Oncology Investor Event ESMO 2021

September 2021

REGENERON®

This non-promotional presentation is intended for the investor audience and contains investigational data

Note Regarding Forward-Looking Statements

This presentation includes forward-looking statements that involve risks and uncertainties relating to future events and the future performance of Regeneron Pharmaceuticals, Inc. ("Regeneron" or the "Company"), and actual events or results may differ materially from these forward-looking statements. Words such as "anticipate," "expect," "intend," "plan," "believe," "seek," "estimate," variations of such words, and similar expressions are intended to identify such forward-looking statements, although not all forward-looking statements contain these identifying words. These statements concern, and these risks and uncertainties include, among others, the impact of SARS-CoV-2 (the virus that has caused the COVID-19 pandemic) on Regeneron's business and its employees, collaborators, and suppliers and other third parties on which Regeneron relies, Regeneron's and its collaborators' ability to continue to conduct research and clinical programs, Regeneron's ability to manage its supply chain, net product sales of products marketed or otherwise commercialized by Regeneron and/or its collaborators (collectively, "Regeneron's Products"), and the global economy; the nature, timing, and possible success and therapeutic applications of Regeneron's Products and product candidates being developed by Regeneron and/or its collaborators (collectively, "Regeneron's Product Candidates") and research and clinical programs now underway or planned, including without limitation Libtayo® (cemiplimab) as monotherapy or in combination with chemotherapy or other of Regeneron's Product Candidates discussed in this presentation, including fianlimab (REGN3767) and REGN7075, Regeneron's and its collaborators' other oncology programs (including odronextamab (REGN1979), REGN5458, REGN5093, and REGN5093-M114), Regeneron's and its collaborators' other hematology programs, Regeneron's and its collaborators' earlier-stage programs, and the use of human genetics in Regeneron's research programs; safety issues resulting from the administration of Regeneron's Products and Regeneron's Product Candidates in patients, including serious complications or side effects in connection with the use of Regeneron's Products and Regeneron's Product Candidates in clinical trials; the likelihood, timing, and scope of possible regulatory approval and commercial launch of Regeneron's Product Candidates and new indications for Regeneron's Products, including without limitation those listed above; the possible success of Regeneron's oncology strategy and the likelihood and timing of achieving any of the anticipated milestones described in this presentation; the extent to which the results from the research and development programs conducted by Regeneron and/or its collaborators may be replicated in other studies and/or lead to advancement of product candidates to clinical trials, therapeutic applications, or regulatory approval; ongoing regulatory obligations and oversight impacting Regeneron's Products (such as Libtayo), research and clinical programs, and business, including those relating to patient privacy; determinations by regulatory and administrative governmental authorities which may delay or restrict Regeneron's ability to continue to develop or commercialize Regeneron's Products and Regeneron's Product Candidates; competing drugs and product candidates that may be superior to, or more cost effective than, Regeneron's Products and Regeneron's Product Candidates; uncertainty of the utilization, market acceptance, and commercial success of Regeneron's Products and Regeneron's Product Candidates and the impact of studies (whether conducted by Regeneron or others and whether mandated or voluntary) on the commercial success of Regeneron's Products and Regeneron's Product Candidates; the availability and extent of reimbursement of Regeneron's Products from third-party payors, including private payor healthcare and insurance programs, health maintenance organizations, pharmacy benefit management companies, and government programs such as Medicare and Medicaid; coverage and reimbursement determinations by such payors and new policies and procedures adopted by such payors; the ability of Regeneron to manufacture and manage supply chains for multiple products and product candidates; the ability of Regeneron's collaborators, suppliers, or other third parties (as applicable) to perform manufacturing, filling, finishing, packaging, labeling, distribution, and other steps related to Regeneron's Products and Regeneron's Product Candidates; unanticipated expenses; the costs of developing, producing, and selling products; the ability of Regeneron to meet any of its financial projections or guidance and changes to the assumptions underlying those projections or guidance; risks associated with intellectual property of other parties and pending or future litigation relating thereto, other litigation and other proceedings and government investigations relating to the Company and/or its operations, the ultimate outcome of any such proceedings and investigations, and the impact any of the foregoing may have on Regeneron's business, prospects, operating results, and financial condition; and the potential for any license or collaboration agreement, including Regeneron's agreements with Sanofi, Bayer, and Teva Pharmaceutical Industries Ltd. (or their respective affiliated companies, as applicable), to be cancelled or terminated. A more complete description of these and other material risks can be found in Regeneron's filings with the U.S. Securities and Exchange Commission, including its Form 10-K for the fiscal year ended December 31, 2020 and Form 10-Q for the quarterly period ended June 30, 2021, in each case in the section thereof captioned "Item 1A. Risk Factors." Any forward-looking statements are made based on management's current beliefs and judgment, and the reader is cautioned not to rely on any forward-looking statements made by Regeneron. Regeneron does not undertake any obligation to update (publicly or otherwise) any forward-looking statement, including without limitation any financial projection or guidance, whether as a result of new information, future events, or otherwise.

George D. Yancopoulos, MD, PhD
Co-Founder, President & Chief Scientific Officer

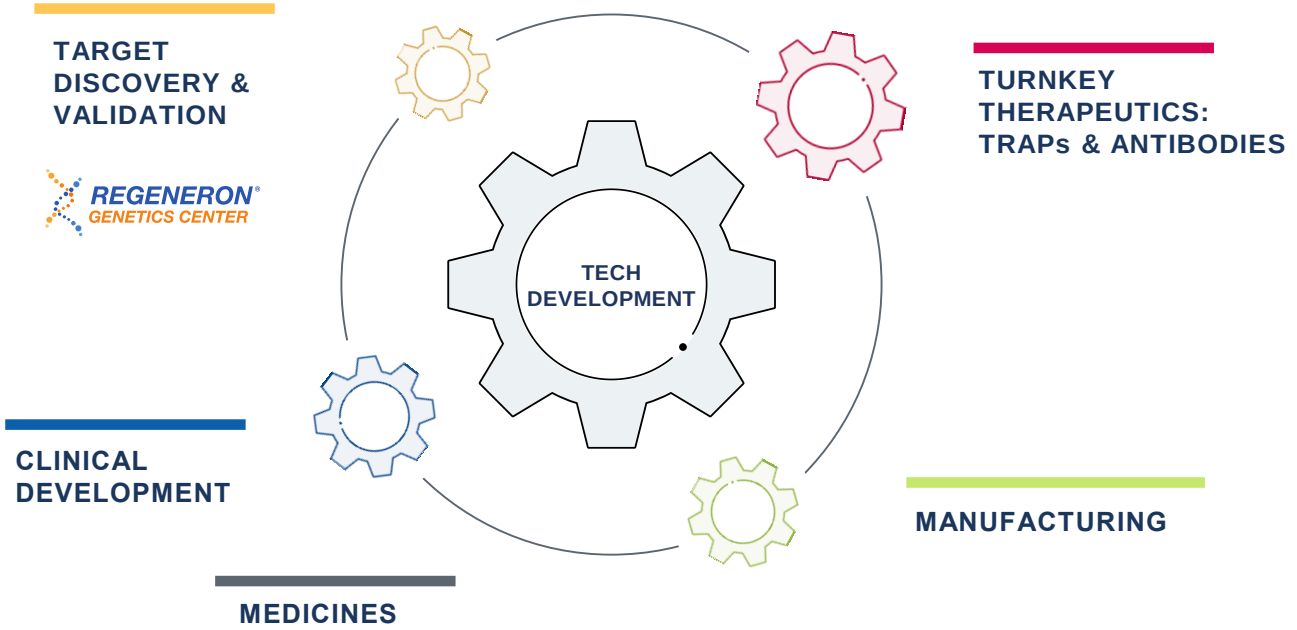
Israel Lowy, MD, PhD
SVP, Translational Sciences and Oncology

