliary Cancers 8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)
Friday April 29	**Small Cell Lung Cancer** 6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)
	Chronic Lymphocytic Leukemia 12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)
	Breast Cancer 6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)
	Acute Myeloid Leukemia and Myelodysplastic Syndromes 8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)
Saturday April 30	**Cervical and Endometrial Cancer** 6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)
	Bladder Cancer 12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

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What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

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Prostate Cancer

Thursday, April 28, 2022

6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty

Kathy D Burns, RN, MSN, AGACNP-BC, OCN
Robert Dreicer, MD, MS
Sandy Srinivas, MD
Ronald Stein, JD, MSN, NP-C, AOCNP

Non-Small Cell Lung Cancer

Thursday, April 28, 2022

6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

Faculty

Edward B Garon, MD, MS
Kelly EH Goodwin, MSN, RN, ANP-BC
Tara Plues, APRN, MSN
Anne S Tsao, MD, MBA

Ovarian Cancer

Thursday, April 28, 2022

12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty

Jennifer Filipi, MSN, NP
Kathleen N Moore, MD, MS
Krishnansu S Tewari, MD
Deborah Wright, MSN, APRN, AGCNS-BC

Hepatobiliary Cancers

Thursday, April 28, 2022

8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

Faculty

Richard S Finn, MD
Amanda K Wagner, APRN-CNP, AOCNP

What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

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Small Cell Lung Cancer

Friday, April 29, 2022
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Faculty
Marianne J Davies, DNP, MSN, RN, APRN
Matthew Gubens, MD, MS
Lowell L Hart, MD
Chaely J Medley, MSN, AGNP

Breast Cancer

Friday, April 29, 2022
6:00 PM – 8:00 PM PT (9:00 PM – 11:00 PM ET)

Faculty
Jamie Carroll, APRN, MSN, CNP
Sara A Hurvitz, MD
Kelly Leonard, MSN, FNP-BC
Hope S Rugo, MD

Chronic Lymphocytic Leukemia

Friday, April 29, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Lesley Camille Ballance, MSN, FNP-BC
Amy Goodrich, CRNP
Anthony R Mato, MD, MSCE
Susan O'Brien, MD

Acute Myeloid Leukemia and Myelodysplastic Syndromes

Friday, April 29, 2022
8:20 PM – 9:20 PM PT (11:20 PM – 12:20 AM ET)

Faculty
Ilene Galinsky, NP
Eunice S Wang, MD

What I Tell My Patients: Expert Insights into Patient Education on New Treatments and Clinical Trial Participation

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Cervical and Endometrial Cancer

Saturday, April 30, 2022
6:00 AM – 7:30 AM PT (9:00 AM – 10:30 AM ET)

Faculty
Paula J Anastasia, MN, RN, AOCN
Robert L Coleman, MD
David M O'Malley, MD
Jaclyn Shaver, MS, APRN, CNP, WHNP

Bladder Cancer

Saturday, April 30, 2022
12:15 PM – 1:45 PM PT (3:15 PM – 4:45 PM ET)

Faculty
Monica Averia, MSN, AOCNP, NP-C
Shilpa Gupta, MD
Brenda Martone, MSN, NP-BC, AOCNP
Sumanta Kumar Pal, MD

Join Us After ONS for Our Series Continuation

What I Tell My Patients —
A 2-Part NCPD Webinar Series

Hodgkin and Non-Hodgkin Lymphomas

Date and time to be announced

Gastroesophageal Cancers

Wednesday, May 18, 2022

5:00 PM – 6:00 PM ET

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How was it different to take care of this patient versus another patient in the same oncologic setting?

What unique biopsychosocial factors (eg, attitude, comorbidities, social support) were considered in the overall management of this case?

How often do you feel emotionally drained by your work?

1. Never
2. A few times per year
3. Once a month
4. A few times per month
5. Once a week
6. A few times per week
7. Every day

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Faculty

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Nurse Practitioner
Smilow Cancer Hospital at Yale New Haven
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Small Cell Lung Cancer

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Neil Love, MD

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Agenda

Module 1 – Overview of Small Cell Lung Cancer (SCLC)

Module 2 – First-Line Therapy; Prevention of Cytopenias

Module 3 – Second-Line and Beyond

Module 4 – SVC, SIADH and Other Paraneoplastic Syndromes

Module 5 – Complementary Treatments

Agenda

Module 1 – Overview of Small Cell Lung Cancer (SCLC)

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SELF-ASSESSMENT QUIZ

Patients presenting with SCLC often…

1. Have extensive history of tobacco use
2. Are very symptomatic
3. Both
4. Neither
5. I don’t know

Overview of Small Cell Lung Cancer

Cell of origin

- Neuroendocrine

Initial presentation

- Smoking history/comorbidities
- Hilar and mediastinal nodes/symptomatic
- Brain metastases, high growth rate
- Superior vena cava (SVC) syndrome

Clinical issues

- Chemoresponsive/now with CIs
- Paraneoplastic syndromes (SIADH, neurologic)

Questions — Matthew Gubens, MD, MS

Patients with newly diagnosed extensive-stage (ES) SCLC

- **What is the typical clinical presentation of SCLC and your approach to treatment, and how do you explain prognosis to patients?**

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Commentary — Matthew Gubens, MD, MS

Patients with newly diagnosed extensive-stage (ES) SCLC

- **Clinical presentation**
- **SCLC is not NSCLC! Much more aggressive**
  - **Doubling time can be fast (Ki67 often >90%) — symptoms can progress to severe in a few weeks:**
    - **Dyspnea and hypoxia from mass effect of lung masses and especially lymphadenopathy**
    - **Neurologic changes from CNS metastases**
    - **Other changes from paraneoplastic syndromes**
  - **Almost always metastatic at presentation — extensive vs limited stage**
  - **Which means treatment has to start fast! No need to wait for DNA mutation testing, or PD-L1, or even a radiation consult — admit to the hospital if you have to expedite**

Commentary — Matthew Gubens, MD, MS

- **Discussion of prognosis**
  - **Patients often feel the stigma of lung cancer (especially if tobacco-associated)**
  - **Patients have sometimes heard of advances like immunotherapies and targeted therapies…but usually don’t realize these aren’t as successful in SCLC, without the same proportion of patients on the “tail of the curve”**
  - **Recent first-line trials: median overall survival 12.3 mos (IMpower133) and 13.0 mos (CASPIAN)…and these were the trial-fit patients with good performance status**

Questions — Chaely J Medley, MSN, AGNP

Patients with newly diagnosed extensive stage (ES) NSCLC

- **What are typical smoking-related comorbidities seen in patients with lung cancer?**
- **What are some of the psychosocial issues that arise in these situations?**

Commentary — Chaely J Medley, MSN, AGNP

Patients with newly diagnosed extensive stage (ES) NSCLC

What are typical smoking-related comorbidities seen in patients with lung cancer?

- **Cardiovascular disease**
  - **Coronary heart disease**
  - **Ischemic stroke**
  - **Peripheral arterial disease**
  - **Abdominal aortic aneurysm**
- **COPD**
  - **Pulmonary infections**

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Commentary — Chaely J Medley, MSN, AGNP

Time Elapsed After Smoking Cessation	Health Benefits
2 weeks – 3 months	Improvements in circulation, oral hygiene, pulmonary function and skin tone
1 – 9 months	Ciliary function restored in lungs
12 months	Coronary artery disease rise reduced 50% compared to current smokers
5 – 15 years	Stroke risk reduced to that of nonsmokers
10 years	Risk of death from lung cancer reduced by 50% compared to current smokers
15 years	Coronary heart disease risk reduced to that of nonsmokers

Advanced Oncology Nursing Certification: Review & Resource manual. Second edition. Chapters 1 & 2.

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Agenda

Module 1 – Overview of Small Cell Lung Cancer (SCLC)

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Module 5 – Complementary Treatments

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SELF-ASSESSMENT QUIZ

The combination of chemotherapy and a checkpoint inhibitor has become the standard first-line treatment for extensive-stage small cell lung cancer.

1. Agree
2. Disagree
3. I don’t know

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SELF-ASSESSMENT QUIZ

The benefits and risks of adding durvalumab to platinum/etoposide and of adding atezolizumab to carboplatin/etoposide are very similar, and from a clinical point of view selecting between the 2 regimens as first-line treatment for a patient with extensive-stage SCLC can be considered a "coin flip."

1. Agree
2. Disagree
3. I don't know

The benefits and risks of adding durvalumab to platinum/etoposide and of adding atezolizumab to carboplatin/etoposide are very similar, and from a clinical point of view selecting between the 2 regimens as first-line treatment for a patient with extensive-stage SCLC can be considered a “coin flip.”

 Dr Aggarwal	Agree	 Dr Hanna	Agree
 Dr Goldberg	Agree	 Dr Liu	Agree
 Dr Govindan	Agree	 Dr Ramalingam	Agree

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SELF-ASSESSMENT QUIZ

In a clinical trial evaluating the addition of an immune checkpoint inhibitor to chemotherapy as first-line therapy for patients with extensive-stage SCLC, what proportion of patients in the *placebo* arm experienced immune-related adverse events?

1. None
2. Less than 5%
3. 25%
4. I don’t know

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IMpower133: Adverse Events

Patients — no. (%)	Atezolizumab + CP/ET (N = 198)	Placebo + CP/ET (N = 196)
Patients with ≥ 1 AE	198 (100)	189 (96.4)
Grade 3–4 AEs	133 (67.2)	125 (63.8)
Treatment-related AEs[a]	188 (94.9)	181 (92.3)
Serious AEs	74 (37.4)	68 (34.7)
Immune-related AEs	79 (39.9)	48 (24.5)
AEs leading to withdrawal from any treatment[a]	22 (11.1)	6 (3.1)
AEs leading to withdrawal from atezolizumab/placebo	21 (10.6)	5 (2.6)
AEs leading to withdrawal from carboplatin	5 (2.5)	1 (0.5)
AEs leading to withdrawal from etoposide	8 (4.0)	2 (1.0)
Treatment-related deaths	3 (1.5)	3 (1.5)

- Median duration of treatment with atezolizumab was 4.7 months (range: 0 to 21)
- Median number of doses received:
  - Atezolizumab: 7 (range: 1 to 30)
  - Chemotherapy: 4 doses for carboplatin; 12 doses for etoposide (same for both treatment groups)

Liu SV et al. WCLC 2018;Abstract PL02.07

SELF-ASSESSMENT QUIZ

Trilaciclib is used to prevent chemotherapy-induced _____.

1. Nausea and vomiting
2. Cytopenias
3. Alopecia
4. None of the above
5. I don’t know

SELF-ASSESSMENT QUIZ

Patients receiving trilaciclib report which of the following?

