



Bristol-Myers Squibb

# CMSTO 2014 Highlights\*

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**Investor Meeting**

October 31, 2014

\*Chicago Multidisciplinary Symposium in Thoracic Oncology

October 30 – November 1, 2014

# Forward-Looking Information

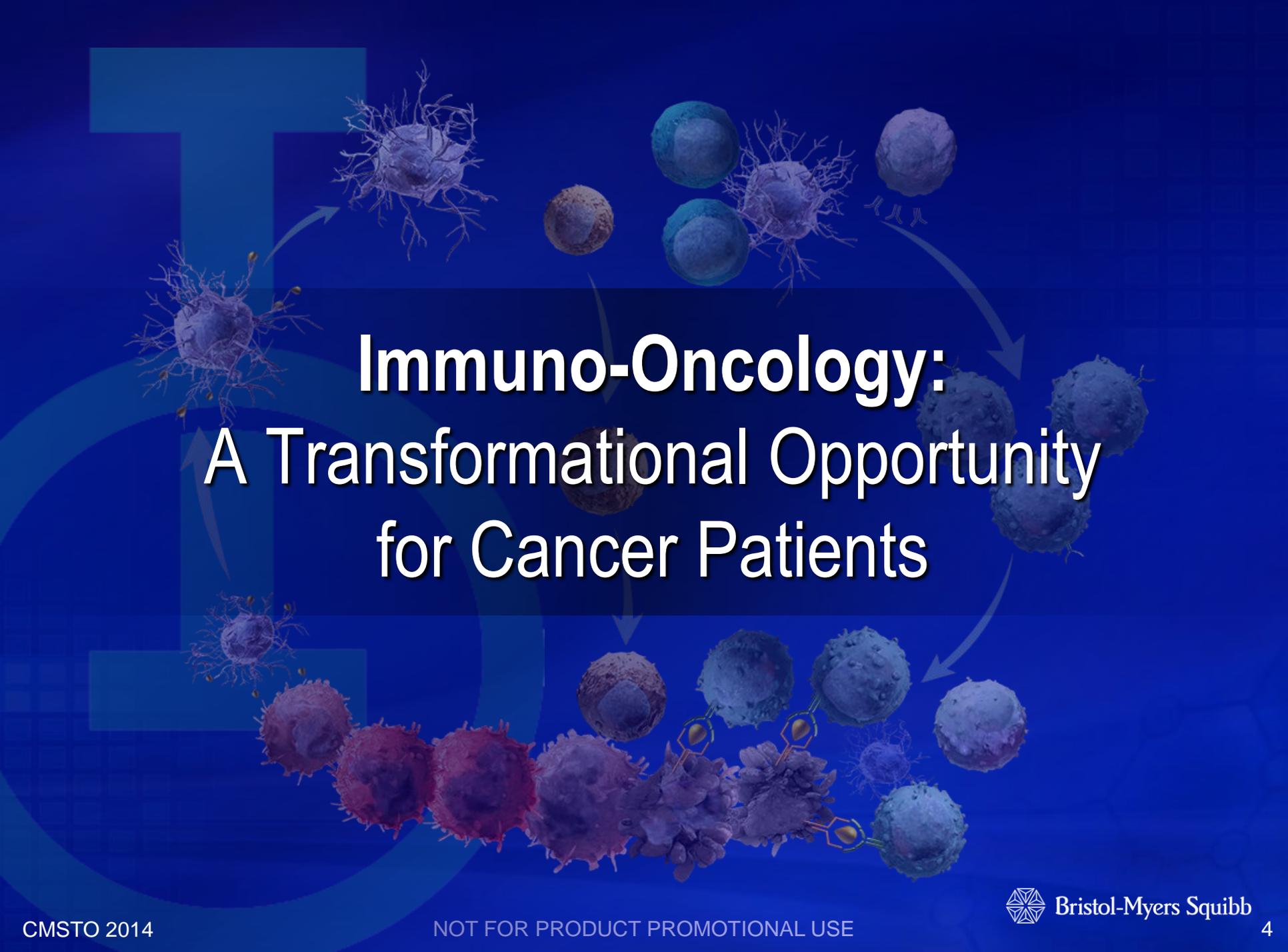
During this meeting, we will make statements about the Company's future plans and prospects that constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated as a result of various important factors, including those discussed in the company's most recent annual report on Form 10-K and reports on Form 10-Q and Form 8-K. These documents are available from the SEC, the Bristol-Myers Squibb website or from Bristol-Myers Squibb Investor Relations.

