



ESMO 2020

Investor Presentation
September 21, 2020

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Samit Hirawat

Executive VP
Chief Medical Officer
Global Drug Development

ESMO 2020: Broadening Opdivo-based options for patients with renal and gastroesophageal cancers

1L Renal

CM-214: Opdivo + Yervoy

- Dual I-O demonstrates durable survival in 1L renal
 - 53% patients alive after 4 years

CM-9ER: Opdivo + Cabometyx

- Provides a new potential treatment option for patients with 1L RCC

Gastroesophageal

CM-649: 1L Gastric

- Opportunity to be 1st I-O treatment option

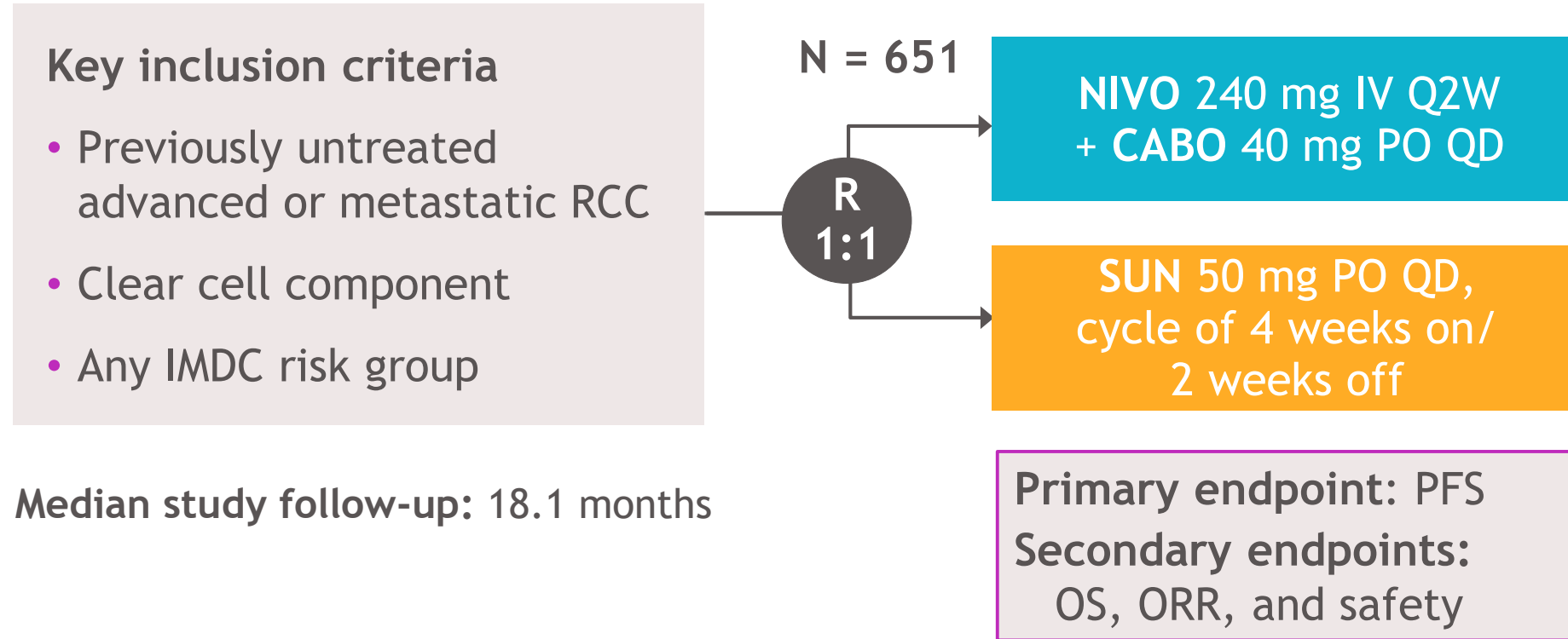
CM-577: Early Stage Esophageal

- Clear benefit demonstrated for patients with early stage esophageal cancer
 - 2nd tumor type where Opdivo has demonstrated a benefit in early stage disease