Agenda

- **Oncology Strategy Overview**
- **Focus on Lung Cancer**
- **EMPOWER-Lung 3 Data Review**
- **Q&A**

Regeneron technologies power our pipeline

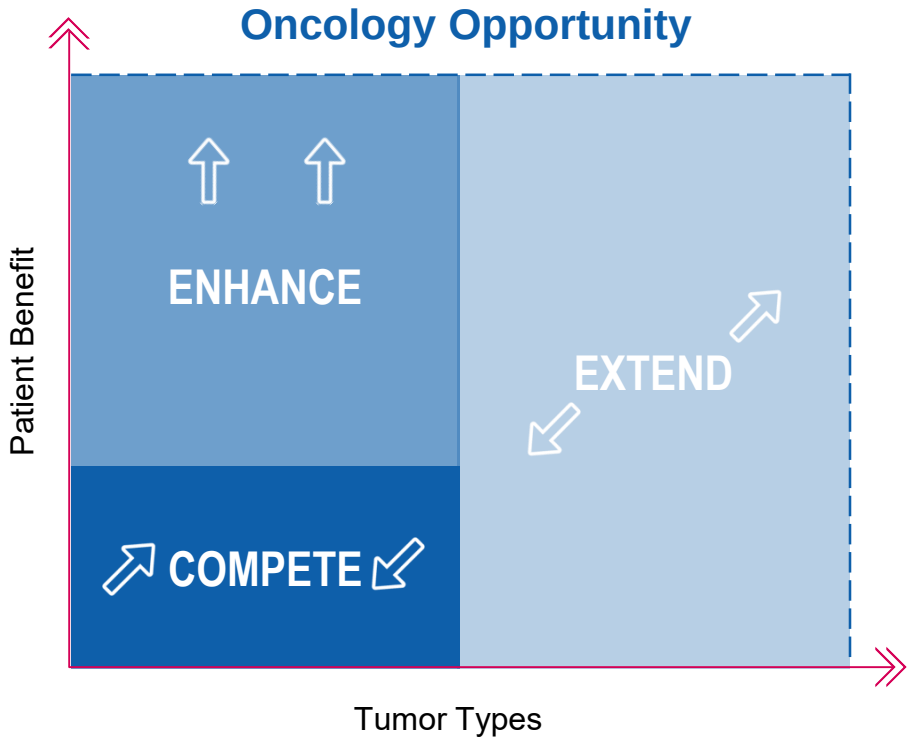
- VELOCIGENE®
- VELOCIMOUSE®
- VELOCIMMUNE®
- VELOCIMAB®
- VelociT™
- VELOCIHUM®
- VELOCI-BI®



Regeneron technologies deliver repeated breakthroughs by addressing limitations and bottlenecks in every step of the drug discovery

Oncology Strategy Overview

Oncology strategy: aspire to compete, enhance & extend



COMPETE

Libtayo® delivers potentially 'best-in-class' data in tumors responsive to PD-1 monotherapy

ENHANCE

Even for PD-1 responsive tumors, more than half of patients do not respond

EXTEND

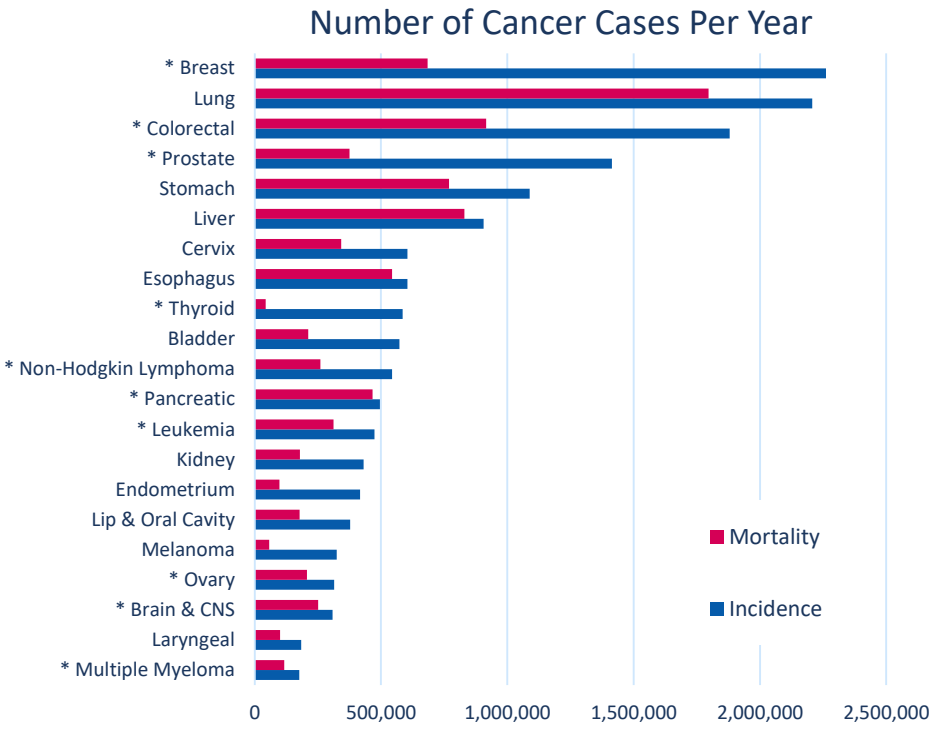
Many tumor settings have limited responses to checkpoint inhibition

Significant opportunity to enhance & extend treatment benefits

Despite the advancements in the field, there are many cancers that don't respond to anti PD-1 monotherapy

Even for those cancers that are responsive, many patients unfortunately do not benefit

Regeneron's clinical development pipeline of 12+ candidates has potential to address unmet need of the most prevalent cancer types



Source: The Global Cancer Observatory November 2020
* Cancers where anti-PD-1 treatments have limited or no approval

REGENERON

Regeneron's oncology toolkit provides unique combinatorial flexibility

VelocImmune® Antibodies

PD-1 (Libtayo)

LAG3

GITR

CTLA-4

Bispecifics

CD3 Bispecifics

CD20

BCMA

MUC16

Costimulatory Bispecifics

PSMA

EGFR

MUC16

New Classes of Bispecifics

METxMET

PiGs

VelociNator™

Collaborations

Adicet

BioNTech

Vyriad

Replimmune

Others

Libtayo is jointly developed with Sanofi.

Broad pipeline continues to advance

	LIBTAYO*			Advanced Lung cancer (chemo combo); Adjuvant CSCC
ONGOING	REGN3767 (LAG-3)	+	LIBTAYO*	Advanced melanoma
	REGN6569 (GITR)	+	LIBTAYO*	Solid tumors
	REGN4018 (MUC16xCD3)	+	LIBTAYO*	2+ line Ovarian cancer
	REGN5668 (MUC16xCD28)	+	REGN4018 / LIBTAYO*	2+ line Ovarian cancer
	REGN5678 (PSMAxCD28)	+	LIBTAYO*	3+ line Prostate cancer
	REGN7075 (EGFRxCD28)	+	LIBTAYO*	Solid tumors
	REGN5093 (METxMET)			Advanced MET altered Lung cancer
	Odronextamab (CD20xCD3)			3+ line Lymphoma
	Odronextamab (CD20xCD3)	+	LIBTAYO*	3+ line Lymphoma
	REGN5458/9 (BCMAxCD3)			3+ line Multiple myeloma
	PSMAxCD3	+	REGN5678/LIBTAYO*	Prostate cancer
UPCOMING	REGN5093-M114 (METxMET ADC)			Advanced MET altered Lung cancer
	odronextamab (CD20xCD3)	+	B cell/CD28 costim	B-NHL
	odronextamab (CD20xCD3)	+	Standard of Care	B-NHL
	REGN5458/9 (BCMAxCD3)	+	Plasma cell/CD28 costim	Multiple myeloma
	REGN5458/9 (BCMAxCD3)	+	Standard of Care	Multiple myeloma

VelocImmune® Antibodies | Anti-PD-1 | CD3 BiSpecifics | Costim BiSpecifics | New BiSpecifics

* In collaboration with Sanofi

This slide contains investigational products not yet approved by regulatory authorities.