In addition, any forward-looking statements represent our estimates only as of today and should not be relied upon as representing our estimates as of any subsequent date. While we may elect to update forward-looking statements at some point in the future, we specifically disclaim any obligation to do so, even if our estimates change.

# Today's Agenda

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- ◆ **Immuno-Oncology Strategic Overview**
- ◆ **Developments since ASCO**
- ◆ **Lung Cancer Strategy**
- ◆ **Key Data Presented at CMSTO 2014**
- ◆ **Upcoming Key Events**
- ◆ **Q&A**



# Immuno-Oncology: A Transformational Opportunity for Cancer Patients

# BMS Immuno-Oncology Vision

- ◆ **Displace standard of care in multiple tumor types, lines of therapy and histologies**
  - **Monotherapy**
  - **Combination**
  - **Biomarker**
- ◆ **Use I-O combinations to meaningfully increase likelihood of long-term survival**
- ◆ **Expand and accelerate broad portfolio of novel mechanisms**

# Developments Since ASCO

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# Positive Results from 2 Phase 3 Studies

## ◆ Checkmate -066:

- Previously untreated BRAF Wild Type patients with advanced melanoma
- Primary endpoint met: superior survival vs. DTIC

## ◆ Checkmate -037:

- Advanced melanoma patients previously treated with Yervoy or BRAF inhibitor (BRAF Mutant)
- Co-primary endpoints
  - Overall response rate: 32% for nivolumab and 11% for chemotherapy
  - Overall survival: not yet evaluated

# Regulatory Filings for 2 Tumor Types

## ◆ Melanoma

- US: Filed advanced melanoma based on -037
  - Priority Review, Breakthrough Therapy status granted by FDA
  - PDUFA date March 30, 2015
- EU: Filed advanced melanoma
  - Accelerated assessment granted by EMA

## ◆ Lung

- EU: Filed advanced lung cancer based on -063

# New Study Starts

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- ◆ **Renal Cell Carcinoma**
  - **Checkmate-214: Phase 3 study of nivolumab in combination with Yervoy in 1<sup>st</sup> line**
- ◆ **Hodgkin Lymphoma**
  - **Checkmate-205: Phase 2B trial**
- ◆ **Glioblastoma**
  - **Checkmate-143: Phase 3 portion initiated**