New Opportunity

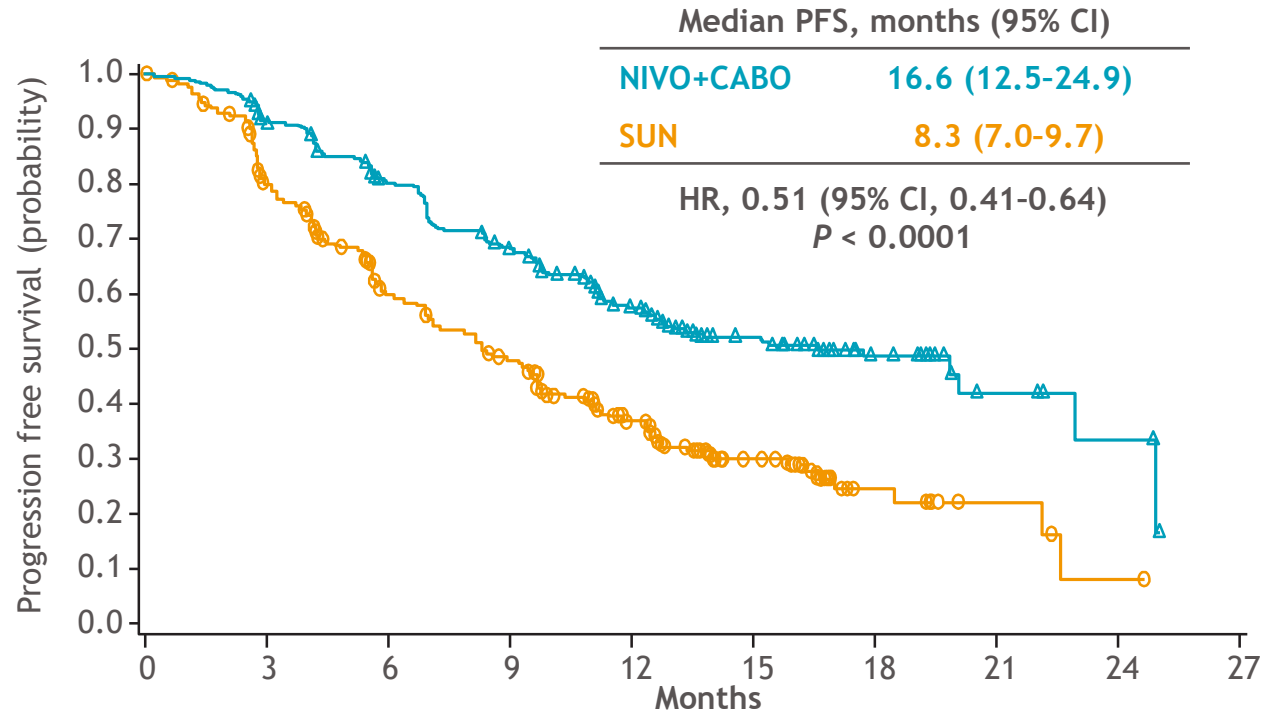


Checkmate-9ER: Opdivo + Cabometyx in 1L RCC

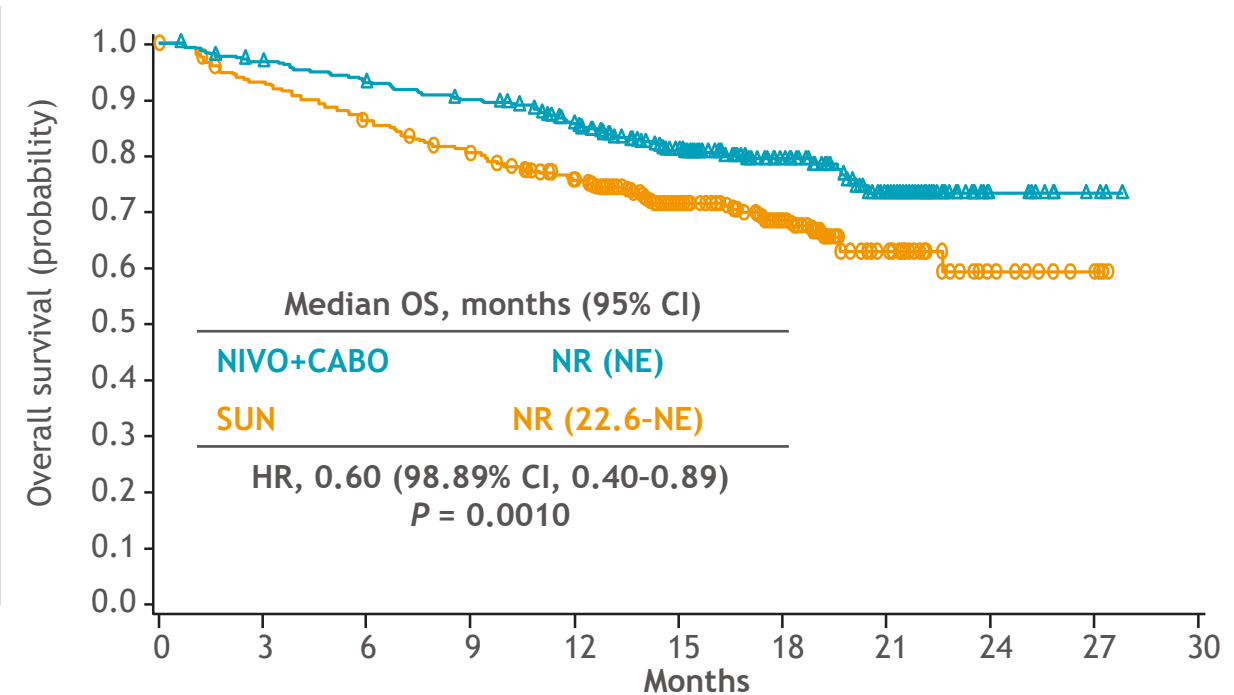


Strong efficacy for Opdivo + Cabometyx in 1L RCC

Progression Free Survival



Overall Survival



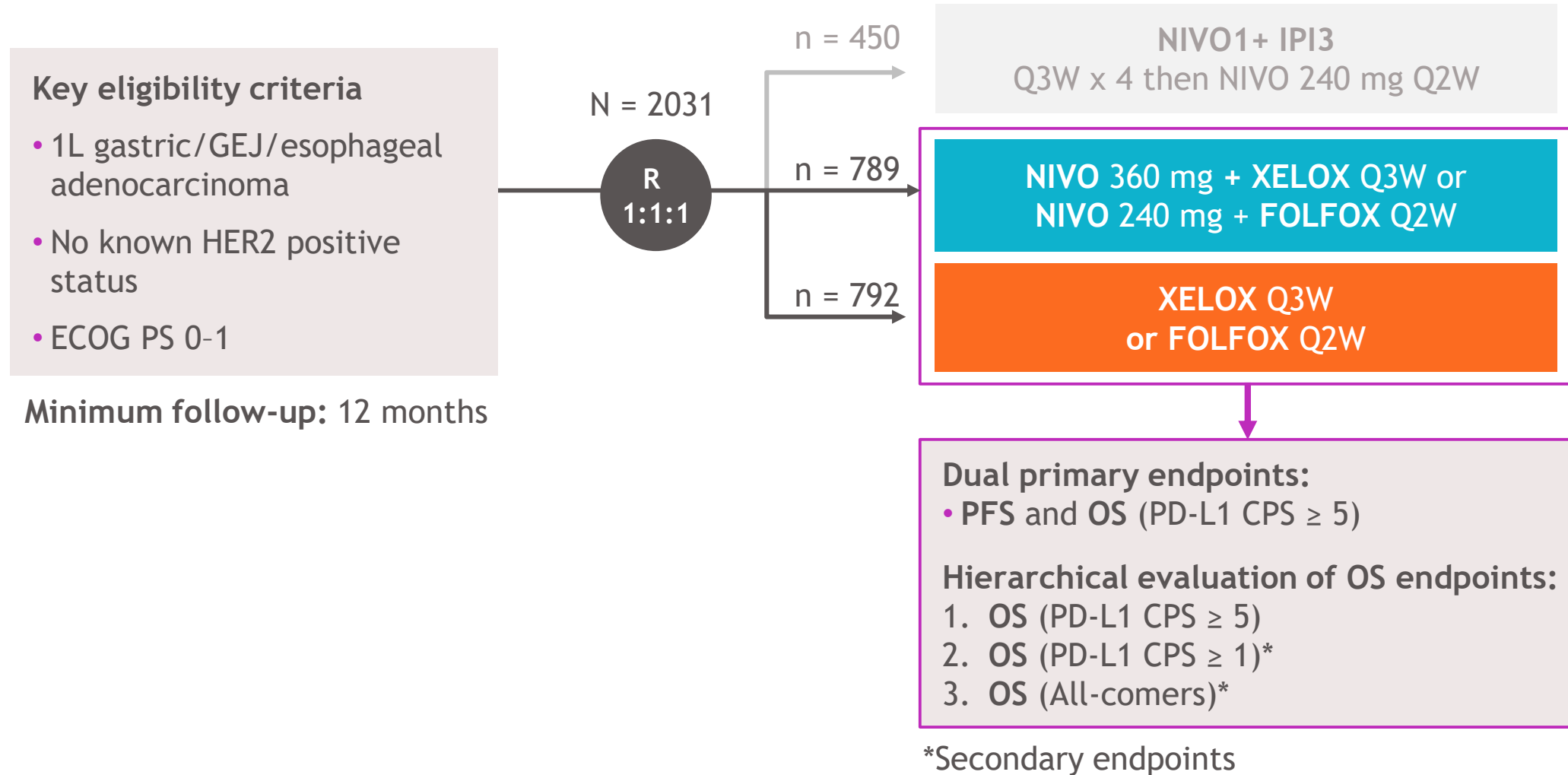
Consistent PFS and OS benefit observed across all patient subgroups, including risk status and PD-L1 expression