Libtayo: foundational therapy to our oncology strategy

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Dermato-oncology

Advanced CSCC
- **First approved** anti-PD-1; adjuvant studies enrolling

Advanced BCC
- **First-in-class** anti-PD-1 now **FDA and EMA approved**

Advanced Melanoma (in combination with fianlimab)
- **Positive clinical data** in advanced melanoma; Phase 3 to begin in 2022

Cervical Cancer

2L Advanced Cervical
- **1st immunotherapy** to demonstrate improvement in **overall survival**
- **Regulatory submissions** expected in **2H21**

Non-Small Cell Lung Cancer

1L Advanced NSCLC
- **Approved as monotherapy** in 1L ≥50% PD-L1 **NSCLC** by **FDA and EMA**
- **Overall survival** benefit demonstrated in combination with **chemotherapy**

Libtayo is a foundational piece to Regeneron's oncology strategy with expanding and maturing clinical data across many cancer settings

CSCC – Cutaneous Squamous Cell Carcinoma; BCC – Basal Cell Carcinoma; NSCLC – Non-Small Cell Lung Cancer

Libtayo is jointly developed with Sanofi.

This slide contains investigational products not yet approved by regulatory authorities.

REGENERON

Focus on Lung Cancer

Foundational data establishing Libtayo as a potential leading option in lung cancer

✓ **EMPOWER Lung-1**

LIBTAYO MONOTHERAPY in 1L NSCLC

Approved by FDA and EMA

✓ **EMPOWER Lung-3**

LIBTAYO CHEMO COMBINATION (*ESMO 2021*)

Innovative trial design combining both squamous and non-squamous histologies

OS benefit demonstrated along with positive PFS, ORR results

Regulatory submissions in preparation

Libtayo is one of only two PD-1/PD-L1s antibodies with positive Phase 3 studies both as monotherapy and in combination with chemotherapy in 1L NSCLC of any histology

Libtayo is not approved for combination therapy and no regulatory authority has evaluated it for this indication.

REGENERON

EMPOWER-Lung 1: Libtayo monotherapy demonstrated a significant and clinically meaningful survival benefit over chemotherapy in 1L NSCLC

Improved Overall Survival vs. Chemo

Study Design – High Crossover

- 74% patients who progressed on platinum-based chemotherapy crossed over to Libtayo

Benefit in Underrepresented Patients

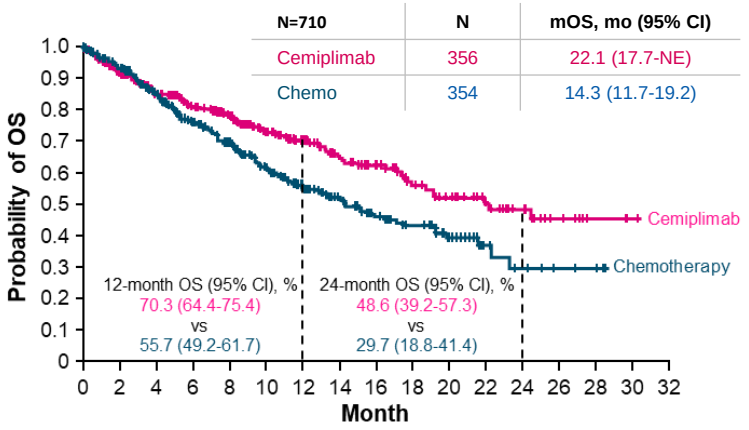
- 12% had pretreated and stable brain metastases
- 16% had locally advanced disease

Favorable Safety Profile

- Libtayo was discontinued due to adverse reactions in 6% of patients

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Overall Population

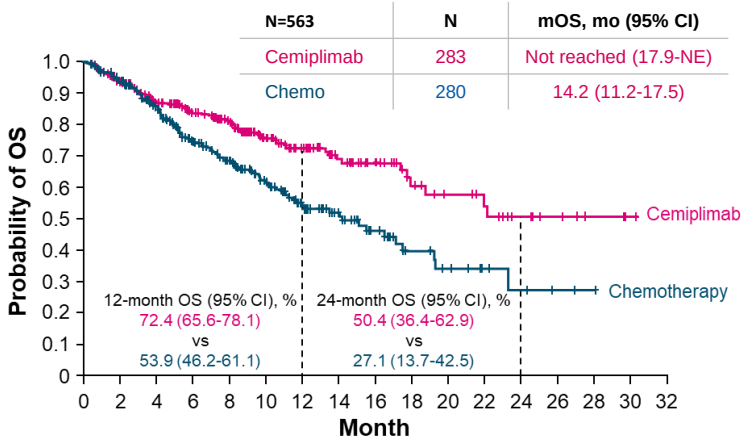


Overall Population

32% Reduction in risk of Death

HR =0.68; p=0.0022

Confirmed PD-L1 ≥50%



Confirmed PD-L1 ≥50%

43% Reduction in risk of Death

HR =0.57; p=0.0002

REGENERON

Libtayo is jointly developed with Sanofi.

EMPOWER-Lung 3 Data Review

2021 ESMO congress

EMPOWER

EMPOWER-Lung 3: Cemiplimab in Combination With Platinum-Doublet Chemotherapy (Chemo) for First-Line (1L) Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC)

Miranda Gogishvili,[1] Tamar Melkadze,[2] Tamta Makharadze,[3] David Giorgadze,[4] Mikhail Dvorkin,[5] Konstantin Penkov,[6] Konstantin Laktionov,[7] Gia Nemsadze,[8] Marina Nechaeva,[9] Irina Rozhkova,[10] Ewa Kalinka,[11] Christian Gessner,[12] Brizio Moreno-Jaime,[13] Rodolfo Passalacqua,[14] Siyu Li,[15] Kristina McGuire,[15] Ruben G. W. Quek,[15] Bo Gao,[15] Frank Seebach,[15] David M. Weinreich,[15] George D. Yancopoulos,[15] Israel Lowy,[15] Giuseppe Gullo,[15] Petra Rietschel[15]

[1]High Technology Medical Centre, University Clinic Ltd, Tbilisi, Georgia; [2]Georgia Medical Institute, Jonesboro, Georgia, USA; [3]LTD High Technology Hospital Med Center, Batumi, Georgia; [4]David Tvildiani Medical University, Tbilisi, Georgia; [5]State Budgetary Healthcare Institution of Omsk Region, Omsk, Russia; [6]Private Medical Institution Euromedservice, St Petersburg, Russia; [7]Federal State Budgetary Institution "N.N. Blokhin National Medical Research Center of Oncology" of the Ministry of Health of the Russian Federation (N.N. Blokhin NMRCO), Moscow, Russia; [8]The Institute of Clinical Oncology, Tbilisi, Georgia; [9]Chelyabinsk Regional Clinical Oncology Center, Chelyabinsk, Chelyabinsk Oblast, Russia; [10]State Budgetary Healthcare Institution of Kaluga Region, Kaluga, Russia; [11]Polish Mother's Memorial Hospital Research Institute, Łódź, Poland; [12]POIS Leipzig GbR Steffi Geßner, Leipzig, Germany; [13] Hospital Regional ISSSTE, León, Mexico; [14]Istituti Ospitalieri Di Cremona, Cremona, Italy; [15]Regeneron Pharmaceuticals, Inc, Tarrytown, New York