# Extending Leadership through Partnerships



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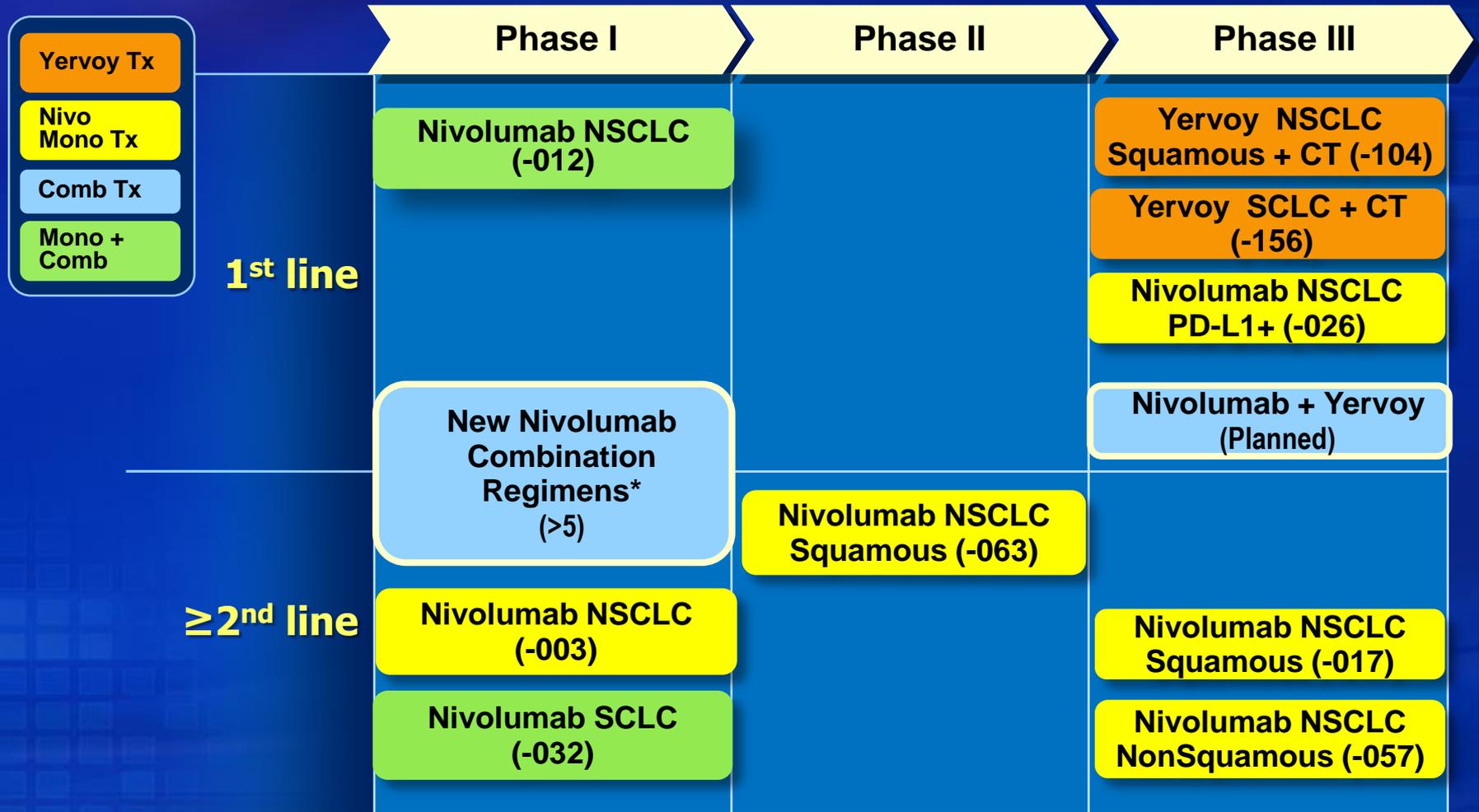
# Lung Cancer Strategy

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# BMS Lung Cancer Development Strategy