Opdivo + Cabometyx safety profile supports favorable net clinical benefit

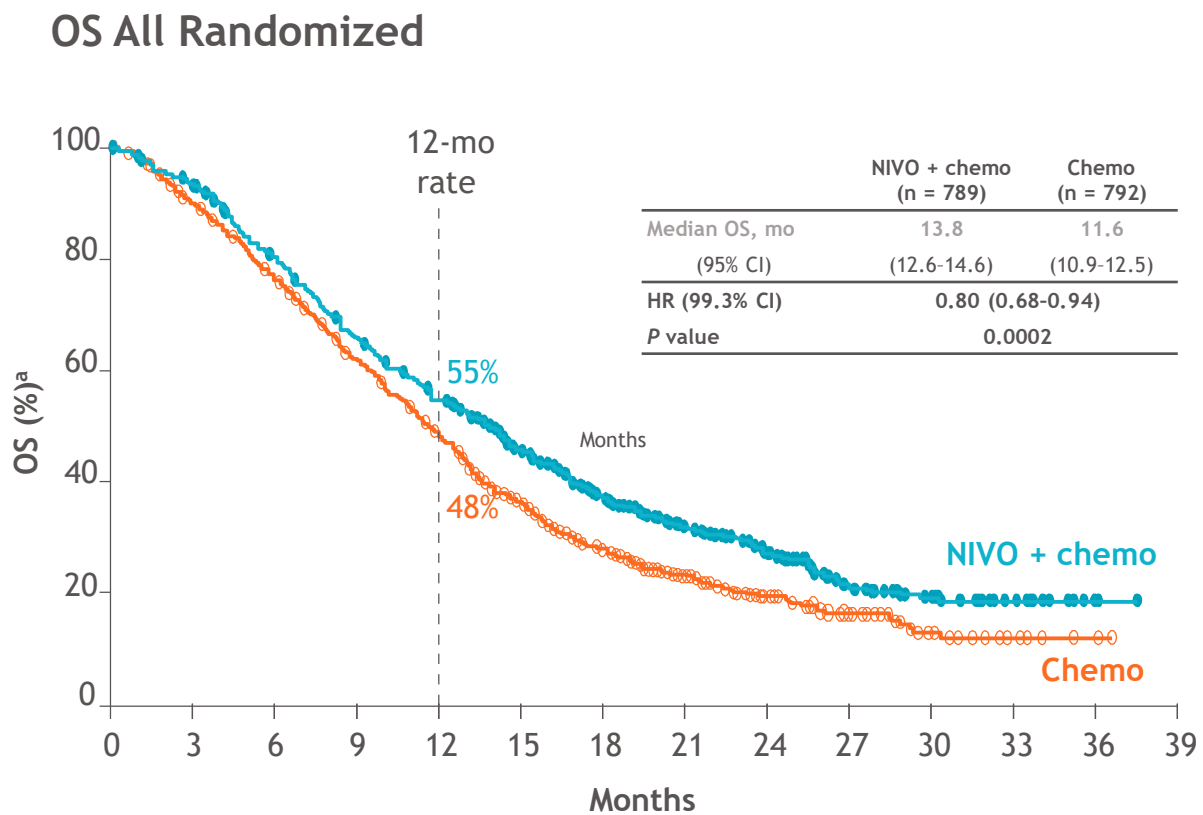
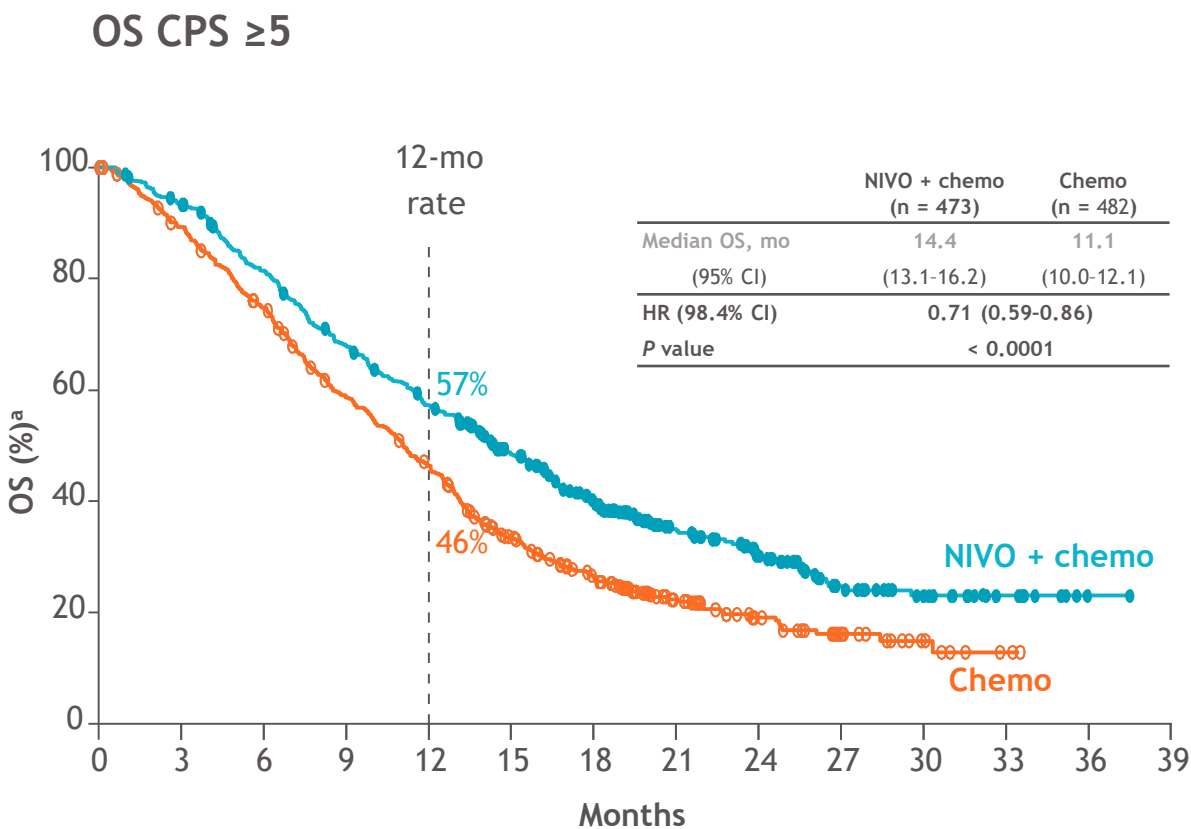
	NIVO+CABO (n = 320)	SUN (n = 320)
Median duration of therapy (range), months	14.3 (0.2-27.3)	9.2 (0.8-27.6)
Patients with at least 1 dose reduction (CABO or SUN), %	56.3	51.6
Treatment discontinuation, %	44.4	71.3
Treatment discontinuation due to disease progression, %	27.8	48.1
Any grade treatment-related AEs leading to discontinuation, %	15.3	8.8
NIVO only	5.6	-
CABO only	6.6	-
NIVO+CABO (both)	3.1	-