EMPOWER-Lung 3 (Part 2) Study Design (NCT03409614)

Background: Cemiplimab (a high-affinity, fully human anti–PD-1) is approved as first-line monotherapy for advanced NSCLC with PD-L1 ≥50% (EMPOWER-Lung 1 Study[1])

Key eligibility criteria
- Treatment-naive advanced NSCLC (non-squamous and squamous histology; Stage IIIb/c†, IV)
- Any PD-L1 expression
- No *EGFR*, *ALK*, or *ROS1* mutations
- ECOG PS 0 or 1
- Treated, clinically stable CNS metastases ‡

Stratification factors
- PD-L1 expression: <1% vs 1–49% vs ≥50%
- Histology: non-squamous vs squamous

Endpoints
- Primary: OS
- Key secondary: PFS and ORR
- Additional secondary: DOR, BOR, safety, and PRO

R 2:1

Arm A
Cemiplimab 350 mg Q3W + investigator's choice platinum-doublet chemo Q3W for 4 cycles§

PD or 108 weeks

Arm B
Placebo Q3W + investigator's choice platinum-doublet chemo Q3W for 4 cycles§

PD or 108 weeks

Follow-up

N=466

Two interim analyses were prespecified per protocol
Second interim analysis (14 June 2021) presented here

†Patient not a candidate for definitive chemoradiation. ‡Patient must have neurologically returned to baseline (except for residual signs or symptoms related to the CNS treatment). §For patients with non-squamous NSCLC, pemetrexed is mandatory as maintenance therapy for those patients initially assigned to receive a pemetrexed-containing regimen. *ALK*, anaplastic lymphoma kinase gene; BOR, best overall response; chemo, chemotherapy; CNS, central nervous system; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; *EGFR*, epidermal growth factor receptor gene; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PRO, patient-reported outcomes; Q3W, every 3 weeks; R, randomised; *ROS1*, c-ros oncogene 1.

1. Sezer A et al. *Lancet* 2021;397:592–604.

Disposition and Baseline Characteristics

n	Cemiplimab + chemo (n=312)	Placebo + chemo (n=154)
Number of patients treated	312	153
Ongoing treatment	108	15
Discontinued treatment†	204	138
PD	137	100
Death‡	24	10
AE	14	4
Patient decision	13	7
Withdrew consent	8	3
Physician decision	4	1
Lost to follow-up	1	3

n (%), unless otherwise stated		Cemiplimab + chemo (n=312)	Placebo + chemo (n=154)	Total (n=466)
Age	Median (range), years	63.0 (25–82)	63.0 (34–84)	63.0 (25–84)
	≥65 year	128 (41.0)	60 (39.0)	188 (40.3)
Male		268 (85.9)	123 (79.9)	391 (83.9)
Histology	Non-squamous	179 (57.4)	87 (56.5)	266 (57.1)
	Squamous	133 (42.6)	67 (43.5)	200 (42.9)
PD-L1 expression	<1%	95 (30.4)	44 (28.6)	139 (29.8)
	1–49%	114 (36.5)	61 (39.6)	175 (37.6)
	≥50%	103 (33.0)	49 (31.8)	152 (32.6)
ECOG PS	0	51 (16.3)	18 (11.7)	69 (14.8)
	1	259 (83.0)	134 (87.0)	393 (84.3)
Brain metastases		24 (7.7)	7 (4.5)	31 (6.7)
Cancer stage at screening	Metastatic	267 (85.6)	130 (84.4)	397 (85.2)
	Locally advanced	45 (14.4)	24 (15.6)	69 (14.8)
Smoking history	Current smoker	173 (55.4)	75 (48.7)	248 (53.2)
	Past smoker	96 (30.8)	55 (35.7)	151 (32.4)
	Never smoked	43 (13.8)	24 (15.6)	67 (14.4)

†Median duration of exposure (range) was 38.45 (1.4–102.6) weeks for cemiplimab + chemo and 21.30 (0.6–95.0) weeks for placebo + chemo. ‡Only includes deaths that led to discontinuation of treatment; does not reflect overall death count.
AE, adverse event; chemo, chemotherapy; ECOG PS, Eastern Cooperative Oncology Group performance status; PD, progressive disease; PD-L1, programmed cell death-ligand 1.

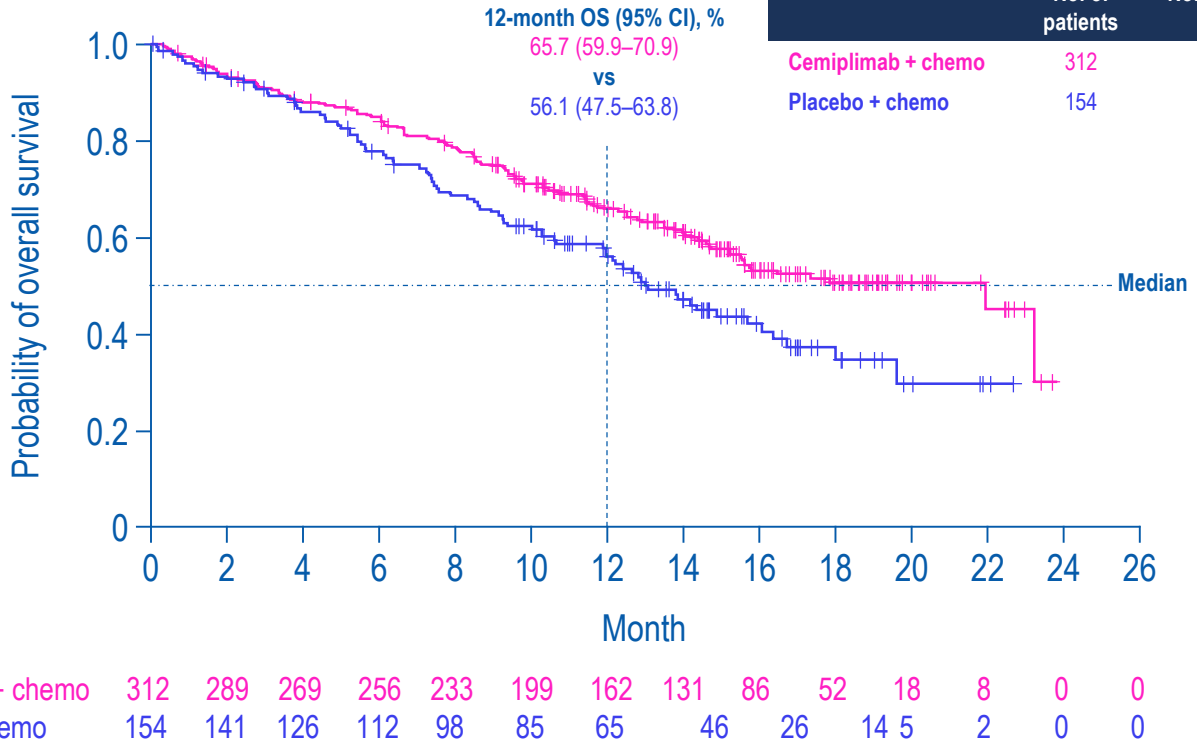
Data cut-off date: 14 June 2021

Overall Survival

Median duration of follow-up (range): 16.4 (8.5–24.0) months

	No. of patients	No. of events, n (%)	OS, median (95% CI), months
Cemiplimab + chemo	312	132 (42.3)	21.9 (15.5–NE)
Placebo + chemo	154	82 (53.2)	13.0 (11.9–16.1)

HR (95% CI) = 0.71 (0.53–0.93); *P*=0.014



Chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; OS, overall survival.