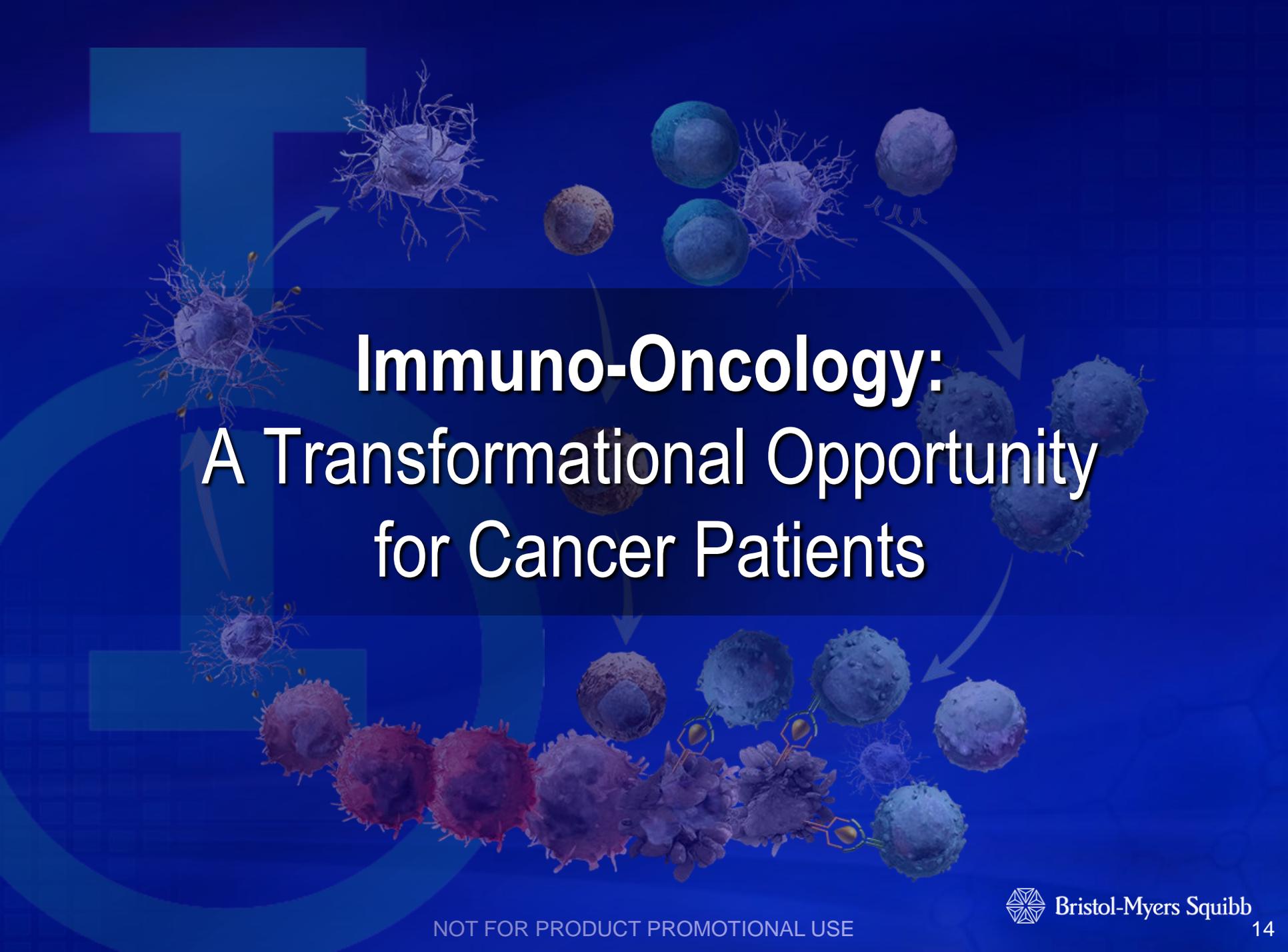
- ◆ **Deliver the potential of I-O to the broad population**
  - **Across histologies, lines of therapy and PD-L1 status**
- ◆ **Characterize benefits of I-O with broad clinical program**
  - **Demonstrate Overall Survival**
  - **Determine role of biomarker(s)**
- ◆ **Realize the full potential of I-O with combination regimens**

# Lung Cancer Development Program



\* Includes collaborations

CT = chemotherapy



# Immuno-Oncology: A Transformational Opportunity for Cancer Patients

# CMSTO 2014

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# CMSTO 2014 – Highlights of Key Data