Nivo + Cabo was generally well tolerated
Low overall any grade TRAE discontinuation rate of 15.3%

Checkmate-649: Opdivo + Chemo in 1L Gastric/GEJ/EAC



Checkmate-649: OS benefit observed in the CPS ≥ 5 and the all randomized populations



Potential new standard of care in 1L Gastric Cancer

Checkmate-649: Safety profile

Patients, n (%)	NIVO + chemo N = 782			Chemo N = 767		
	Any grade	Grade 3-4	Grade 5	Any grade	Grade 3-4	Grade 5
Any TRAEs	738 (94)	462 (59)	4 (<1)	679 (89)	341 (45)	0
Serious TRAEs	172 (22)	131 (17)	4 (<1)	93 (12)	77 (10)	0
TRAEs leading to discontinuation	284 (36)	132 (17)	4 (<1)	181 (24)	67 (9)	0
Treatment-related deaths	12 (2)			4 (<1)		

I-O in early stage disease

Early stage cancer is a **potentially curative** setting

I-O therapy is proven and well established in **adjuvant melanoma**, with continued durable responses

I-O may play an important role **more broadly** in early stage disease (immune system generally more intact in these patients)

Benefit now demonstrated in a 2nd tumor type (esophageal) with CM-577

High unmet need for early stage Esophageal/GEJ cancer

Today

Majority of patients who undergo surgery with CRT do not achieve a Complete Response, leading to poor outcomes



High risk of recurrence



Median survival
< 1 year



No systemic treatments available

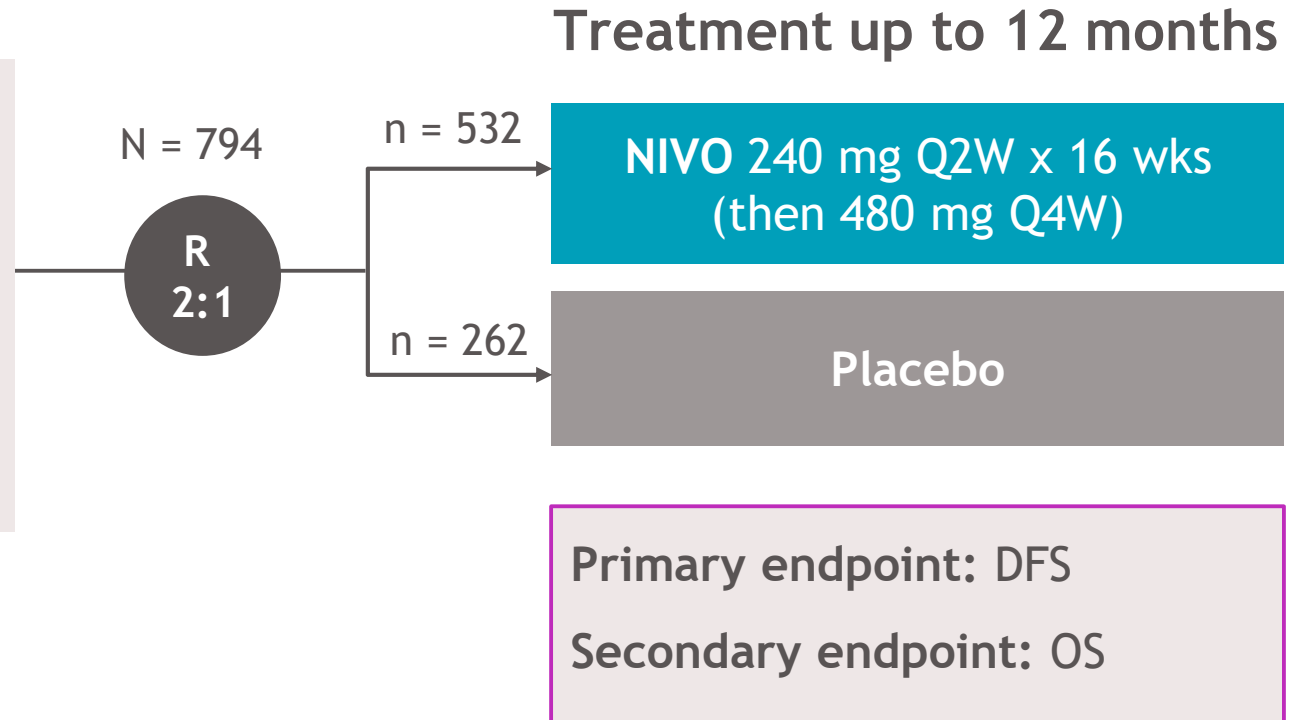
Patients and physicians **need new treatment options** that can stem disease progression and prolong life