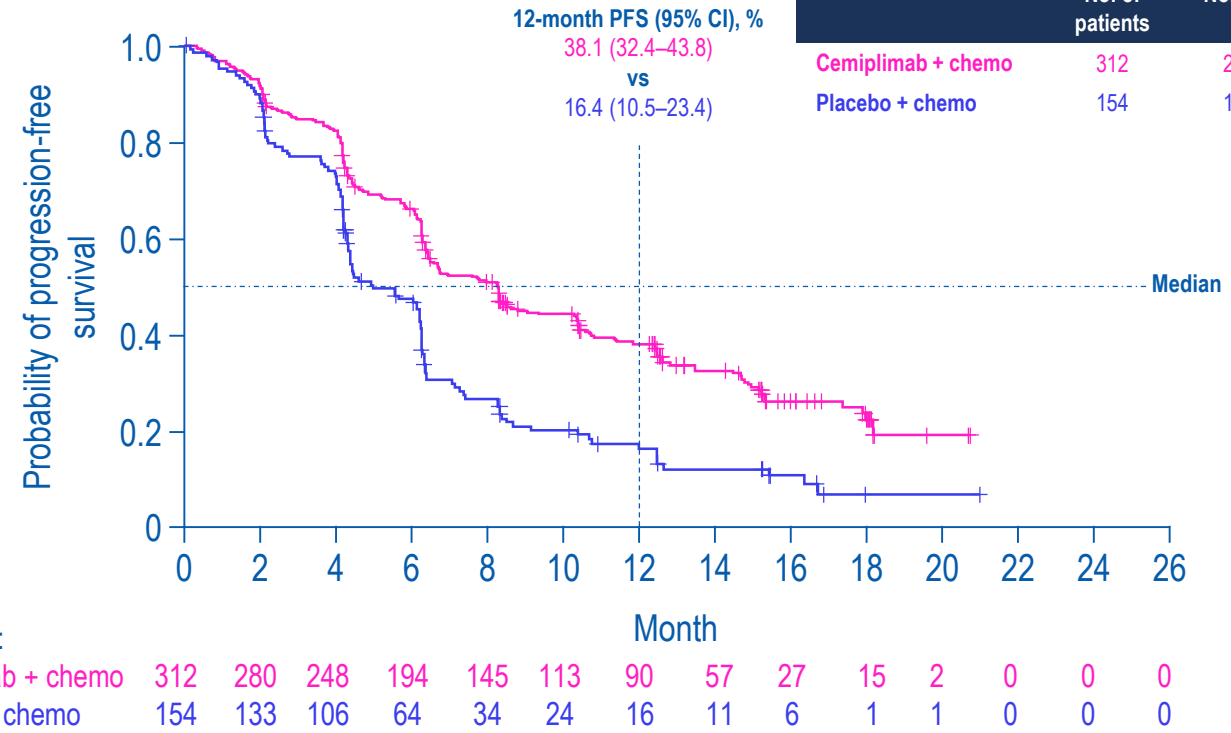
Data cut-off date: 14 June 2021

Progression-Free Survival

Median duration of follow-up (range): 16.4 (8.5–24.0) months

	No. of patients	No. of events, n (%)	PFS, median (95% CI), months
Cemiplimab + chemo	312	204 (65.4)	8.2 (6.4–9.3)
Placebo + chemo	154	122 (79.2)	5.0 (4.3–6.2)

HR (95% CI) = 0.56 (0.44–0.70); *P*<0.0001



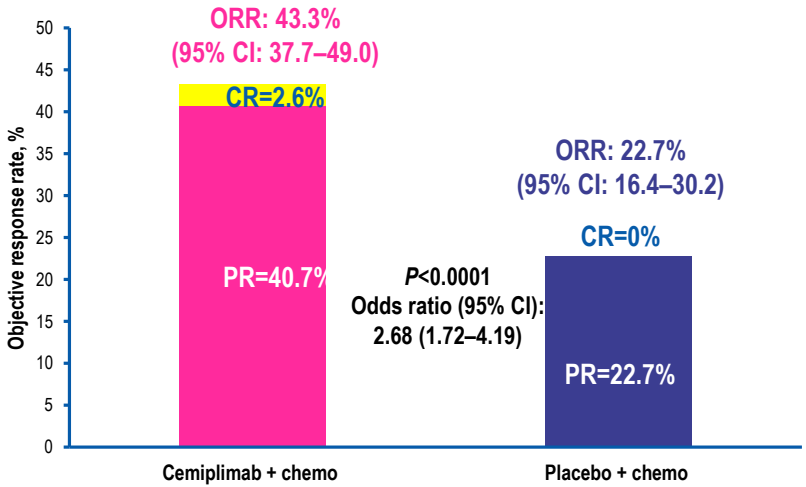
Chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; PFS, progression-free survival.

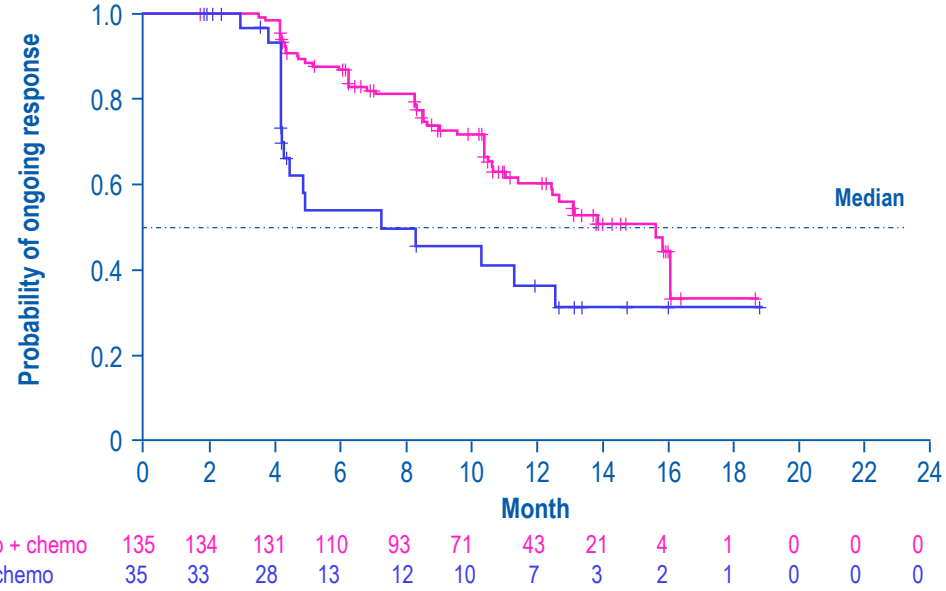
Data cut-off date: 14 June 2021

Tumour Response and DOR

Among patients with objective response

	No. of patients	No. of events, n (%)	DOR, median (95% CI), months
Cemiplimab + chemo	135	53 (39.3)	15.6 (12.4–NE)
Placebo + chemo	35	18 (51.4)	7.3 (4.3–12.6)