1. Pruritis
2. Bone pain
3. Improved quality of life
4. All of the above
5. None of the above
6. I don’t know

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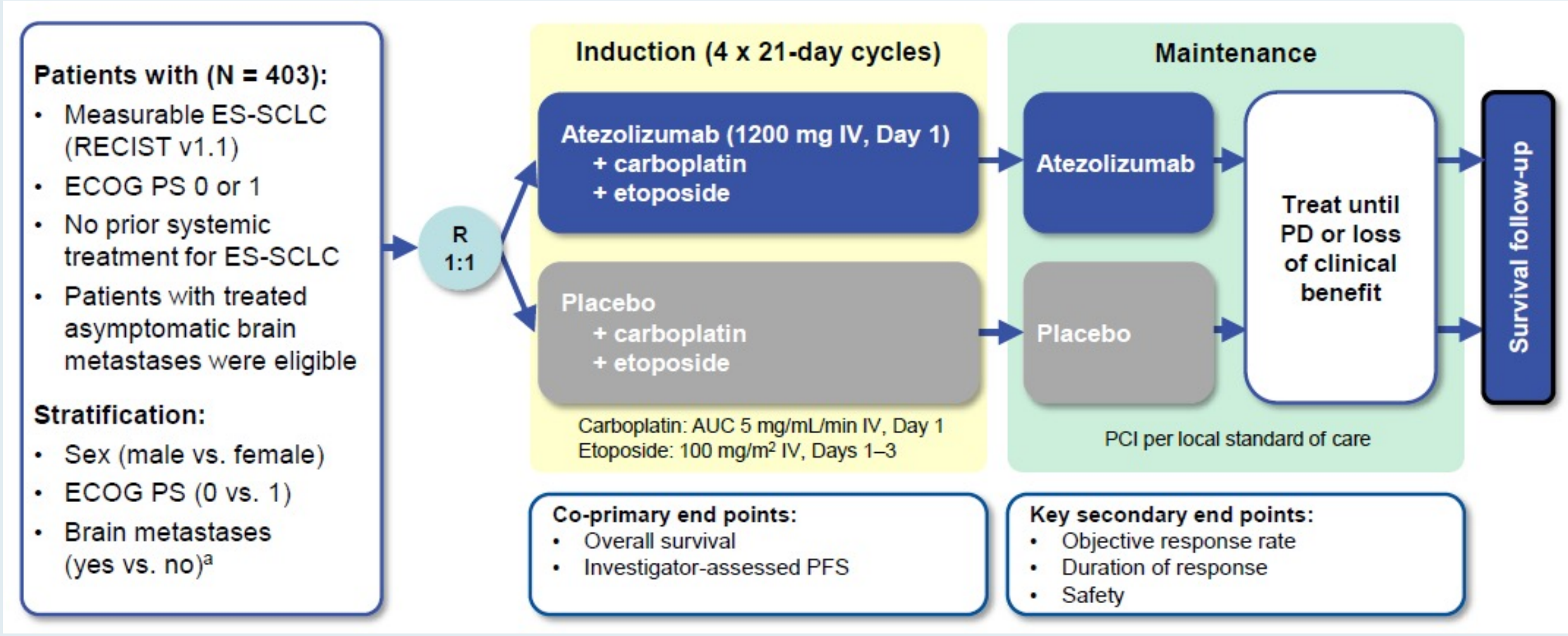
IMpower133: Phase III Study Design

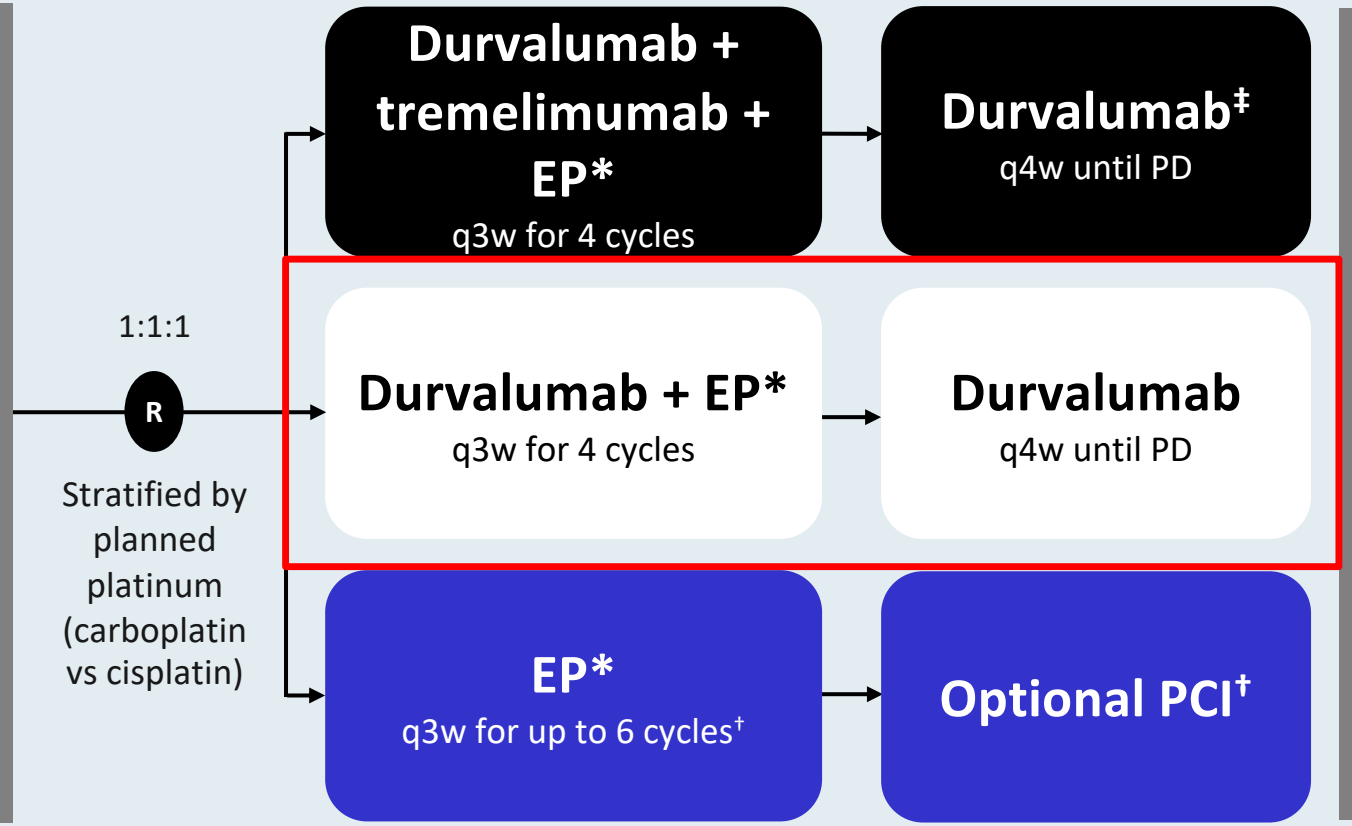


Liu SV et al. *J Clin Oncol* 2021;39(6):619-30.

CASPIAN: Phase III Study Design

- Treatment-naïve ES-SCLC
- WHO PS 0 or 1
- Asymptomatic or treated and stable brain metastases permitted
- Life expectancy ≥12 weeks
- Measurable disease per RECIST v1.1

N=805 (randomized)



Primary endpoint

- OS

Secondary endpoints

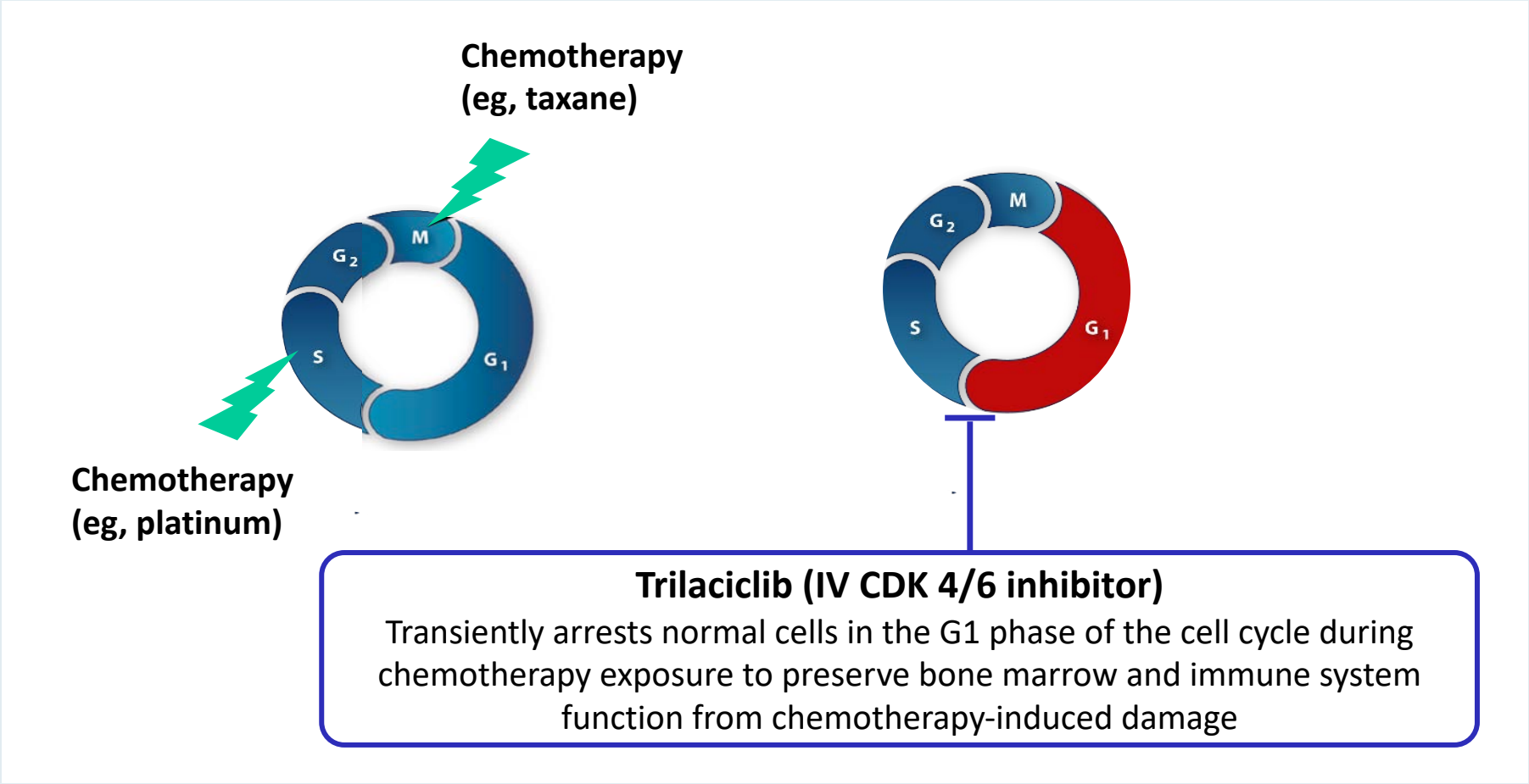
- PFS §
- ORR §
- Safety & tolerability
- PROs

***EP consists of etoposide 80–100 mg/m2 with either carboplatin AUC 5–6 or cisplatin 75–80 mg/m2, durvalumab dosed at 1500 mg, tremelimumab dosed at 75 mg**
†Patients could receive an additional 2 cycles of EP (up to 6 cycles total) and PCI at the investigator's discretion
‡Patients received an additional dose of tremelimumab post-EP; § By investigator assessment per RECIST v1.1

AUC = area under the curve; ORR = objective response rate; OS = overall survival; PCI = prophylactic cranial irradiation; PD = disease progression; PFS = progression-free survival; PROs = patient-reported outcomes; PS = performance status; q3w = every 3 weeks; q4w = every 4 weeks; RECIST v1.1 = Response Evaluation Criteria in Solid Tumors version 1.1

Paz-Ares L et al. ASCO 2020;Abstract 9002.