Checkmate-577: Opdivo in early stage Esophageal/GEJ

Key Eligibility Criteria

- Resected Stage II, III EC/GEJC
- Completed pre-op CRT
- Residual pathologic disease i.e. non-pCR ($\geq$ ypN1 or ypT1)

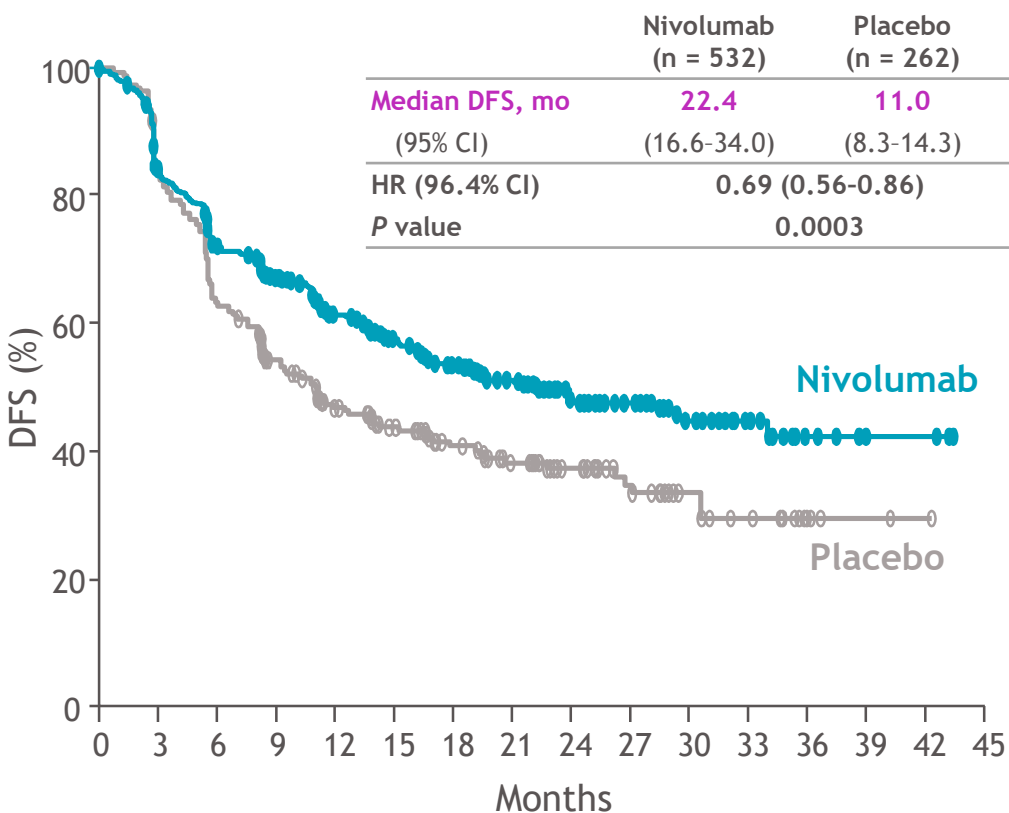
Minimum follow-up: 24.4 months



1st global phase 3 study to evaluate adjuvant treatment in this patient population

Checkmate-577: Opportunity for Opdivo to establish adjuvant treatment for stage II/III esophageal patients

Strong efficacy with highly significant survival benefit, doubling median DFS



Consistent DFS benefit across subgroups including histology

Subgroup		Median DFS, months		Unstratified HR	Unstratified HR (95% CI)
		Nivolumab	Placebo		
Overall (N = 794)		22.4	11.0	0.70	◆
Age, years	< 65 (n = 507)	24.4	10.8	0.65	◆
	≥ 65 (n = 287)	17.0	13.9	0.80	◆
Sex	Male (n = 671)	21.4	11.1	0.73	◆
	Female (n = 123)	Not reached	11.0	0.59	◆
Race	White (n = 648)	21.3	10.9	0.71	◆
	Asian (n = 117)	24.0	10.2	0.70	◆
ECOG PS	0 (n = 464)	29.4	11.1	0.73	◆
	1 (n = 330)	17.0	10.9	0.66	◆
Disease stage at initial diagnosis	II (n = 278)	34.0	13.9	0.72	◆
	III (n = 514)	19.4	8.5	0.68	◆
Tumor location	EC (n = 462)	24.0	8.3	0.61	◆
	GEJC (n = 332)	22.1	20.6	0.87	◆
Histology	Adenocarcinoma (n = 563)	19.4	11.1	0.75	◆
	Squamous cell carcinoma (n=230)	29.7	11.0	0.61	◆
Pathologic lymph node status	ypN0 (n = 336)	Not reached	27.0	0.74	◆
	≥ ypN1 (n = 457)	14.8	7.6	0.67	◆
Tumor cell PD-L1 expression	≥ 1% (n = 129)	19.7	14.1	0.75	◆
	< 1% (n = 570)	21.3	11.1	0.73	◆
Indeterminate/nonevaluable (n = 95)		Not reached	9.5	0.54	◆

Checkmate-577: Opdivo was well tolerated with an acceptable safety profile

	Nivolumab n = 532		Placebo n = 260	
	Any grade	Grade 3-4	Any grade	Grade 3-4
Patients^a, n (%)				
Any AEs	510 (96)	183 (34)	243 (93)	84 (32)
SAEs	158 (30)	107 (20)	78 (30)	53 (20)
AEs leading to discontinuation	68 (13)	38 (7)	20 (8)	16 (6)
Any TRAEs	376 (71)	71 (13)	119 (46)	15 (6)
Serious TRAEs	40 (8)	29 (5)	7 (3)	3 (1)
TRAEs leading to discontinuation	48 (9)	26 (5)	8 (3)	7 (3)
TRAEs leading to death	-		-	

Broad registrational program across multiple tumors in metastatic and early stage settings