Study	Description	Key Data Presented
<b>-003</b>	◆ Nivo monotherapy	◆ 3-year survival rate
	◆ Monotherapy	◆ ORR, Durability of Response
<b>-012</b>	◆ Nivo plus platinum doublets	◆ 18-month survival rate
	◆ Nivo plus erlotinib	◆ 18-month survival rate
	◆ Nivo plus bevacizumab	◆ Durability of Response, OS
	◆ Nivo plus ipilimumab	◆ Durability of Response, OS
<b>-063</b>	◆ Nivo monotherapy in 3 <sup>rd</sup> line squamous	◆ ORR, Durability of Response, 1-year survival rate

ORR – Overall Response Rate; OS – Overall Survival

# Checkmate-012 Key Takeaways

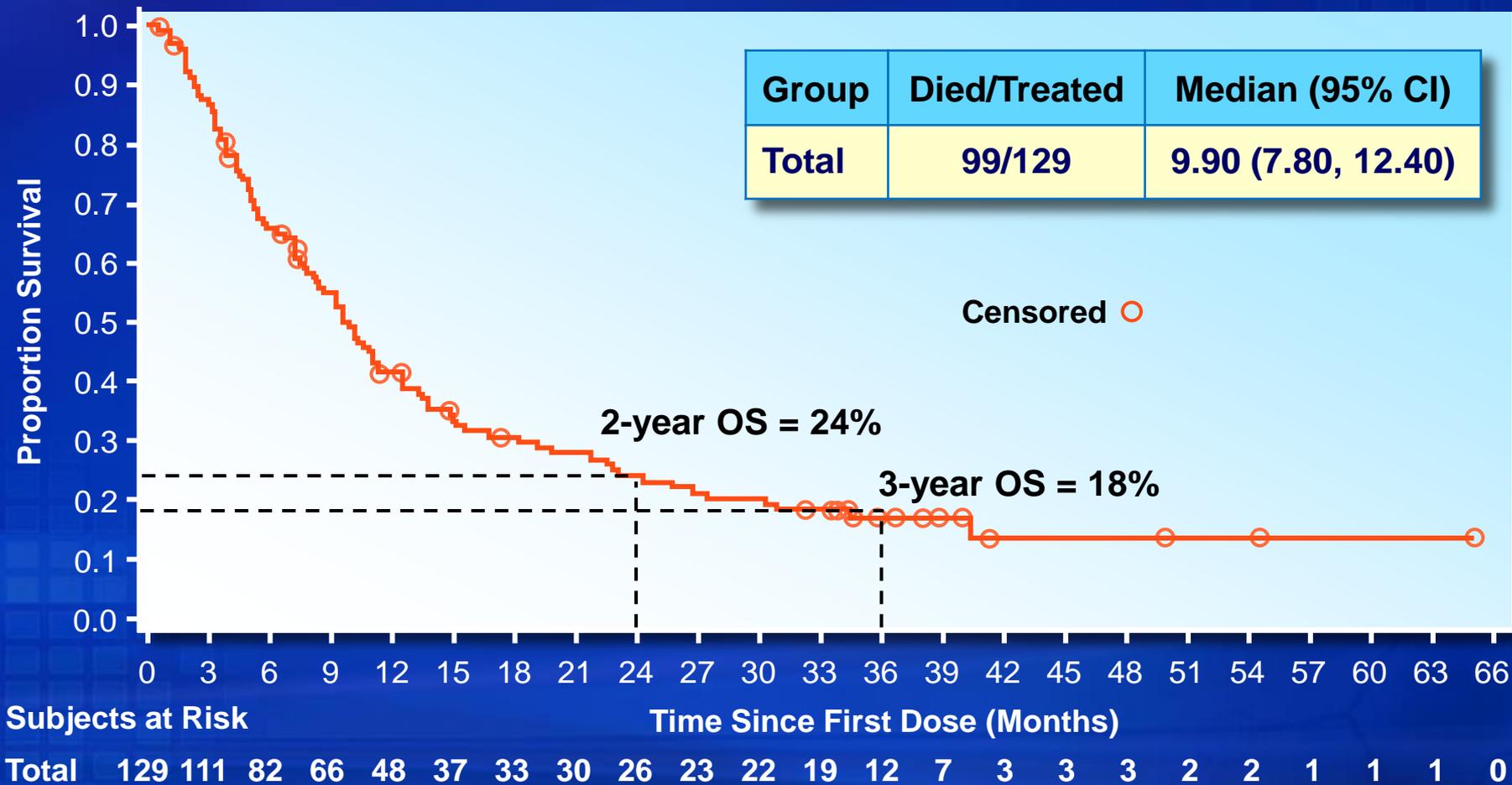
- ◆ In the 1st line setting, nivolumab monotherapy or in combination provided durable responses with encouraging survival
- ◆ Nivolumab monotherapy was associated with a safety profile consistent with previous studies
- ◆ Nivolumab in combination was associated with a safety profile that reflected additive toxicities of the individual agents that were managed with well established safety algorithms
- ◆ Activity was observed in PD-L1<sup>+</sup> and PD-L1<sup>-</sup> patients