Trilaciclib: Mechanism of Action



https://www.sec.gov/Archives/edgar/data/1560241/000119312517261065/d431298dex991.htm

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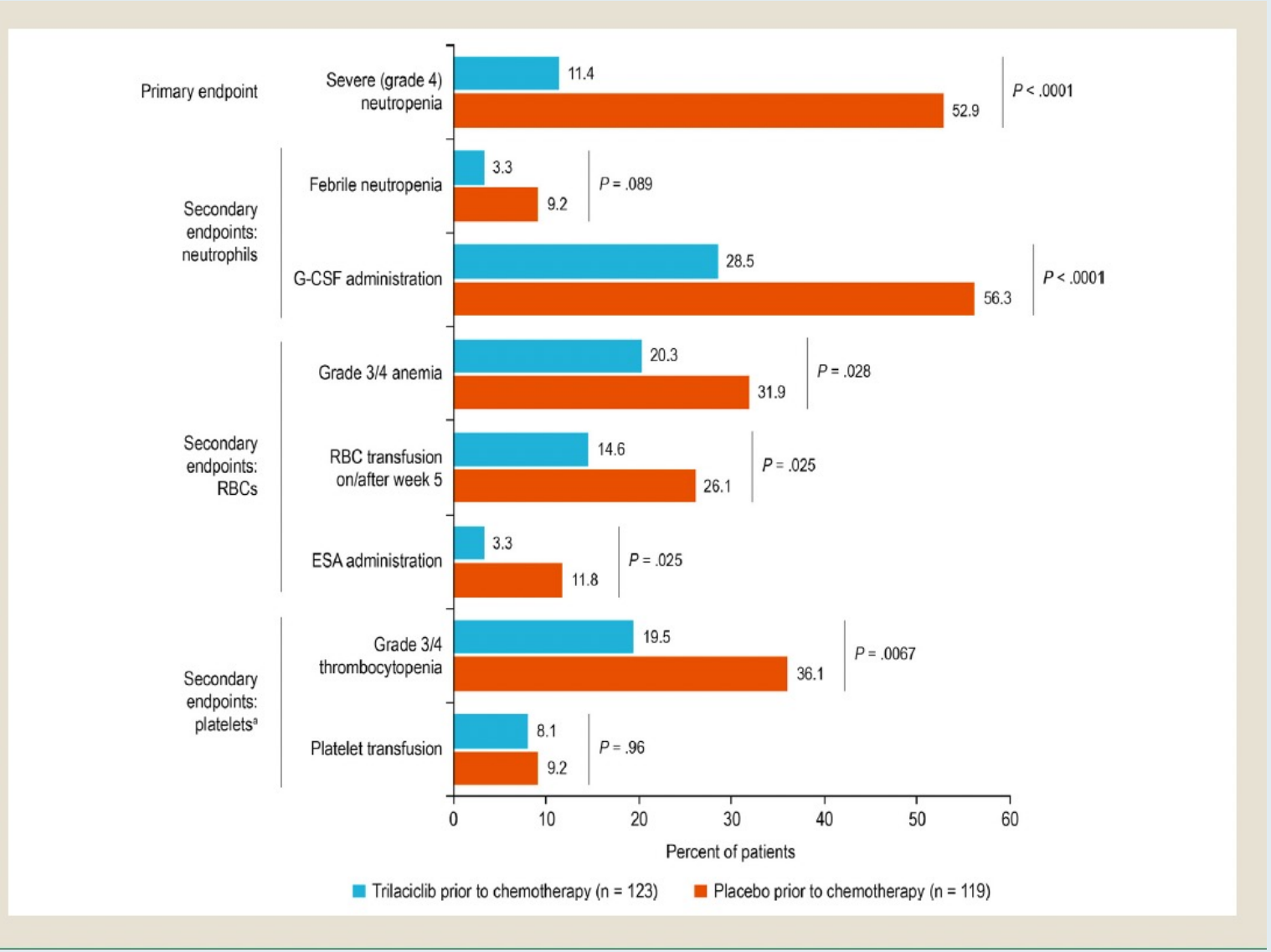
Effects of Trilaciclib on Chemotherapy-Induced Myelosuppression and Patient-Reported Outcomes in Patients with Extensive-Stage Small Cell Lung Cancer: Pooled Results from Three Phase II Randomized, Double-Blind, Placebo-Controlled Studies

Jared Weiss,[1] Jerome Goldschmidt,[2] Zoran Andric,[3] Konstantin H. Dragnev,[4] Chad Gwaltney,[5] Konstantina Skaltsa,[6] Yili Pritchett,[7] Joyce M. Antal,[7] Shannon R. Morris,[7] Davey Daniel[8,9]

***Clin Lung Cancer* 2021;22(5):449-60.**

Myelopreservation Benefits with Trilaciclib Administered Prior to Chemotherapy



Weiss J et al. *Clin Lung Cancer* 2021;22(5):449-60.

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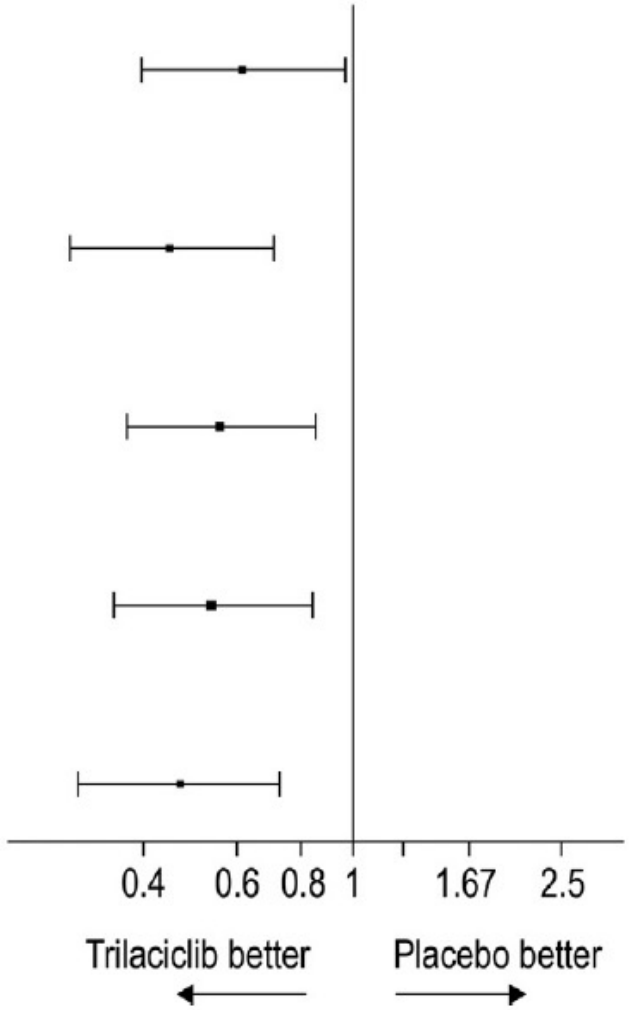
Time to Confirmed Deterioration (TTCD) in Selected Patient-Reported Outcome Measures with Trilaciclib

Domain	Events, n Trilaciclib/placebo	TTCD, months Trilaciclib/placebo	Hazard ratio (95% CI)
Physical wellbeing	32/51	NYR/5.16	0.62 (0.40–0.97)
Functional wellbeing	31/55	7.62/3.78	0.45 (0.29–0.71)
Fatigue	39/61	7.03/2.33	0.56 (0.37–0.85)
Anemia trial outcome index	33/55	7.20/3.78	0.54 (0.35–0.84)
FACT-An total	31/58	NYR/3.48	0.47 (0.30–0.73)



Weiss J et al. *Clin Lung Cancer* 2021;22(5):449-60.

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Questions — Lowell L Hart, MD

Selection of treatment for patients with ES-SCLC

- **What are the typical first-line treatments for ES-SCLC, and what do you say to patients regarding what to expect in terms of potential risks and benefits?**

Commentary — Lowell L Hart, MD

Selection of treatment for patients with ES-SCLC

- **Small cell lung cancer is one of the fastest growing human cancers, so a very important starting point is not to delay treatment, especially in symptomatic patients with extensive-stage disease.**
- **Occasionally inpatient care for rapid evaluation and therapy may still be indicated for these patients, although multidisciplinary outpatient management is preferable whenever possible.**
- **Common first-line therapy in 2022 is carboplatin plus etoposide for 4 cycles, given every three weeks, along with immunotherapy unless there is a contraindication such as severe autoimmune disease or a prior organ transplant. Commonly atezolizumab or durvalumab are used and continued as maintenance until disease progression or severe immune adverse events occur.**

Commentary — Lowell L Hart, MD

- **Commonly this chemotherapy can lead to severe cytopenias, as has been known since it became standard in 1992. Common approaches to avoiding infections include pegfilgrastim, and the recently approved trilaciclib, which may also support red cells and platelets.**
- **Radiation therapy as consolidation is sometimes used for the thorax or other sites but does not improve survival.**
- **Prophylactic cranial radiation is sometimes given to patients with a complete or strong partial response to first-line treatment but is still controversial especially in older patients given the potential for adverse neurologic effects.**

Commentary — Lowell L Hart, MD

Results with current treatments for ES-SCLC first line

- **In the large trial testing treatment with chemotherapy plus atezolizumab versus chemo alone the median survival was improved to 12.3 months versus 10.3 months, regardless of PD-L1 status in the tumor. The durvalumab trial had similar results with a median survival of 12.9 months, and 13.5% of patients were still responding at 2 years.**
- **These are modest but definite improvements over the historic figures with chemotherapy alone which showed good response rates of 70%-80% in this chemosensitive cancer but survivals in the 8–10-month range.**

Commentary — Lowell L Hart, MD

My approach to first-line therapy:

- **I explain to patients that the disease will very likely respond to our therapy quickly, but it is not felt to be curable. However, without therapy the survival may be weeks to a few months. Our goal is to preserve quality of life and extend their life if possible. I also say that there are occasional excellent responders to chemoimmunotherapy who may live years, but that we can't yet predict who those will be. Of course, we also explain about any research trials for which they may be eligible.**

- **We explain that we have excellent antiemetics available now, so significant emesis is rarely a problem. Fatigue and malaise persist often, and many of these patients have previous breathing issues such as COPD, so flare ups and infections can occur. Immunotherapy has the well-known potential for inflammatory issues and "itis" diseases of all types, so careful patient education is mandatory.**

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Commentary — Lowell L Hart, MD

- **Patients who are elderly are a large group of SCLC patients, about half are over 70 years. If they are frail from preexisting comorbid illnesses, there is not much data from trials to help us, but if their symptoms are mostly from the cancer I offer standard first-line treatment, sometimes with slight dose modifications.**

- **For patients who present also with brain metastases I start with systemic treatment if the brain involvement is small and asymptomatic, or with radiation therapy first if there are neurologic symptoms. Whole-brain radiation has been standard, but stereotactic radiation is sometimes used now.**

Commentary — Lowell L Hart, MD

Current case #1 ES-SCLC

- **67-year-old man who moved from TN to FL 9/2021. He had a 100+ pack-year smoking history. He has COPD and Type 2 diabetes also.**
- **His new MD adroitly ordered a screening chest CT scan (rarely done in the Southeast US, although we are working to improve this). It showed a RUL lung nodule, spiculated and suspicious. Bronchoscopy proved small cell lung cancer and mediastinal nodes were positive also. Brain MRI had several tiny and asymptomatic mets, so we started systemic therapy with carbo/etoposide/atezolizumab. We supported him with pegfilgrastim for cycle one which gave him some bone aches transiently. He otherwise tolerated treatment well. For the second through fourth cycles we had approval for trilaciclib along with chemo and he did well without bone aches, infections or transfusions.**

Commentary — Lowell L Hart, MD

- **Follow up CT and MRI in November showed resolution in chest and brain so Atezo maintenance was continued. Unfortunately in Feb. 2022 he developed a left adrenal nodule and worsening disease in the lung and new multifocal brain mets so he was started on dexamethasone and whole brain radiation. He did not have severe symptoms, only some mild headaches.**

- **He needed to start insulin due to the steroids. Temozolomide was given orally during the radiation with dosing similar to that used in gliomas. He tolerated the brain radiation well and will come to clinic this week to see if his performance status is adequate to consider further systemic therapy such as lurbinectedin. We will discuss second-line therapies next.**

Commentary — Lowell L Hart, MD

- **The patient also asked recently about using unapproved therapies such as high-dose vitamin C, and we had a conversation about the lack of documented benefit and potential toxic effects at very high doses. For patients with incurable cancers, I generally will allow alternative medicine use if it is spaced out from conventional therapy and is not known to be toxic.**
- **I will update the group on this patient's status at the meeting, after his appointment this week.**

Questions — Chaely J Medley, MSN, AGNP

Potential complications of treatment for ES-SCLC

- **How do you explain potential complications of first-line treatment for ES-SCLC, including the risk of cytopenias?**
- **How do you explain to a patient the potential benefit of trilaciclib?**
- **What are some of the psychosocial issues that arise in this situation?**

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Commentary — Chaely J Medley, MSN, AGNP

Potential complications of treatment for ES-SCLC

How do you explain potential complications of first-line treatment for ES-SCLC, including the risk of cytopenias?

- **Common side effects of cytotoxic therapy include peripheral neuropathy, nausea, vomiting, diarrhea, ototoxicity, nephrotoxicity, alopecia, fatigue, mucositis and myelosuppression (anemia, leukopenia, thrombocytopenia; dose-related)**
  - **Chemotherapy-induced myelosuppression is one of the most common adverse events associated with first-line cisplatin and etoposide treatments and second-line treatment with topotecan.**
- **Common side effects of immune checkpoint blockade include fatigue, colitis, pneumonitis, endocrinopathies including thyroid dysfunction, rash, transaminitis, arthritis and myalgias.**

RTP RESEARCH TO PRACTICE

Commentary — Chaely J Medley, MSN, AGNP

How do you explain to a patient the potential benefit of trilaciclib?

- **Trilaciclib is an IV medication given prior to chemotherapy with the purpose of providing myeloprotection to avoid treatment delays and dose reductions.**
- **This medication works by holding bone marrow progenitors out of the cell cycle.**
- **Consequences of chemotherapy-induced myelosuppression include infection, sepsis, fatigue, bleeding, dose reductions and treatment delays.**
- **By using trilaciclib prior to administering chemotherapy for ES-SCLC, we are preempting the need for reactive supportive care interventions and increasing quality of life for patients.**

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Agenda

Module 1 – Overview of Small Cell Lung Cancer (SCLC)

Module 2 – First-Line Therapy; Prevention of Cytopenias

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Module 4 – SVC, SIADH and Other Paraneoplastic Syndromes

Module 5 – Complementary Treatments

SELF-ASSESSMENT QUIZ

Which of the following best describes the mechanism of action of lurbinectedin?

1. Antibody-drug conjugate
2. Monoclonal antibody
3. Cytotoxic chemotherapy
4. Small molecule
5. I don’t know

SELF-ASSESSMENT QUIZ

The major clinical advantage of lurbinectedin as compared to topotecan is _____.

1. Greater efficacy and tolerability
2. Greater efficacy
3. Greater tolerability
4. I don't know

SELF-ASSESSMENT QUIZ

In general, what is the usual preferred second-line treatment for a patient with extensive-stage SCLC with metastases and disease progression on chemotherapy/atezolizumab?

1. Topotecan or irinotecan
2. Lurbinectedin
3. Nivolumab/ipilimumab
4. Pembrolizumab
5. Nivolumab

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In general, what is your preferred second-line treatment for a patient with extensive-stage SCLC with metastases and disease progression on chemotherapy/atezolizumab?

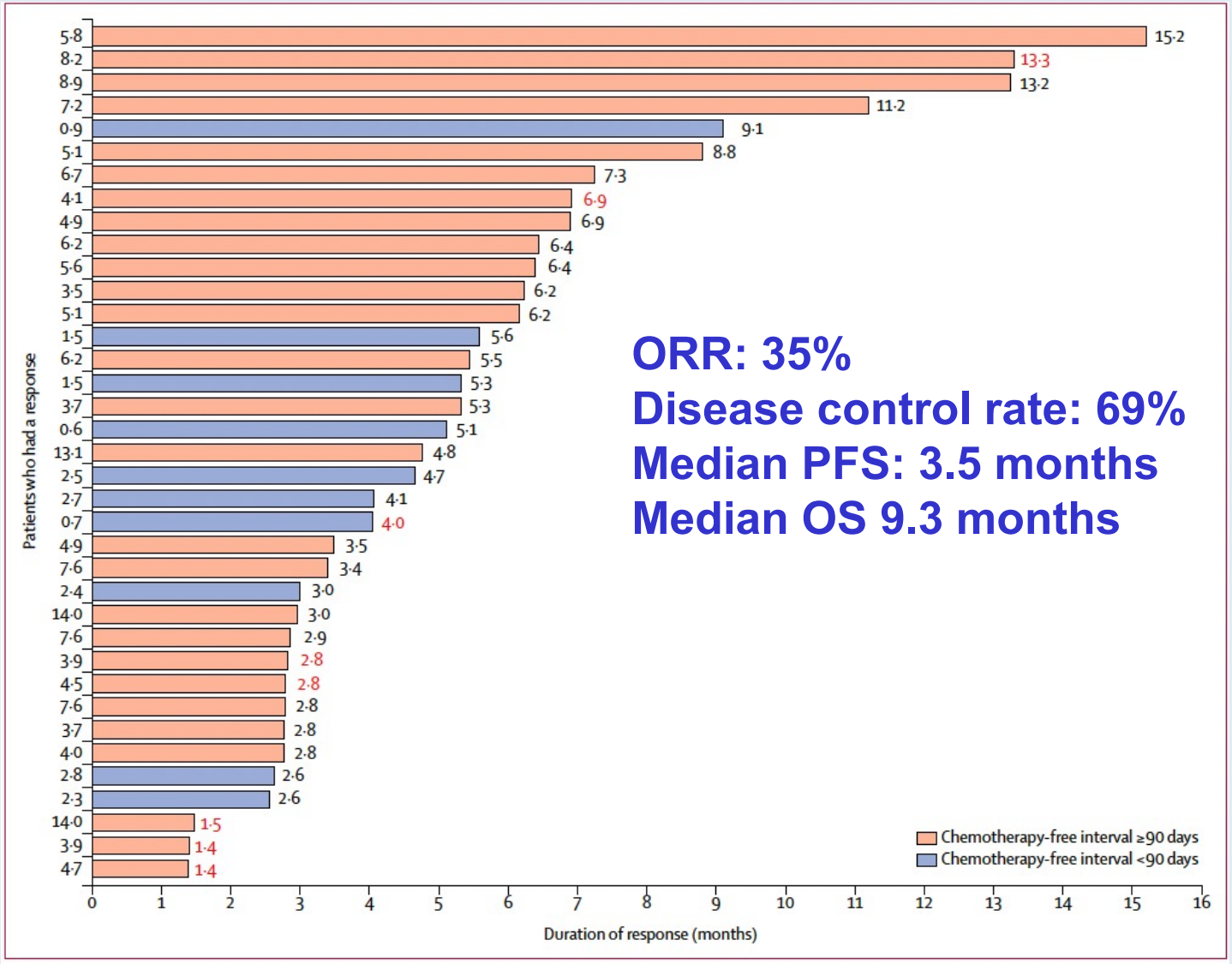
 Dr Aggarwal	Lurbinectedin	 Dr Hanna	Lurbinectedin
 Dr Goldberg	Lurbinectedin	 Dr Liu	Lurbinectedin
 Dr Govindan	Topotecan or irinotecan	 Dr Ramalingam	Lurbinectedin

Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial

José Trigo, Vivek Subbiah*, Benjamin Besse, Victor Moreno, Rafael López, María Angeles Sala, Solange Peters, Santiago Ponce, Cristian Fernández, Vicente Alfaro, Javier Gómez, Carmen Kahatt, Ali Zeaiter, Khalil Zaman, Valentina Boni, Jennifer Arrondeau, Maite Martínez, Jean-Pierre Delord, Ahmad Awada, Rebecca Kristeleit, Maria Eugenia Olmedo, Luciano Wannesson, Javier Valdivia, María Jesús Rubio, Antonio Anton, John Sarantopoulos, Sant P Chawla, Joaquín Mosquera-Martinez, Manolo D'Arcangelo, Armando Santoro, Victor M Villalobos, Jacob Sands, Luis Paz-Ares*

Lancet Oncol 2020; 21: 645–54

Response, Survival and Common Adverse Events in the Pivotal Phase II Study of Lurbinectedin for SCLC After 1 Line of Chemotherapy



Common treatment-related adverse events		
	Grade 1-2	Grade 3-4
Anemia	87%	9%
Leukopenia	50%	29%
Neutropenia	26%	46%
Thrombocytopenia	37%	7%

Trigo J et al. *Lancet Oncol* 2020;21:645-54.