Metastatic Setting

Tumor/Trial	Expected Readout	Tumor/Trial	Expected Readout
1L NSCLC CM-9LA Opdivo + Chemo vs Chemo	ASCO ✓	1L Gastric CM-649 Opdivo + Yervoy, Opdivo + Chemo, vs Chemo	ESMO ✓
1L RCC CM-9ER Opdivo + Cabo vs Sutent	ESMO ✓	1L Mesothelioma CM-743 Opdivo + Yervoy vs Chemo	Positive Topline ✓
1L Melanoma CA224-047 Relatlimab + Opdivo vs Opdivo mono	Early 2021	1L GBM CM-548 Chemo + RadTx + Opdivo vs Placebo	Late 2021
1L Head & Neck CM-651 Opdivo + Yervoy vs Extreme regimen	2021	1L Melanoma Opdivo + NKTR-214 vs Opdivo	End 2021/ Early 2022
1L Bladder CM-901 Opdivo + Yervoy + Chemo vs Chemo	2021 PD-L1+	1L HCC CM-9DW Opdivo + Yervoy vs Sorafenib/lenvatinib	2022+
1L Esophageal CM-648 Opdivo+Yervoy vs Cis/5FU; Opdivo + Cis/5FU vs Cis/5FU	2022	Prostate (MRPC) CM-7DX Opdivo + Chemo vs Placebo + Chemo	2022+

Early Stage Setting

Tumor/Trial	Expected Readout	Tumor/Trial	Expected Readout
Esophageal CM-577 Opdivo vs Placebo	ESMO ✓	HCC CM-9DX Opdivo vs Placebo	2022+
Melanoma CM-915 Opdivo + Yervoy vs Opdivo	2020	NSCLC (Adj) CM-427 (ANVIL) Opdivo vs Observation	2022+
NSCLC (Neo-Adj) CM-816 Opdivo + Yervoy, Opdivo + Chemo vs Chemo	2020 pCR* 2022+ EFS	Stage 3 NSCLC (Unresectable) CM-73L Opdivo mono, Opdivo + Yervoy vs Infanzi	2022+
MIBC CM-274 Opdivo vs Placebo	Late 2020 / Early 2021	NSCLC (Peri-Adj) CM-77T Neo-adj Opdivo + Chemo followed by Adj Opdivo, vs Chemo	2022+
Renal CM-914 Opdivo + Yervoy vs Placebo	2022+	MIBC (Peri-Adj) CA017-078 Opdivo + Chemo, Opdivo + IDO + Chemo, vs Chemo	2022+

*Subject to DMC review

Next generation I-O assets: Two programs with comparative designs and potentially registrational data

Bempegaldesleukin (IL-2)

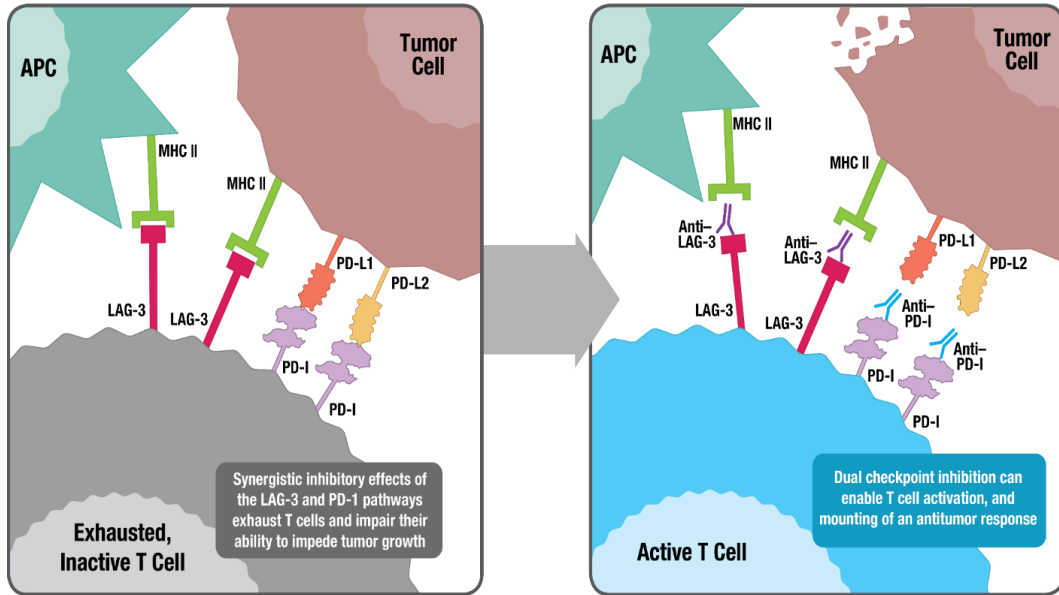
- Pegylated IL-2 (NKTR-214) partnered with NEKTAR Therapeutics
- 5 registrational trials planned and/or in progress across Melanoma, Renal and Bladder
- First data late 2021/early 2022

Relatlimab (anti-LAG3)

- T-cell checkpoint associated with T-cell exhaustion
- Potentially complementary to PD-1
- Ph 2/3 study in metastatic melanoma:
 - Opdivo + Rela vs Opdivo
 - Primary endpoint: PFS
 - Data expected early next year
- Potential additional LCMs

Relatlimab: LAG-3 pathway potentially complementary to PD-1

Mechanism of Action



Trial design

1L Melanoma
N=700

Randomization 1:1

Active Arm
Nivo & Rela

Comparator Arm
Nivo Mono

Endpoints
Primary: PFS
Secondary: OS,
ORR, DOR

- T-cell checkpoint associated with T-cell exhaustion
- **Data expected early next year** for Ph 2/3 study in metastatic melanoma
- Prepared to pivot quickly to a **broader LCM program** where data suggest benefit

ESMO 2020: Pivotal data from three important ph3 trials

CM-9ER Second potential Opdivo combination option for patients with 1L RCC

CM-649 Potential to establish a new SoC for patients with 1L Gastric

CM-577 Potential to introduce a new adjuvant treatment in esophageal cancer

We've now demonstrated that Opdivo provides a benefit in two tumors in the early stage setting

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- Robust LCM program for Opdivo and Yervoy in metastatic and early stage disease
 - Continuing to invest in next generation I-O therapies incl. Relatlimab and Bempeg