# Checkmate-003

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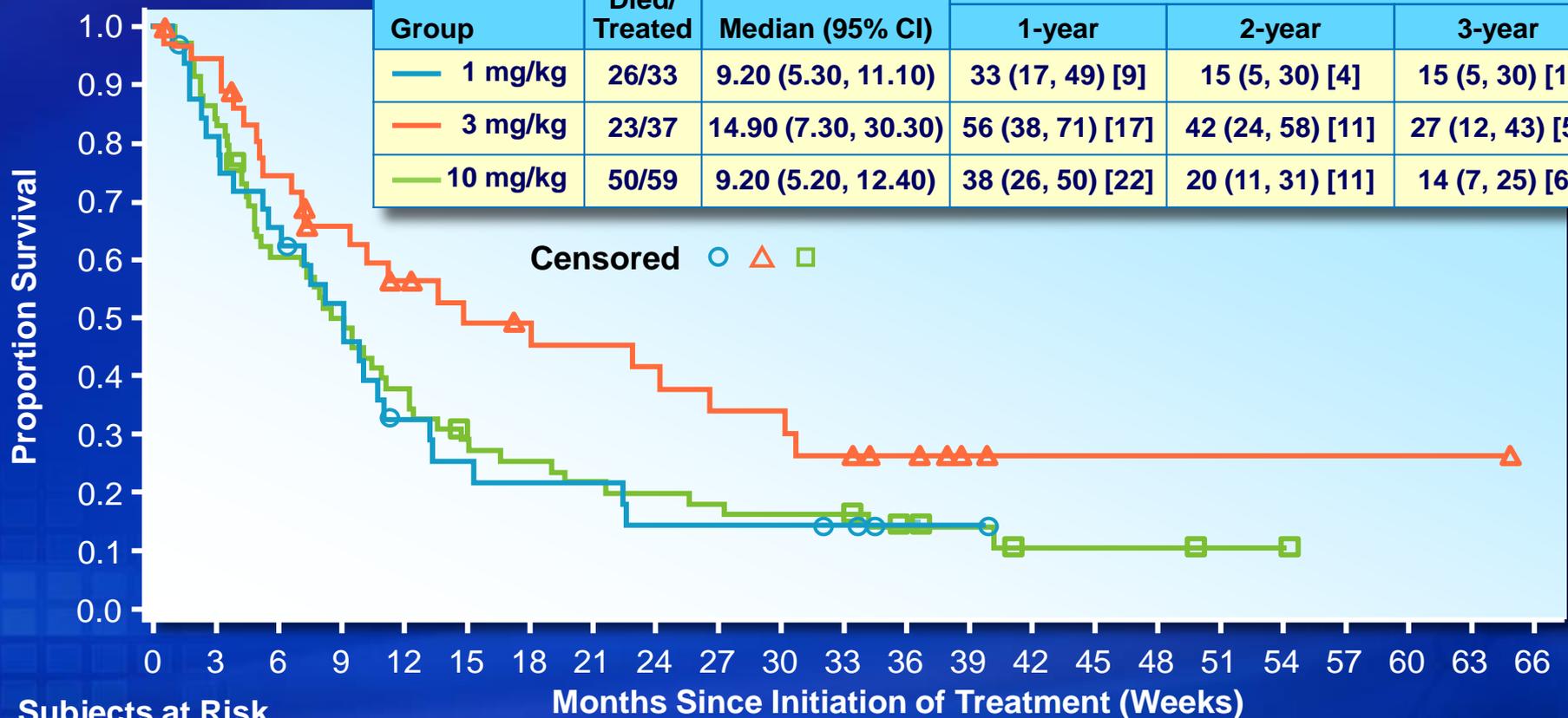
# Overall Survival in NSCLC Patients (Up to 5 Prior Lines of Therapy)