RTP RESEARCH TO PRACTICE

Lurbinectedin/doxorubicin *versus* CAV or topotecan in relapsed SCLC patients: Phase III randomized ATLANTIS trial

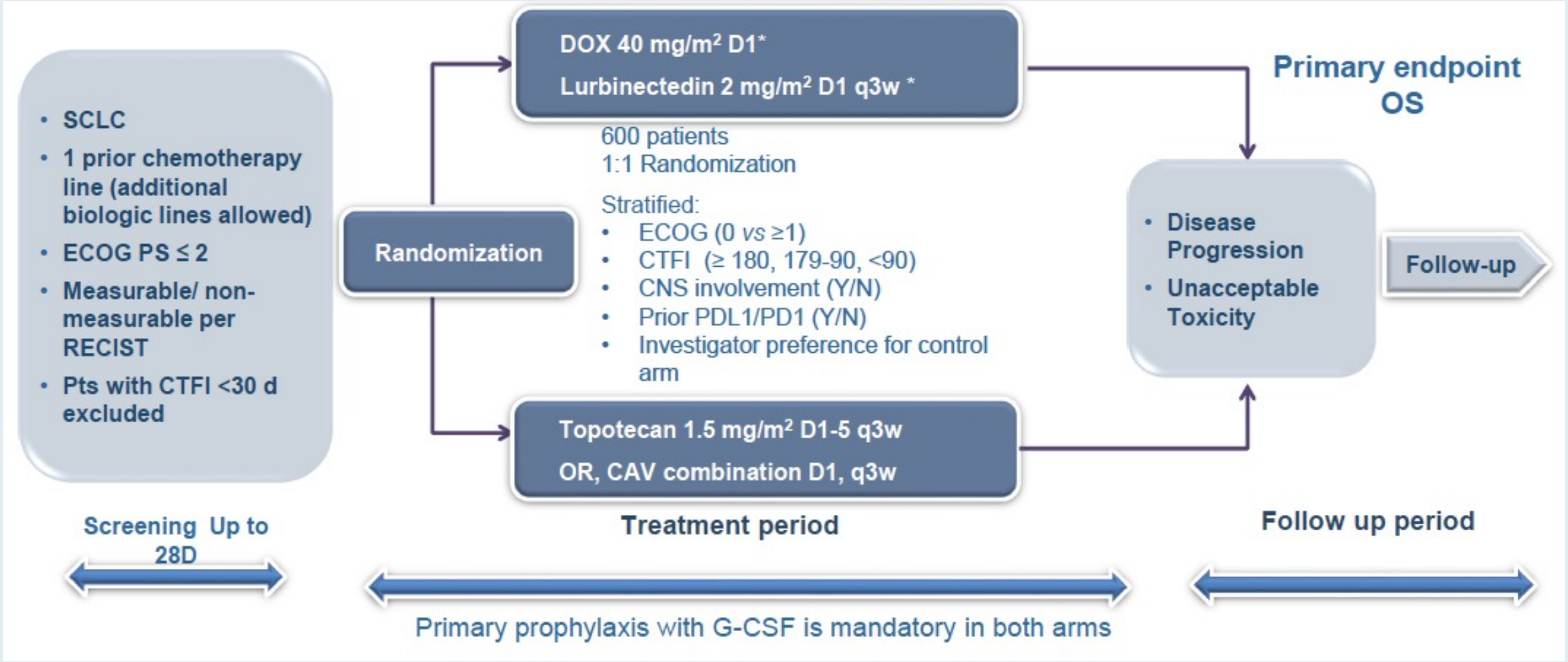
Luis Paz-Ares[1]

[1]Hospital Universitario 12 de Octubre, Madrid, Spain

Tudor Eliade Ciuleanu[2], Alejandro Navarro[3], Andrea Fulop[4], Sophie Cousin[5], Laura Bonanno[6], Egbert Smit[7], Alberto Chiappori[8], Mª Eugenia Olmedo[9], Ildiko Horvath[10], Christian Gröhé[11], José Antonio López-Vilariño[12], Rafael Núñez[12], Antonio Nieto[12], Martin Cullell-Young[12], Noelia Vasco[12], Carmen Kahatt[12], Ali Zeaiter[12], Enric Carcereny[13], Jaromir Roubec[14], Konstantios Syrigos[15], Gregory Lo[16], Isidoro Barneto[17].

WCLC 2021;Abstract PL02.03.

ATLANTIS: Phase III Trial Design



CTFI = chemotherapy-free interval

Paz-Ares et al. WCLC 2021;Abstract PL02.03.

Questions — Lowell L Hart, MD

Selection of treatment for patients with ES-SCLC

- **What are the typical second-line treatments for ES-SCLC, and what do you say to patients regarding what to expect in terms of potential risks and benefits?**

Commentary — Lowell L Hart, MD

Second-line treatments and beyond

- **With the approval of lurbinectedin in 2020, this agent has become the standard second-line therapy for extensive-stage SCLC patients who have an adequate performance status. It was developed from a Spanish sea sponge and is similar to trabectedin, which is used for some sarcomas. In studies the drug had about a 33% response rate and the median duration of response was about 5 months. It is given IV every three weeks and can lead to neutropenia. In our practice it is usually given with premedication and growth factor support.**

- **Topotecan has been our long-term second-line agent but has moved to third line now due to its lower response rate which is around 20% in most trials. It also comes in an oral formulation, but I prefer the daily IV times five days every 4 weeks approach. This can be given with trilaciclib to avoid severe cytopenias, as we presented at the ASCO 2019 meeting. Some oncologists prefer to give a once weekly dosing, but this seems to be less effective in comparison studies.**

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Commentary — Lowell L Hart, MD

- **Irinotecan also has some activity in SCLC trials and is occasionally used in the US, more in Asia for this cancer. The usual side effect is diarrhea.**
- **Paclitaxel is also sometimes used as a late line of therapy with response rates of about 30% but a brief duration.**
- **Temozolomide has about a 16% response rate in studies but has the advantage of being an oral drug given for 5 days each 4 weeks, with good CNS penetration and I have used it successfully as a palliative agent in late line patients with brain mets.**

Questions — Marianne J Davies, DNP, MSN, RN

Selection of treatment for patients with ES-SCLC

- **What do you say to patients who are about to initiate treatment with lurbinectedin in terms of what they should expect with this treatment?**
- **What are some of the psychosocial issues that arise in this situation?**

Selection of treatment for patients with ES-SCLC

Initiating treatment with lurbinectedin

1. Assess baseline performance status and symptoms
2. Treatment administration
   a. Intravenous administration every 21 days over 1 hour
   b. Premedication
3. Common treatment-related adverse events (trAEs):
   a. Pancytopenia: neutropenia, thrombocytopenia, anemia
   b. Hepatotoxicity: elevation of ALT, AST
   c. Nephrotoxicity
   d. Hyperglycemia
   e. Hyponatremia
   f. Gastrointestinal: nausea, anorexia, constipation
4. What should you report?
   a. Signs & symptoms to report
   b. All medications including OTC as risk for drug-drug interactions

Commentary — Marianne J Davies, DNP, MSN, RN

Psychosocial issues with ES-SCLC progression

- **Distress related to progression of disease, uncertainty**
- **Fear of ineffective treatment**
- **Change in family, friend and work dynamics**
- **Distress related to increased symptom burden and impact on functional status and quality of life**
- **Distress related to lung cancer stigma**
- **Financial toxicities**
- **Available resources for patient and family**
  - **Support groups, social worker, psychooncology, palliative**
  - **Longevity, Cancer Support Community, LVNG, GO2 Foundation for Lung Cancer**

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Commentary — Lowell L Hart, MD

Illustrative current patient case study:

- **62-year-old woman, former smoker, seen as a second opinion in March 2021. She had seen her former oncologist in 6/20 with a LLL mass and left adrenal mass. Biopsy showed small cell lung carcinoma. Also had cerebral and cerebellar mets at diagnosis. She got whole brain radiation then carbo/etoposide and durvalumab. She was stable on this for a few months then her PET was worse and lurbinectedin was started but she rapidly progressed in the brain. Hospice was recommended, but she came for a second opinion to see me.**

- **She still had a reasonable performance status and after a long discussion with me and her husband she decided on topotecan salvage chemo, to hopefully extend her life and delay symptoms. She received slightly decreased doses with pegfilgrastim support since trilaciclib was not available at the cancer center. She progressed further after two cycles, with more CNS disease. She was switched to oral temozolomide which kept her stable for 10 months, also had some stereotactic brain radiation.**

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Commentary — Lowell L Hart, MD

- **By 12/21 she was progressing slowly in nodes and thorax, so a liquid biopsy was sent showing a high TMB of 16.7, so we tried pembrolizumab and later added compassionate olaparib due to known high PARP levels in SCLC and known safety profile with this combo in ovarian cancer trials. She was stable for 4 cycles but is now progressing in multiple areas with a declining performance status and will have a meeting with us this week in person or via telemedicine to discuss hospice care, approximately 14 months after it was first recommended.**

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SELF-ASSESSMENT QUIZ

Patients with SIADH often have…

1. Jaundice
2. Neuropathy
3. Low serum sodium levels
4. Hypercalemia
5. I don’t know

Questions — Matthew Gubens, MD, MS

Patients with ES-SCLC and SVC or SIADH syndrome

- **What are SVC (superior vena cava) and SIADH syndromes, and how do you explain your management strategy to patients?**

Commentary — Matthew Gubens, MD, MS

Patients with ES-SCLC and SVC syndrome

- **Seen in about 10% of SCLC**
- **Caused by direct invasion or extrinsic compression, sometimes with thrombosis**
- **Symptoms: Face/neck/arm swelling (esp when leaning forward), dyspnea, chest pain**
  - **Occasionally central airway obstruction, laryngeal edema, cerebral edema**
- **Treatment: cancer treatment! (And if need to temporize: stenting, radiation, anticoagulation for thrombosis)**

Commentary — Matthew Gubens, MD, MS

Patients with ES-SCLC and SIADH syndrome

- **Seen in about 10% of SCLC**
- **Caused by tumor production of ADH → impaired water excretion**
- **Labs: hyponatremia, hypoosmolality, high urine osmolality**
- **Symptoms: nausea/vomiting, headache, confusion/restlessness, muscle weakness**
- **Treatment: cancer treatment! (And if need to temporize: fluid restriction, hypertonic saline, vasopressin receptor antagonist (eg, tolvaptan), sometimes salt)**

Questions — Chaely J Medley, MSN, AGNP

Paraneoplastic syndromes seen in SCLC

- **What are some of the common paraneoplastic syndromes seen in SCLC and how do you explain this to patients?**
- **What are some of the psychosocial issues that arise in these situations?**

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Commentary — Chaely J Medley, MSN, AGNP

Paraneoplastic syndromes seen in SCLC

What are some of the common paraneoplastic syndromes seen in SCLC and how do you explain this to patients?