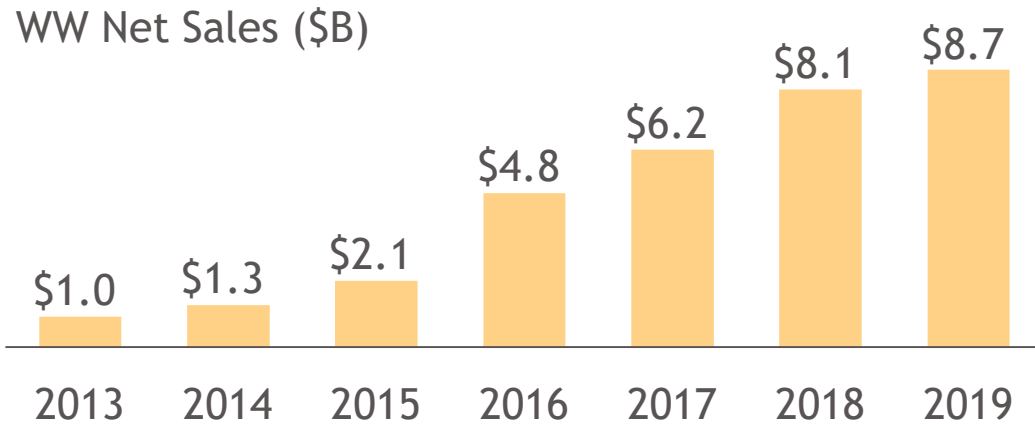
Chris Boerner

Executive VP

Chief Commercialization Officer

I-O: Strong foundation for growth

Immuno-Oncology (I-O) Net Sales



- Successfully executed 23 launches across I-O portfolio
- Established BMS I-O as a standard of care in 9 tumors
- Holding leadership in core tumors despite intense competition
- Launched 2 complementary 1L lung regimens; launches progressing well with use in a variety of patient types

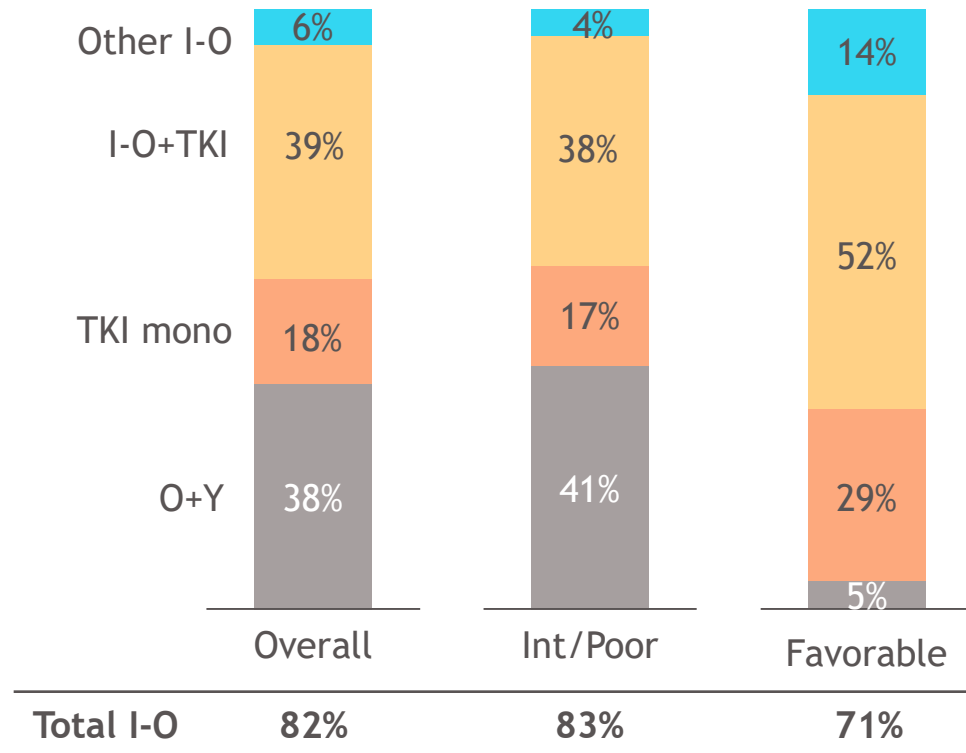
...with continued growth potential

✓ Existing Indication ✓ New Opportunity

	Metastatic	Early Stage
Melanoma	✓ ✓ ✓ ✓	✓ ✓ ✓ ✓
Lung	✓ ✓ ✓	✓ ✓ ✓ ✓
RCC	✓ ✓ ✓ ✓	✓
H&N	✓ ✓	
Bladder	✓ ✓ ✓	✓ ✓ ✓
Gastric/Eso	✓ ✓ ✓ ✓	✓ ✓
HCC	✓ ✓	✓ ✓
CRC	✓ ✓	
Others	✓ GBM ✓ Prostate ✓ TMB Pan Tumor	✓ Breast