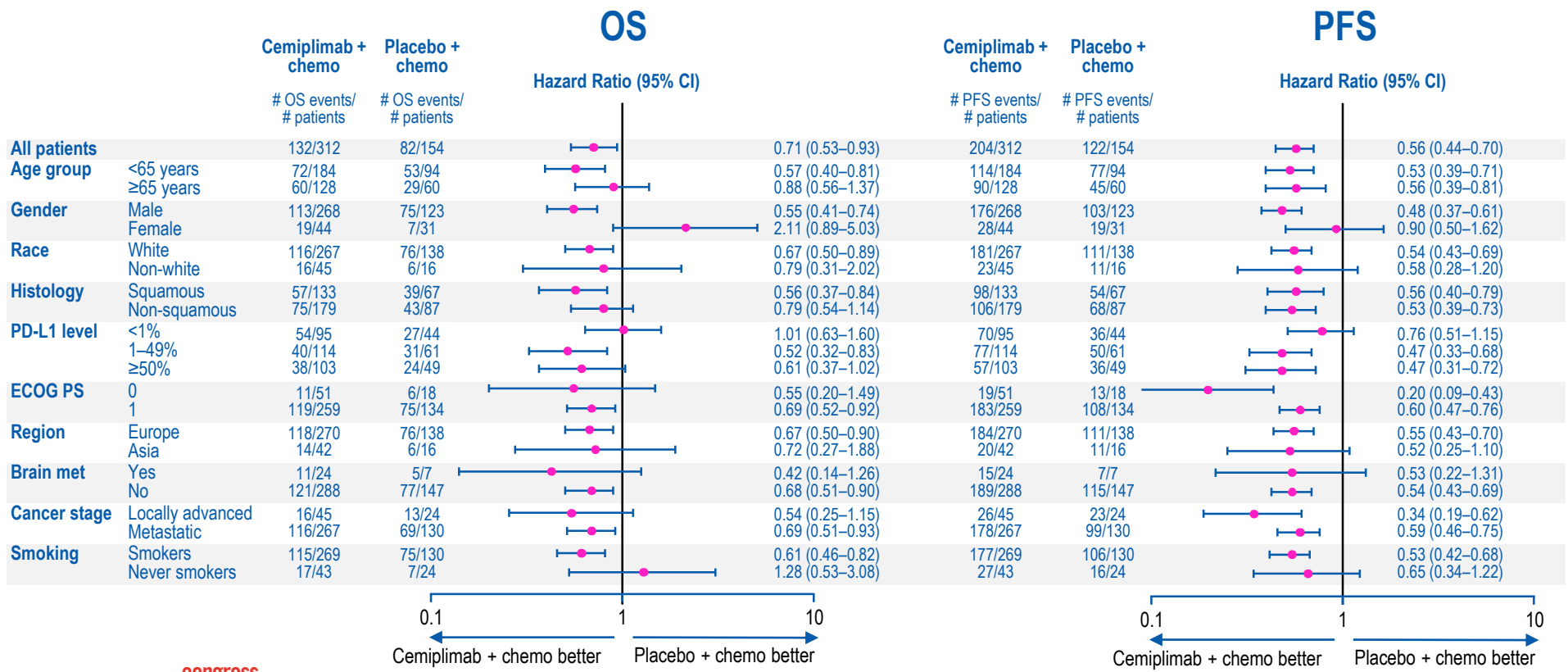




Chemo, chemotherapy; CI, confidence interval; CR, complete response; DOR, duration of response; NE, not evaluable; No., number; ORR, objective response rate; PR, partial response.

Data cut-off date: 14 June 2021

OS and PFS by Subgroup



		Cemiplimab + chemo # OS events/ # patients	Placebo + chemo # OS events/ # patients	OS Hazard Ratio (95% CI)	Cemiplimab + chemo # PFS events/ # patients	Placebo + chemo # PFS events/ # patients	PFS Hazard Ratio (95% CI)
All patients		132/312	82/154	0.71 (0.53–0.93)	204/312	122/154	0.56 (0.44–0.70)
Age group	<65 years	72/184	53/94	0.57 (0.40–0.81)	114/184	77/94	0.53 (0.39–0.71)
	≥65 years	60/128	29/60	0.88 (0.56–1.37)	90/128	45/60	0.56 (0.39–0.81)
Gender	Male	113/268	75/123	0.55 (0.41–0.74)	176/268	103/123	0.48 (0.37–0.61)
	Female	19/44	7/31	2.11 (0.89–5.03)	28/44	19/31	0.90 (0.50–1.62)
Race	White	116/267	76/138	0.67 (0.50–0.89)	181/267	111/138	0.54 (0.43–0.69)
	Non-white	16/45	6/16	0.79 (0.31–2.02)	23/45	11/16	0.58 (0.28–1.20)
Histology	Squamous	57/133	39/67	0.56 (0.37–0.84)	98/133	54/67	0.56 (0.40–0.79)
	Non-squamous	75/179	43/87	0.79 (0.54–1.14)	106/179	68/87	0.53 (0.39–0.73)
PD-L1 level	<1%	54/95	27/44	1.01 (0.63–1.60)	70/95	36/44	0.76 (0.51–1.15)
	1–49%	40/114	31/61	0.52 (0.32–0.83)	77/114	50/61	0.47 (0.33–0.68)
	≥50%	38/103	24/49	0.61 (0.37–1.02)	57/103	36/49	0.47 (0.31–0.72)
ECOG PS	0	11/51	6/18	0.55 (0.20–1.49)	19/51	13/18	0.20 (0.09–0.43)
	1	119/259	75/134	0.69 (0.52–0.92)	183/259	108/134	0.60 (0.47–0.76)
Region	Europe	118/270	76/138	0.67 (0.50–0.90)	184/270	111/138	0.55 (0.43–0.70)
	Asia	14/42	6/16	0.72 (0.27–1.88)	20/42	11/16	0.52 (0.25–1.10)
Brain met	Yes	11/24	5/7	0.42 (0.14–1.26)	15/24	7/7	0.53 (0.22–1.31)
	No	121/288	77/147	0.68 (0.51–0.90)	189/288	115/147	0.54 (0.43–0.69)
Cancer stage	Locally advanced	16/45	13/24	0.54 (0.25–1.15)	26/45	23/24	0.34 (0.19–0.62)
	Metastatic	116/267	69/130	0.69 (0.51–0.93)	178/267	99/130	0.59 (0.46–0.75)
Smoking	Smokers	115/269	75/130	0.61 (0.46–0.82)	177/269	106/130	0.53 (0.42–0.68)
	Never smokers	17/43	7/24	1.28 (0.53–3.08)	27/43	16/24	0.65 (0.34–1.22)

#, number of; chemo, chemotherapy; CI, confidence interval; ECOG PS, Eastern Cooperative Oncology Group performance status; met, metastasis; OS, overall survival; PD-L1, programmed cell death-ligand 1; PFS, progression-free survival.

Data cut-off date: 14 June 2021

Safety Summary

n (%), unless stated	Cemiplimab + chemo (n=312)		Placebo + chemo (n=153)	
Duration of exposure, median (range), weeks	**38.5 (1.4–102.6)**		**21.3 (0.6–95.0)**	
Treatment-emergent AEs, regardless of attribution	**Any grade**	**Grade 3–5**	**Any grade**	**Grade 3–5**
Overall	299 (96)	136 (44)	144 (94)	48 (31)
Led to discontinuation	16 (5)	13 (4)	4 (3)	4 (3)
Led to death	19 (6)	19 (6)	12 (8)	12 (8)
Treatment-related AEs				
Overall	275 (88)	90 (29)	129 (84)	28 (18)
Led to discontinuation	10 (3)	7 (2)	1 (1)	1 (1)
Led to death	4 (1)	4 (1)	1 (1)	1 (1)
Immune-related AEs†				
Overall	59 (19)	9 (3)	–	–
Led to discontinuation	3 (1)	3 (1)	–	–
Led to death	1 (0.3)	1 (0.3)	–	–