SIADH (Syndrome of Inappropriate Antidiuretic Hormone): hyponatremia (plasma sodium <134) associated with increased renal water retention

- **Most common paraneoplastic syndrome associated with SCLC.**
- **Caused by the excessive ectopic production of ADH.**
- **Common presenting symptoms are headache, muscle weakness, memory loss and general fatigue.**
- **First-line treatment is free water restriction (<1 L/d) and adequate sodium intake either by food sources or salt tablets. All through treatment.**
- **Most effective long-term therapy is treatment of the tumor itself.**

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Commentary — Chaely J Medley, MSN, AGNP

Ectopic Cushing Syndrome: a form of Cushing syndrome resulting from the production of adrenocorticotropic hormone (ACTH) from a tumor outside of the pituitary gland

- **Caused by the uncontrolled release of ACTH from nonpituitary tissue.**
- **Common presenting symptoms include moon face, acne, purple striae, proximal muscle weakness, peripheral edema, hypertension, hyperglycemia and metabolic alkalosis with hypokalemia.**
- **Most effective long-term therapy is treatment of the tumor itself, and inhibition of cortisol secretion with medications.**

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Module 5 – Complementary Treatments

Questions — Lowell L Hart, MD

Complementary treatments; “The bond that heals”

- **What are some of the complementary and alternative treatment strategies used by patients, and what do you say to patients in general and specifically about complementary approaches?**

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Commentary — Lowell L Hart, MD

Complementary treatments; “The bond that heals”

- As an oncologist for over 30 years, I have seen many of these come and go. Some were toxic and pure scams on unfortunate patients such as laetrile, licorice and cesium. Others were totally useless scientifically such as magnets, electric fields or shark cartilage.
- Commonly used agents such as green tea, gingko and St John’s wort can have interactions with many cancer meds so it is important to have an open conversation with all patients about any nutraceuticals that they are taking. High-dose vitamin E was found in one trial to decrease radiation effectiveness, and I have personally had a patient experience severe toxicity from very high-dose (30 grams) IV vitamin C from a well known “alternative physician.” Other patients have had severe financial toxicity from expensive treatments in Mexico and in Florida.

Commentary — Lowell L Hart, MD

- **My general approach is to be very supportive of mind-body therapies like yoga, exercise, massage and meditation – which I have found helpful myself in dealing with stress. Acupuncture also has a long history, if a reputable practitioner is available.**
- **Many patients now ask about THC and medical marijuana, and I generally have no objection since they may benefit symptoms such as anorexia and neuropathy. I remind them not to drive on marijuana or dronabinol and tell them I do not expect these agents to directly affect their cancer growth.**
- **I advise patients to avoid high-dose vitamins and supplements around the time of chemo, so we don't "protect the tumor" – otherwise I don't argue much unless I feel the drugs are toxic, but I do encourage them to avoid overpriced products with expansive benefit claims.**

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Questions — Marianne J Davies, DNP, MSN, RN

Complementary treatments; “The bond that heals”

- **What are some examples of longstanding or very close relationships you have had with patients with SCLC, and what are the positives and negatives for you and the patient?**

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Commentary — Marianne J Davies, DNP, MSN, RN

Complementary treatments; “The bond that heals”

Importance of patient-provider relationship

- **Establishing trust**
  - **Meeting patients’ needs and expectations**
  - **Managing symptom burden**
- **Open communication**
  - **Patient-centered**
  - **Reduces distress associated with lung cancer stigma**
  - **Improves adherence to treatment**
- **Shared decision-making**
  - **Alignment of patient-focused goals of care**
  - **Reduce barriers to shared decision-making**

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Appendix of Recent Data Sets

original reports

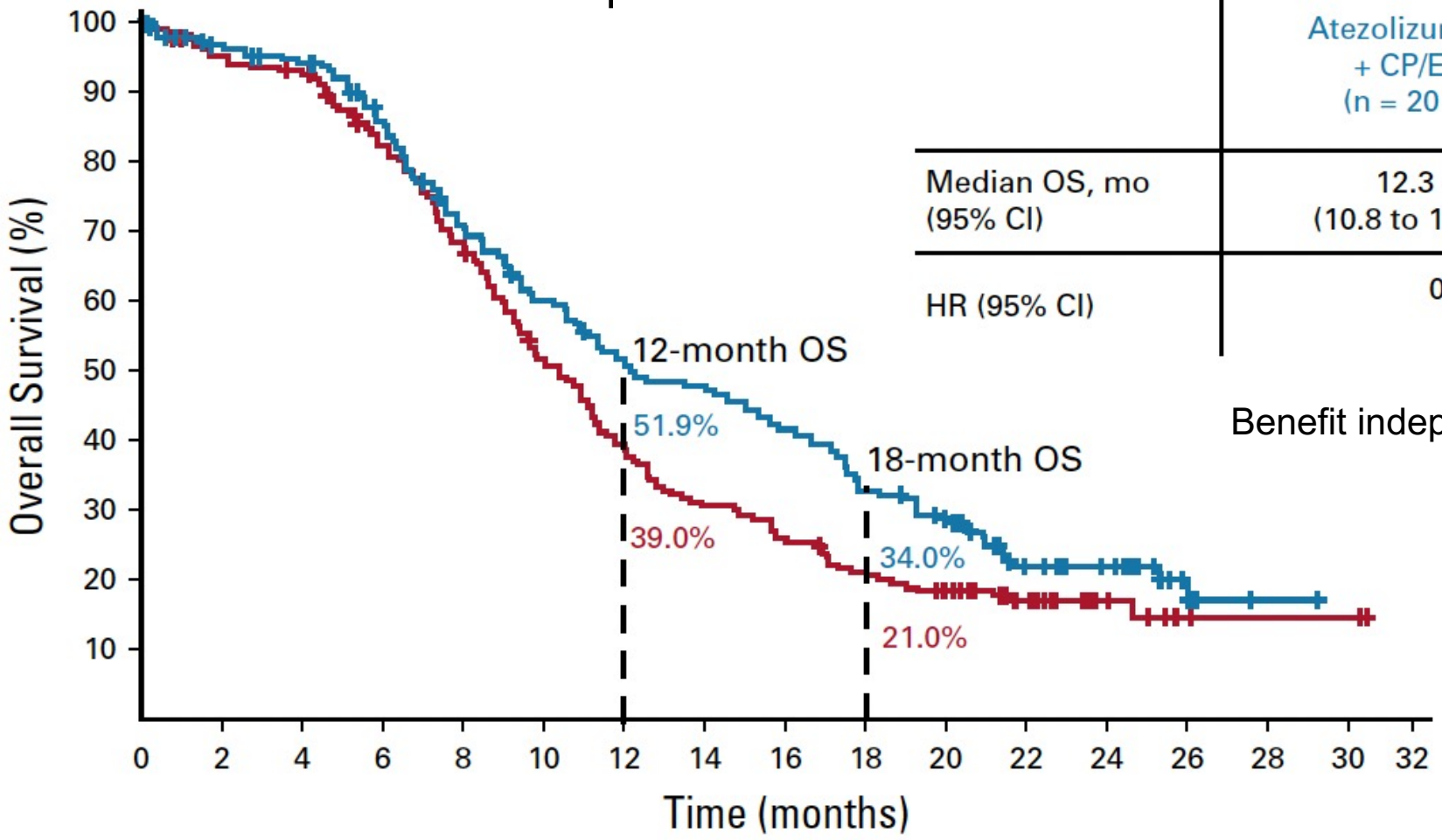
Updated Overall Survival and PD-L1 Subgroup Analysis of Patients With Extensive-Stage Small-Cell Lung Cancer Treated With Atezolizumab, Carboplatin, and Etoposide (IMpower133)

Stephen V. Liu, MD[1]; Martin Reck, MD, PhD[2]; Aaron S. Mansfield, MD[3]; Tony Mok, MD[4]; Arnaud Scherpereel, MD, PhD[5]; Niels Reinmuth, MD, PhD[6]; Marina Chiara Garassino, MD[7]; Javier De Castro Carpeno, MD[8]; Raffaele Califano, MD[9]; Makoto Nishio, MD[10]; Francisco Orlandi, MD[11]; Jorge Alatorre-Alexander, MD[12]; Ticiana Leal, MD[13]; Ying Cheng, MD[14]; Jong-Seok Lee, MD[15]; Sivuonthanh Lam, PharmD[16]; Mark McCleland, PhD[16]; Yu Deng, PhD[16]; See Phan, MD[16]; and Leora Horn, MD[17]

J Clin Oncol 2021;39(6):619-30.

IMpower133: Updated OS in Extensive-Stage Small Cell Lung Cancer Treated with First-Line Atezolizumab, Carboplatin and Etoposide

Median follow up: 22.9 mo



	Atezolizumab + CP/ET (n = 201)	Placebo + CP/ET (n = 202)
Median OS, mo (95% CI)	12.3 (10.8 to 15.8)	10.3 (9.3 to 11.3)
HR (95% CI)	0.76 (0.60 to 0.95) *P* = .0154*	

Benefit independent of PD-L1 status

Liu SV et al. *J Clin Oncol* 2021;39(6):619-30.