Stable base business in 1L RCC with opportunity to grow

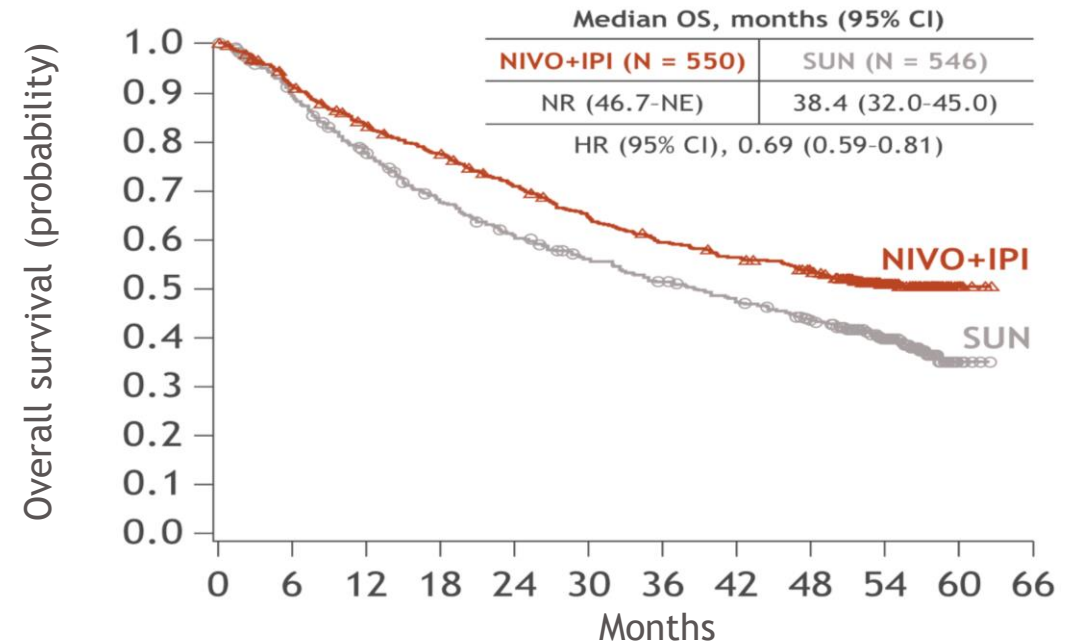
Current 1L RCC Market



Source: IQVIA BrandImpact as of 5/15/2020

Opdivo & Yervoy (CM-214)

- Opdivo/Yervoy remains a standard of care
- Physician use driven by appreciation of differentiated survival
 - 53% OS at 48 months; stable HR at 0.69



Opdivo + Cabometyx: Very competitive IO-TKI profile in 1L RCC

Competitive efficacy vs. other TKI combinations

- OS HR =0.60, PFS HR =0.51

Differentiated safety profile

- 40mg Cabometyx
- 15.3% any grade TRAE discontinuation rate overall for the combination

Important opportunity to potentially expand Opdivo use by:



- Displacing TKI mono therapy
- Broadening label to include favorable risk group
- Competing where I-O TKI combos are used today

Opdivo + chemo: potential new standard 1L treatment option for patients with advanced GC/GEJ/EAC

Today's Market Landscape

- Gastric and esophageal are 3rd and 6th deadliest cancers globally
- High unmet need for 18k U.S. patients and 27k patients in EU5
- Limited options today: Chemo doublet as SOC for over a decade in 1L* with mOS of < 1 year

*non-HER2+

Opportunity with CM-649

First and only regimen to show survival benefit vs SOC

- First new option in a decade

Benefit shown across PD-L1 expression

- In CPS ≥ 5 and all randomized pts

Encouraging physician feedback

- Can use in a broad set of patients with upper GI cancer

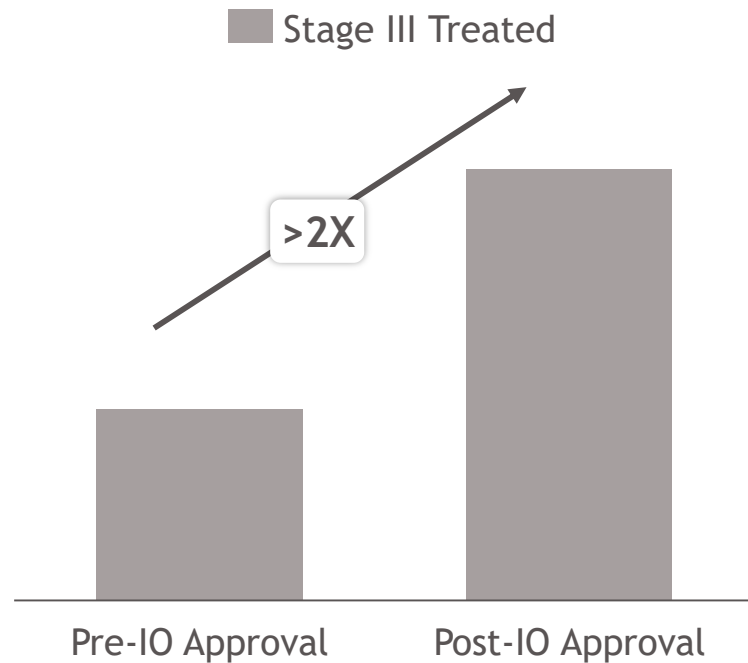
Ready for execution

- Strong overlap with physicians treating other core tumors

Early Stage Esophageal Landscape

BMS adjuvant experience in Melanoma (U.S.)

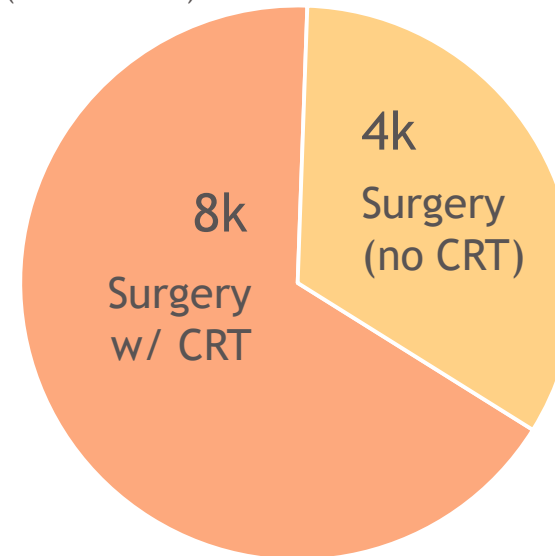
New option expands treatment rates



Opportunity for Opdivo to become the first adjuvant treatment option in Esoph/GEJ

Unmet need is high in early stage Esophageal/GEJ

12k patients undergo surgery (U.S. and EU5)



Potential for increased treatment rates over time

In majority of pts, pCR not achieved with no further treatment available

Source: IQVIA BrandImpact as of 5/15/2020 Note: Above figures for US market only

Continued growth opportunities

Encouraging 1L lung launch execution for O+Y regimen

CM-9ER potential 1L renal option with competitive I-O+TKI profile

- Opportunity to expand in favorable risk population, building on leadership position with O+Y
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Two options to treat gastroesophageal in both metastatic and adjuvant

- CM-649: First I-O option for the treatment of 1L gastroesophageal
 - CM-577: Second tumor type where Opdivo has demonstrated a benefit in early stage disease
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Robust LCM program in both metastatic and early stage disease as well as registrational data for next wave I-O agents near-term including Relatlimab and Bempeg

Q&A



Giovanni Caforio, M.D.

Board Chair,
Chief Executive Officer



Chris Boerner, Ph.D.

Executive VP,
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Samit Hirawat, M.D.

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