Treatment-emergent AEs in ≥10% of patients in either arm, n (%)	Cemiplimab + chemo (n=312)		Placebo + chemo (n=153)	
	Any grade	**Grade 3–5**	**Any grade**	**Grade 3–5**
Overall	299 (96)	136 (44)	144 (94)	48 (31)
Anaemia	136 (44)	31 (10)	61 (40)	10 (7)
Decreased appetite	53 (17)	3 (1)	18 (12)	0
Fatigue	38 (12)	7 (2)	11 (7)	1 (1)
Constipation	43 (14)	1 (0)	17 (11)	0
Nausea	78 (25)	0	25 (16)	0
Vomiting	38 (12)	0	15 (10)	0
Thrombocytopaenia	41 (13)	8 (3)	19 (12)	2 (1)
Neutropaenia	48 (15)	18 (6)	19 (12)	9 (6)
Alopecia	115 (37)	0	66 (43)	0
Hyperglycaemia	55 (18)	6 (2)	18 (12)	0
Alanine aminotransferase increased	51 (16)	7 (2)	22 (14)	3 (2)
Arthralgia	48 (15)	2 (1)	20 (13)	0
Aspartate aminotransferase increased	46 (15)	1 (0)	18 (12)	3 (2)
Dyspnoea	39 (13)	7 (2)	10 (7)	1 (1)
Asthenia	38 (12)	6 (2)	18 (12)	2 (1)
Decreased weight	35 (11)	4 (1)	13 (8)	0
Insomnia	34 (11)	0	11 (7)	0
Diarrhoea	33 (11)	4 (1)	10 (7)	0
Hypoalbuminaemia	32 (10)	2 (1)	9 (6)	0

PRO Summary

- **Delay** in the time to definitive clinically meaningful deterioration in GHS/QoL [HR, 0.78 (95% CI, 0.51–1.19); *P*=0.248] and pain symptoms [HR, 0.39 (95% CI, 0.26–0.60); *P*<0.0001].
- **Improvement** in overall change from baseline in GHS/QoL [0.61 (95% CI, -2.23, 3.45) *P*=0.673] and pain symptoms [-4.98 (95% CI, -8.36, -1.60); *P*=0.004].

†According to sponsor-identified list of terms.

AE, adverse event; chemo, chemotherapy; CI, confidence interval; GHS, global health status; HR, hazard ratio; PRO, patient-reported outcomes; QoL, quality of life.

Data cut-off date: 14 June 2021

Conclusions

- In patients with advanced NSCLC, 1L cemiplimab in combination with chemotherapy demonstrated clinically meaningful and statistically significant improvement in OS, PFS, ORR, and DOR versus chemotherapy alone.
  - OS (primary endpoint): median 21.9 vs 13.0 months; HR, 0.71 (95% CI, 0.53–0.93); *P*=0.014
  - PFS: median 8.2 vs 5.0 months; HR, 0.56 (95% CI, 0.44–0.70); *P*<0.0001
  - ORR: odds ratio, 2.68 (95% CI, 1.72–4.19); *P*<0.0001

- Cemiplimab in combination with chemotherapy demonstrated an acceptable benefit-risk profile, favourable PROs, low rates of AEs leading to discontinuation, and a safety profile generally consistent with those known for cemiplimab and for platinum-based chemotherapy.

- Cemiplimab in combination with platinum-doublet chemotherapy is a new 1L treatment option for patients with advanced NSCLC without targetable mutations irrespective of histology and PD-L1 levels.

1L, first-line; AE, adverse event; CI, confidence interval; DOR, duration of response; HR, hazard ratio; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-L1, programmed cell death-ligand 1; PFS, progression-free survival; PRO, patient-reported outcomes; vs, versus.

Only Libtayo and Keytruda have consistent positive Phase 3 results both as monotherapy and in combination with chemo in 1L NSCLC

Drug	Treatment	Study	Patient Segment	Study Outcome (1º OS Endpoint)
Libtayo	monotherapy	EMPOWER-Lung 1	≥50% PD-L1	Positive
	chemo combo	EMPOWER-Lung 3	Squamous Non-squamous	Positive
Keytruda	monotherapy	Keynote-024	≥50% PD-L1	Positive
	monotherapy	Keynote-042	≥1% PD-L1	Positive
	chemo combo	Keynote-407	Squamous	Positive
	chemo combo	Keynote-189	Non-squamous	Positive
Tecentriq	monotherapy	IMpower110	≥50% PD-L1	Positive
	chemo combo	IMpower130	Non-squamous	Positive
	chemo combo	IMpower131	Squamous	Negative
	chemo combo	IMpower132	Non-squamous	Negative
Opdivo	monotherapy	Checkmate 026	≥5% PD-L1	Negative
	chemo combo	Checkmate 227	Non-squamous	Negative
Imfinzi	monotherapy	MYSTIC	≥25% PD-L1	Negative
	chemo combo	POSEIDON	ITT	Negative

Libtayo is not approved for combination therapy and, for advanced NSCLC, is only approved for monotherapy in patients with ≥50% PD-L1

These published results are provided for context. There are no head-to-head trials comparing Libtayo and any of the products listed. Positive study: study primary endpoints met; negative study: primary endpoints did not reach statistical significance.

Both Libtayo and Keytruda are approved as monotherapy in first line NSCLC with PD-L1≥50%

1L NSCLC monotherapy	PD-L1≥50%			
	Libtayo overall population	**Libtayo** confirmed PD-L1≥50%	**Keytruda KN-042**	**Keytruda KN-024**
N	710	563	599	305
mOS (months)	22.1 vs. 14.3	NR vs. 14.2	20.0 vs. 12.2	30.0 vs. 14.2
OS HR	0.68	0.57	0.69	0.60
mPFS (months)	6.2 vs. 5.6	8.2 vs. 5.7	6.9 vs. 6.4	10.3 vs. 6.0
PFS HR	0.59	0.54	0.82	0.50
ORR	37% vs. 21%	39% vs. 20%	39% vs. 32%	45% vs. 28%

Keytruda is approved with chemo in both squamous and non-squamous 1L NSCLC

Recent Libtayo Phase 3 trial with chemo in 1L NSCLC: subgroup analyses* showing results in squamous and non-squamous histologies

1L NSCLC chemo combo	Squamous		Non-squamous	
	Libtayo*	**Keytruda**	**Libtayo***	**Keytruda**
N	200	559	266	616
mOS (months)	21.9 vs. 13.8	15.9 vs. 11.3	15.8 vs. 13.0	22.0 vs. 10.6†
OS HR	0.56 (0.37-0.84)	0.64 (0.49-0.85)	0.79 (0.54-1.14)	0.56† (0.46-0.69)
mPFS (months)	8.2 vs. 4.9	6.4 vs. 4.8	7.9 vs. 5.5	9.0 vs. 4.9†
PFS HR	0.56	0.56	0.53	0.49†
ORR	47% vs. 28%	58% vs. 35%	41% vs. 18%	48% vs. 20%†

Libtayo is not approved for combination therapy and, for advanced NSCLC, is only approved for monotherapy in patients with ≥50% PD-L1

*These published results are provided for context. There are no head-to-head trials comparing Libtayo with Keytruda. mOS, mPFS, and ORR data shown vs. in-study comparator arm; *subgroups not powered for individual histologies; †final analysis (ASCO 2020)*

REGENERON

Lung cancer pipeline

✓ **LIBTAYO MONOTHERAPY**

Approved by FDA and EMA

✓ **LIBTAYO CHEMO COMBINATION (*ESMO 2021*)**

OS benefit demonstrated; regulatory submissions underway

- **REGN7075 (EGFRxCD28)**

  Dose escalation in combination with **LIBTAYO** ongoing

- **REGN5093 (METxMET)**

  Dose escalation complete; dose expansion enrolling

- **REGN5093-M114 (METxMET ADC)**

  Entering clinic in 2H21

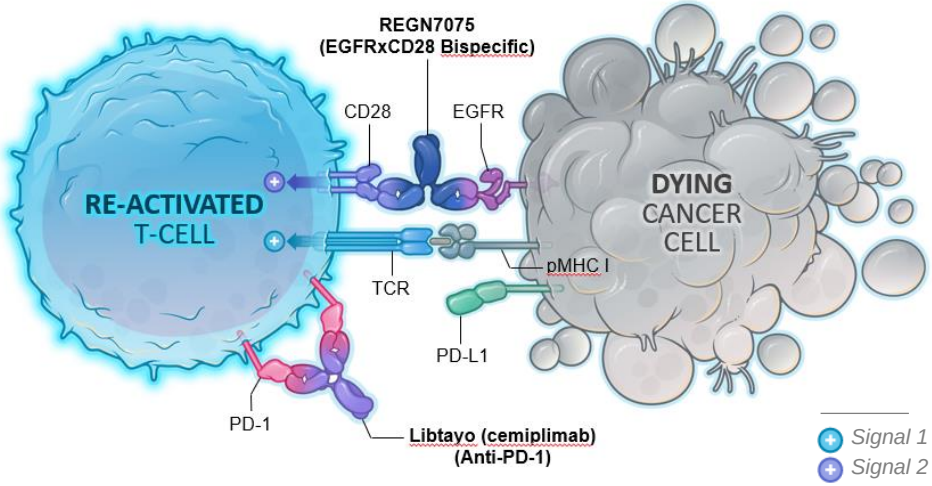
Robust combinatorial potential and flexibility to enhance and extend treatment across many different types of cancers, and NSCLC in particular