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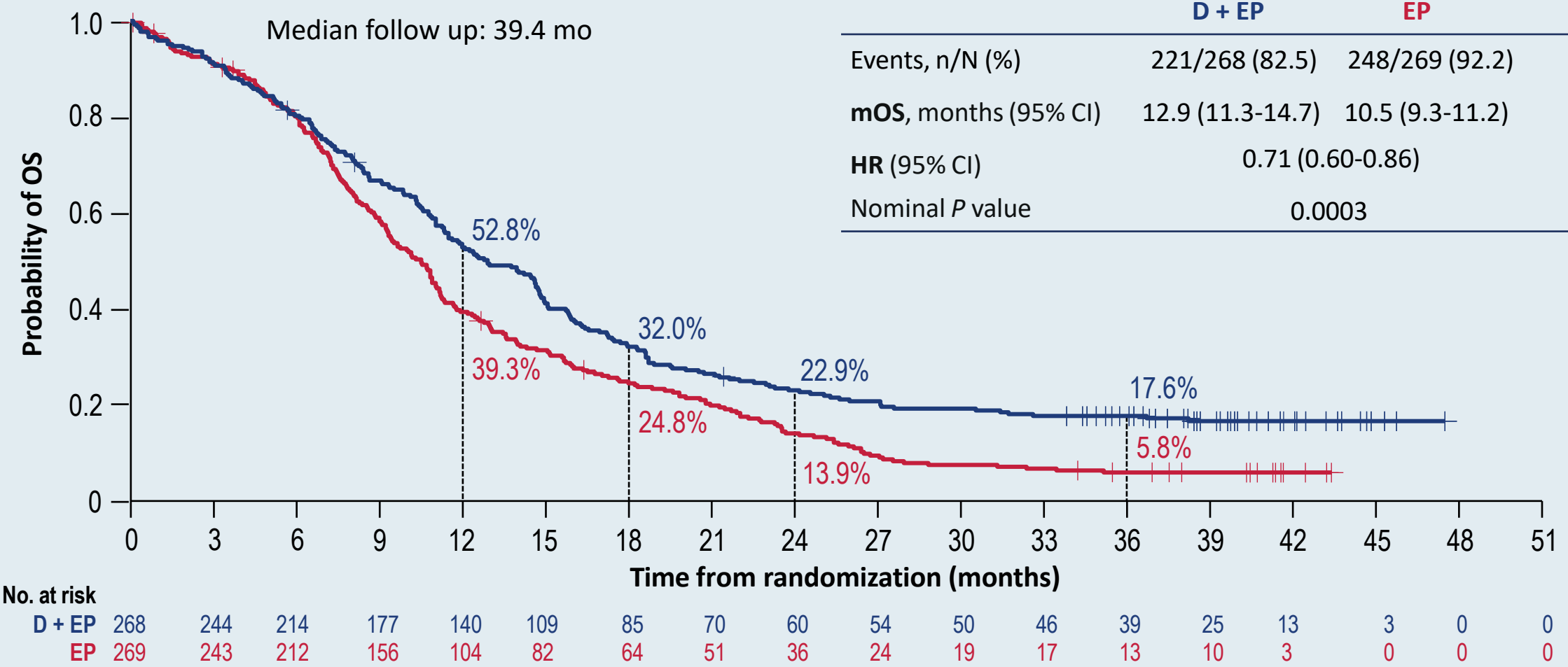
CASPIAN: Three-Year Updated Overall Survival (OS) with First-Line Durvalumab, Platinum and Etoposide for ES-SCLC



	D + EP	EP
Events, n/N (%)	221/268 (82.5)	248/269 (92.2)
mOS, months (95% CI)	12.9 (11.3-14.7)	10.5 (9.3-11.2)
HR (95% CI)	0.71 (0.60-0.86)	
Nominal *P* value	0.0003	

Paz-Ares LG et al. ESMO 2021;Abstract LBA61.

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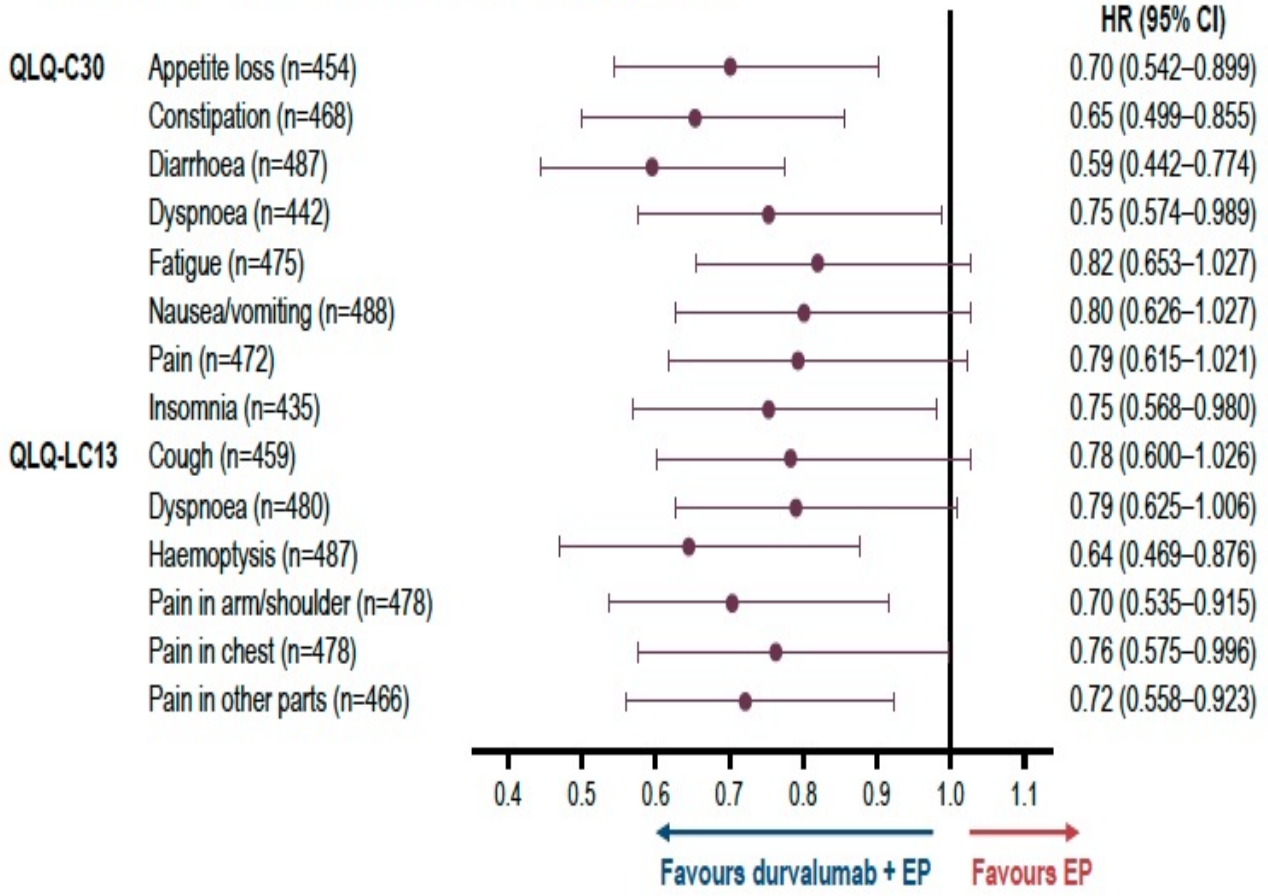
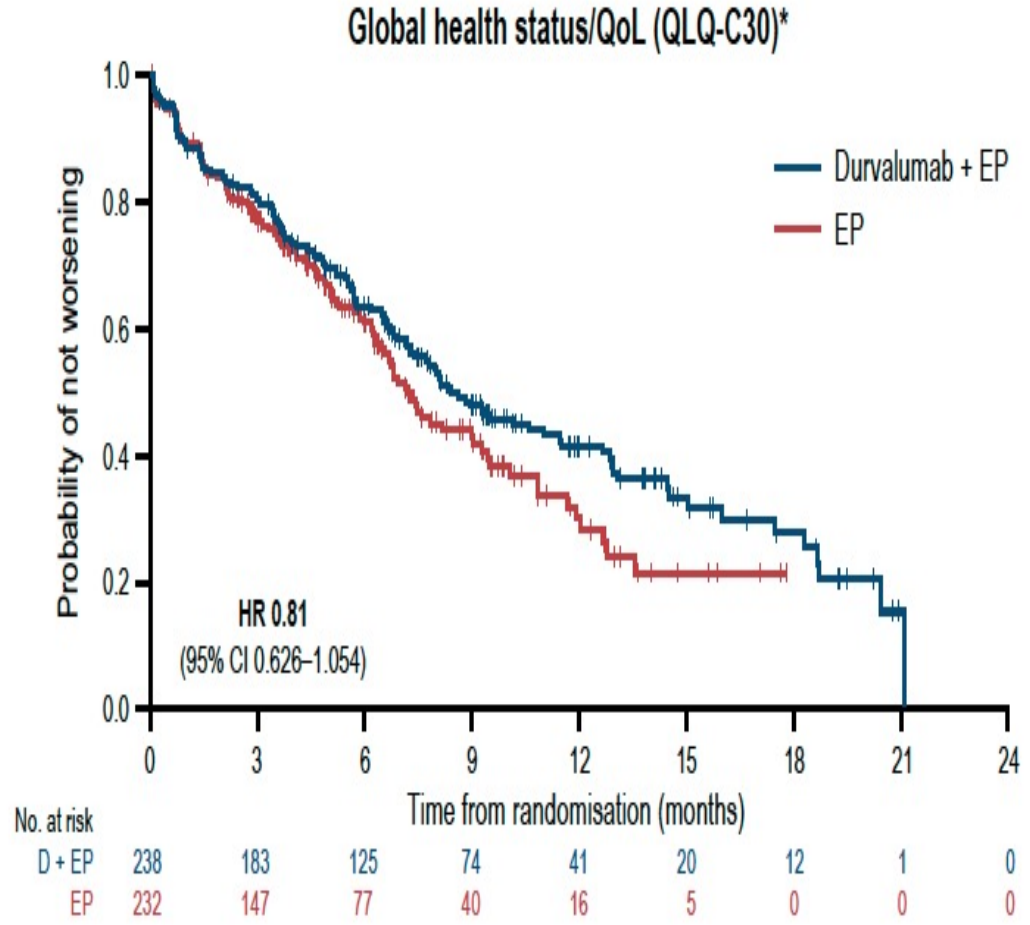
CASPIAN: Quality of Life

- Durvalumab + EP was favoured across all symptoms





Goldman JW et al. *Lancet Oncol* 2021;22(1):51-65.

FDA Approves Drug to Reduce Bone Marrow Suppression Caused by Chemotherapy

Press Release – February 12, 2021

"The US Food and Drug Administration approved trilaciclib as the first therapy in its class to reduce the frequency of chemotherapy-induced bone marrow suppression in adults receiving certain types of chemotherapy for extensive-stage (when the cancer has spread beyond the lungs) small cell lung cancer. Trilaciclib may help protect bone marrow cells from damage caused by chemotherapy by inhibiting cyclin-dependent kinase 4/6, a type of enzyme.

The effectiveness of trilaciclib was evaluated in three randomized, double-blind, placebo-controlled studies in patients with extensive-stage small cell lung cancer. Combined, these studies randomly assigned 245 patients to receive either an infusion of trilaciclib in their veins or a placebo before chemotherapy. The studies then compared the two groups for the proportion of patients with severe neutropenia (a very low count of white blood cells called neutrophils) and the duration of severe neutropenia in the first cycle of chemotherapy. In all three studies, patients who received trilaciclib had a lower chance of having severe neutropenia compared to patients who received a placebo. Among those who had severe neutropenia, patients who received trilaciclib, on average, had it for a shorter time than patients who received a placebo."