## All Treated Subjects with NSCLC



# OS by Nivolumab Dose in NSCLC Patients (Up to 5 Prior Lines of Therapy)

Group	Died/Treated	Median (95% CI)	OS rate % (95% CI) [patients at risk]		
			1-year	2-year	3-year
1 mg/kg	26/33	9.20 (5.30, 11.10)	33 (17, 49) [9]	15 (5, 30) [4]	15 (5, 30) [1]
3 mg/kg	23/37	14.90 (7.30, 30.30)	56 (38, 71) [17]	42 (24, 58) [11]	27 (12, 43) [5]
10 mg/kg	50/59	9.20 (5.20, 12.40)	38 (26, 50) [22]	20 (11, 31) [11]	14 (7, 25) [6]



**Subjects at Risk**

	0	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54	57	60	63	66	
<b>1.0</b>	33	26	21	16	9	7	6	6	4	4	4	3	1	1	0	0	0	0	0	0	0	0	0	0
<b>3.0</b>	37	34	26	21	17	14	13	12	11	9	9	7	5	2	1	1	1	1	1	1	1	1	1	0
<b>10.0</b>	59	51	35	29	22	16	14	12	11	10	9	9	6	4	2	2	2	1	1	0	0	0	0	0

# Safety Summary

Category	Treatment-Related Select AE	
	Any Grade <sup>a</sup> , % (n)	Grade 3–4, % (n)
<b>Patients with any treatment-related select AE</b>	<b>41 (53)</b>	<b>5 (6)</b>
Skin	16 (20)	0
Gastrointestinal	12 (15)	1 (1)
Pulmonary	7 (9) <sup>b</sup>	2 (3)
Endocrinopathies	6 (8)	0
Hepatic	5 (6)	1 (1)
Infusion reaction	4 (5)	1 (1)
Renal	3 (4)	0

<sup>a</sup> Safety results based on a March 2013 database lock

<sup>b</sup> Two patients had treatment-related grade 2 pneumonitis, which occurred prior to the date of the safety analysis, but are not included in the table because these data were not available until after this analysis. One additional patient had treatment-related grade 5 pneumonitis, but is not included in this table because the event occurred after the date of the safety analysis

# Checkmate-063

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# Unmet Need in Refractory SQ NSCLC

	Massarelli <sup>1</sup> , 2003	Scartozzi <sup>2</sup> , 2010	Penrod <sup>3</sup> , 2014	Gettinger <sup>4</sup> , 2014
Population	≥ 3L SQ and NSQ, N = 43	3L SQ and NSQ, N = 52	3L SQ, N = 113	≥ 2L SQ, N = 54
Treatment	Chemo	Chemo or TKI	Real-world Obs Cohort <sup>a</sup>	Nivolumab 1, 3 or 10 mg/kg Q2W
ORR,%	2	8	–	17
Median PFS, mo	2.2	3.4 (TTP)	–	3.8
1 yr PFS,%	2.9	–	–	27
Median OS, mo	4	6.5	5	9.2
1 yr OS,%	5.5	–	18	41