Combinations of our bispecific antibodies and checkpoint inhibitors offer advantage of simultaneously providing multiple signals for activating T cells to kill tumors

Extensive pipeline provides multiple shots on goal for NSCLC

Libtayo is not approved for combination therapy and no regulatory authority has evaluated it for this indication. This slide contains investigational products not yet approved by regulatory authorities.

EGFRxCD28: costimulatory bispecific evaluated for advanced cancers in combination with Libtayo



The epidermal growth factor receptor (EGFR) is widely expressed on tumors of epithelial origin, and abnormal activation of EGFR is a validated target for several tumor types (e.g. NSCLC, H&N, colorectal cancer).

CD3 & CD28 costimulatory bispecifics are potential off-the-shelf drugs that could turn patients' T cells into tumor cell killers

- **Turning on "Signal 2"**: CD28 coreceptor on the T cell is activated in the context of tumor cell expressing EGFR
- **Releasing the "brake"**: utilizing Libtayo to block PD-1 signaling can enhance the efficacy of costimulatory bispecifics
- EGFRxCD28 is not designed to inhibit the function of EGFR, but like most of our other bispecifics, use the tumor antigen to serve as an anchor to bridge to T cells that can be activated to kill the tumor

Phase 1/2 study is enrolling dose escalation cohorts

This slide contains investigational products not yet approved by regulatory authorities.

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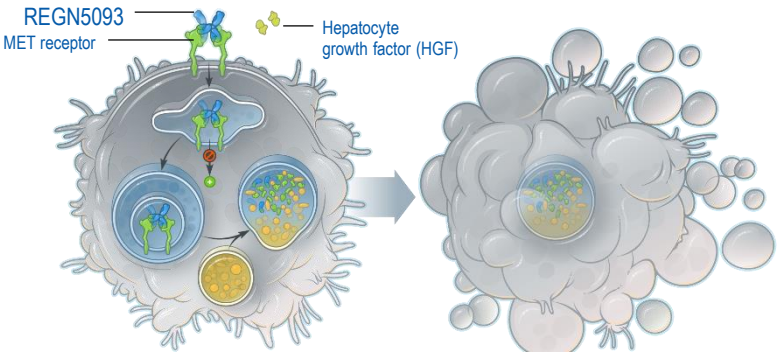
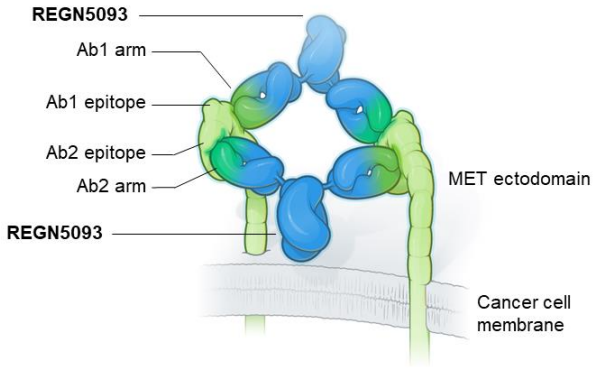
METxMET: novel mechanism directed at Non-Small Cell Lung Cancer

METxMET bispecific induces apoptosis of tumor cells



REGN5093 binds to MET receptors and prevents their interaction with HGF, a protein used by cancer cells to regulate cell growth; the REGN5093/MET complex then traffics to lysosomes for degradation

Unique Properties of REGN5093 Bispecific Antibody



REGN5093 targets two distinct epitopes on the MET receptor, enabling rapid internalization of the surface protein, rather than activation

Phase 1/2 in patients with MET-altered advanced NSCLC: dose escalation complete; dose expansion enrolling

DaSilva, John O., et al. "A Biparatopic Antibody That Modulates MET Trafficking Exhibits Enhanced Efficacy Compared with Parental Antibodies in MET-Driven Tumor Models." Clinical Cancer Research 26.6 (2020): 1408-1419 (link)

This slide contains investigational products not yet approved by regulatory authorities.

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REGN5093-M114: bispecific ADC to enhance activity in MET overexpressing cancers

Proprietary Antibody-Drug Conjugate (ADC) Platform

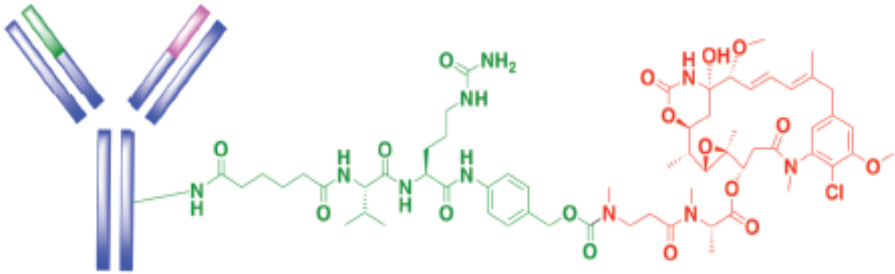
- Regeneron has developed a broad ADC platform with proprietary technologies and capabilities
- In preclinical models, our MET ADCs promote substantial and durable tumor regression with minimal off-target toxicities
- **We are exploring numerous conjugates across cancer and other settings**

REGN5093-M114 takes advantage of the unique trafficking properties of the METxMET bispecific and is a promising candidate for the treatment of MET-overexpressing tumors

MET Protein Overexpression
~25% of lung cancers

REGN5093 (METxMET)

Proprietary Linker-Payload



Using a protease-cleavable linker, METxMET bispecific was conjugated to a maytansinoid payload to generate the METxMET ADC (REGN5093-M114)

Phase 1/2 study in MET overexpressing advanced cancer to initiate in 2H21

This slide contains investigational products not yet approved by regulatory authorities.

REGENERON

Key upcoming oncology milestones (12-18 months)

Libtayo

- Regulatory submissions for 2L Cervical in 2H21
- Regulatory submissions for 1L NSCLC all PD-L1 levels (chemo combo)

Fianlimab (LAG-3)

- Ph3 in 1L Melanoma to initiate in 2022

Odronextamab (CD20xCD3)

- Complete enrollment in potentially pivotal Phase 2 in NHL
- Initiate studies with subcutaneous formulation
- Initiate OLYMPIA Phase 3 program and combinations

REGN5458 (BCMAxCD3)

- Complete enrollment in potentially pivotal Phase 2 in Multiple Myeloma
- Initiate studies with subcutaneous formulation
- Evaluate combinations with standard of care and novel agents

Solid Tumor bispecifics: Potential first data for MUC16xCD3 and PSMAxCD28

NSCLC – Non-Small Cell Lung Cancer
NHL – Non-Hodgkin's Lymphoma

This slide contains investigational products not yet approved by regulatory authorities.

Q&A

Israel Lowy, MD, PhD
SVP, Translational
Sciences and Oncology