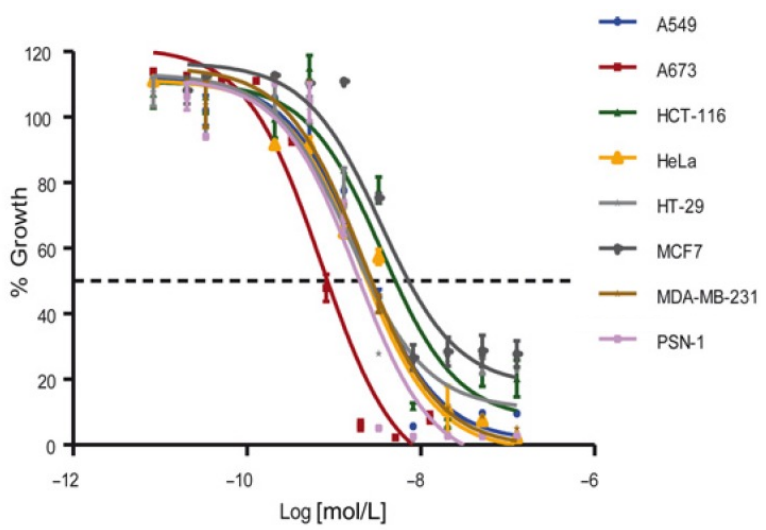
https://www.fda.gov/news-events/press-announcements/fda-approves-drug-reduce-bone-marrow-suppression-caused-chemotherapy

RTP RESEARCH TO PRACTICE

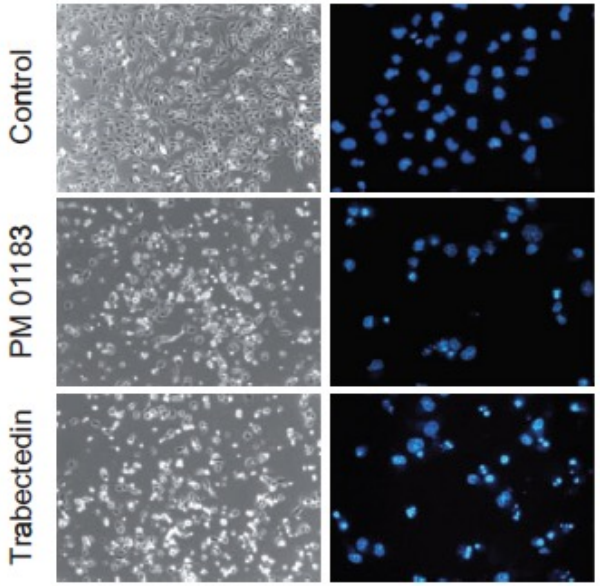
Lurbinectedin: Preclinical Antitumor Activity

Antitumor activity of lurbinectedin (PM01183) has been proven in several preclinical tumor models

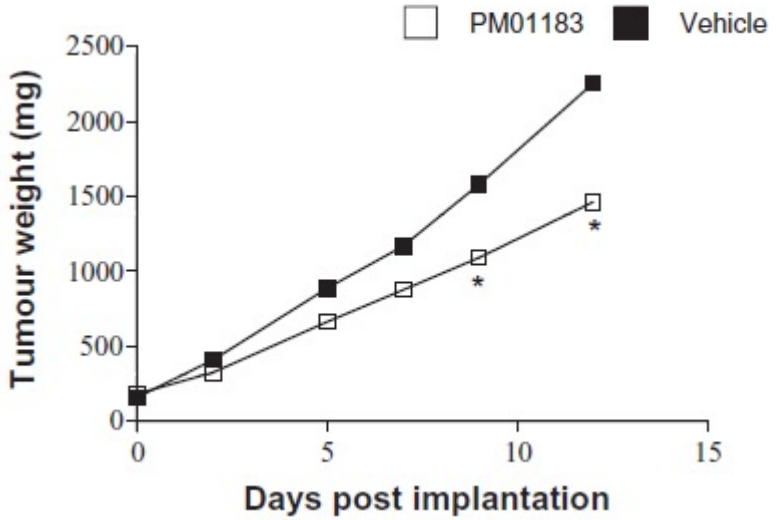
Lurbinectedin showed antiproliferative activity with IC_{50} values in the low nanomolar range in human lung (A549), Ewing sarcoma (A673), colon (HCT-116, HT-29), breast (MCF7, MDA-MB-231), cervix (HeLa), and pancreas (PSN-1) cancer cell lines[1]



Exposure of A549 lung cancer cells to 150 nM lurbinectedin for 24 hours induced cell death by apoptosis[2]



Lurbinectedin (0.18 mg/kg in 3 consecutive weekly doses) showed statistically significant inhibition of tumor growth *in vivo* in an NCI-H460 lung xenograft model compared with vehicle-treated animals[2]



Santamaría Nuñez G et al. *Mol Cancer Ther* 2016;15(10):2399-412; Leal JF et al. *Br J Pharmacol* 2010;161(5):1099-110.

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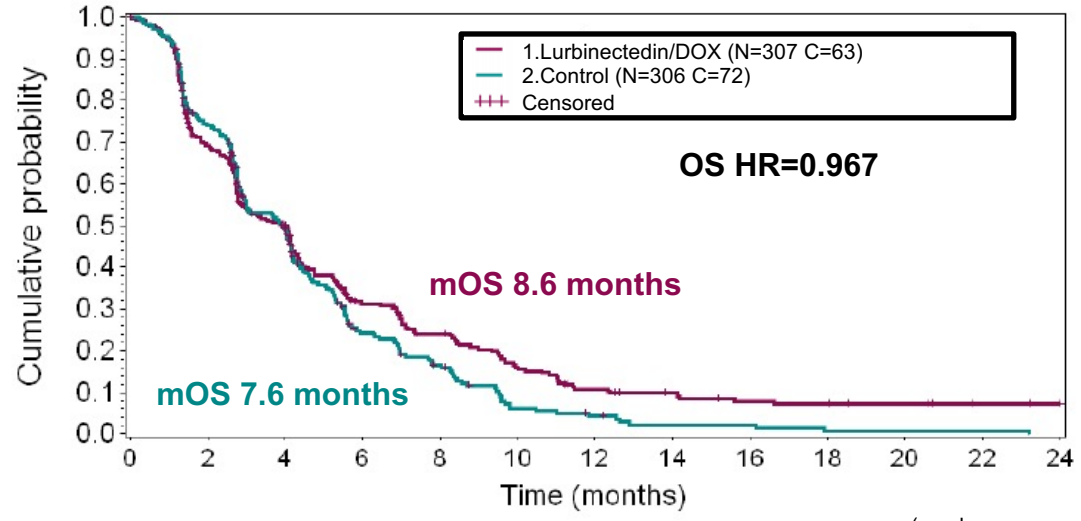
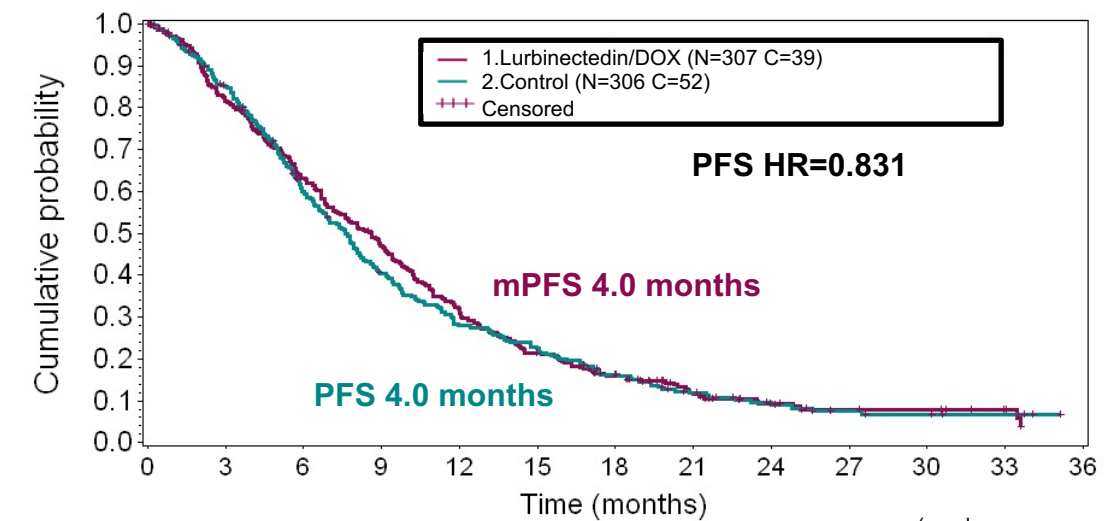
ATLANTIS: Lurbinectedin with Doxorubicin versus Cyclophosphamide/ Doxorubicin/Vincristine or Topotecan for Relapsed SCLC

Overall Survival



Progression-free Survival



Paz-Ares et al. WCLC 2021;Abstract PL02.03.

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ATLANTIS: Safety Summary

Hematological	Lurbinectedin+DOX (n=303)	Control (n=289)	
	Grade ≥3	Grade ≥3	p-value
Anaemia	44 (14.5)	90 (31.1)	<0.0001
Neutropenia	112 (37.0)	200 (69.2)	<0.0001
Febrile neutropenia	12 (4.0)	24 (8.3)	0.0377
Thrombocytopenia	42 (13.9)	90 (31.1)	<0.0001

Non hematological	Lurbinectedin+DOX (n=303)	Control (n=289)	
	Grade ≥3	Grade ≥3	p-value
ALT increased	6 (2.0)	3 (1.0)	0.5057
AP increased	2 (0.7)	3 (1.0)	0.6783
AST increased	7 (2.3)	4 (1.4)	0.5463
Fatigue	26 (8.6)	31 (10.7)	0.4051
Nausea	6 (2.0)	4 (1.4)	0.7525
Vomiting	4 (1.3)	0	0.1242

	Lurbinectedin+DOX (n=303) n (%)	Control (n=289) n (%)
Any AE treatment-related	268 (88.4)	266 (92.0)
Any grade ≥3 AE	**143 (47.2)**	**218 (75.4)**
Any grade 4 AE	**49 (16.2)**	**158 (54.7)**
Any grade ≥3 SAE	38 (12.5)	83 (28.7)
Death associated with AEs	**1 (0.3)**	**10 (3.5)**
Treatment discontinuations associated with AEs	23 (7.6)	45 (15.6)
Delays associated with AEs	79 (26.1)	99 (34.3)
Reductions associated with AEs	66 (21.8)	138 (47.8)

AE = adverse event; SAE = serious AE

Paz-Ares et al. WCLC 2021;Abstract PL02.03.

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What I Tell My Patients:
New Treatments and Clinical Trial Options

An NCPD Hybrid Symposium Series
Held During the 47th Annual ONS Congress

Chronic Lymphocytic Leukemia

Friday, April 29, 2022
12:15 PM – 1:45 PM PT

Faculty

Lesley Camille Ballance, MSN, FNP-BC
Amy Goodrich, CRNP
Anthony R Mato, MD, MSCE
Susan O'Brien, MD

Moderator

Neil Love, MD

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Thank you for joining us!

In-person attendees: Please fill out your Educational Assessment and NCPD Credit Form.

Online attendees: NCPD credit information will be emailed to each participant within 3 business days.

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