<sup>a</sup> Chemo, TKI and monoclonal antibodies  
– = Not reported; Q2W = every 2 weeks

ORR = objective response rate  
PFS = progression free survival  
OS = overall survival

1. Massarelli E, et al. *Lung Cancer* 2003;39: 55-61

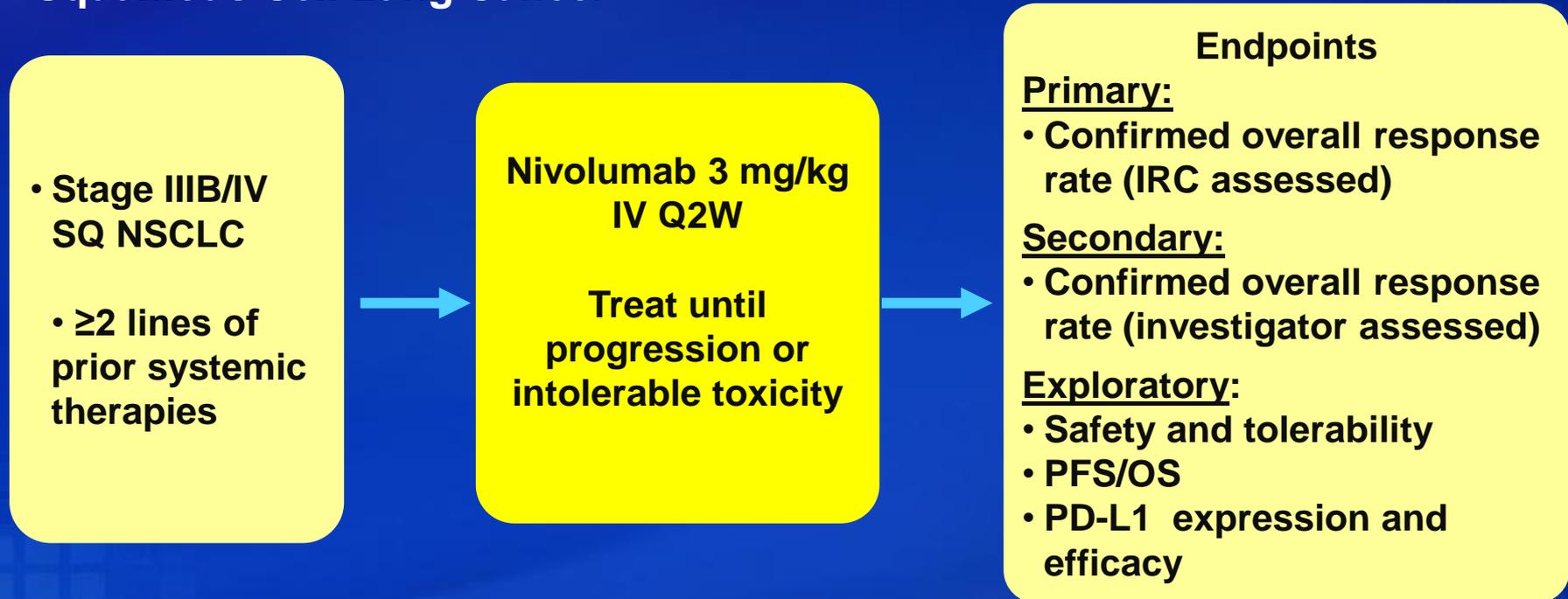
2. Scartozzi M, et al. *Lung Cancer* 2010;68:433-437

3. Penrod JR, et al. Poster presentation at ASCO 2014. Poster 45

4. Gettinger SN, et al. Poster presentation at CMSTO 2014 (Checkmate -003). Poster 170

# -063 Study Design

## Phase II Nivolumab in Advanced, 3<sup>rd</sup> Line + Squamous Cell Lung Cancer



Tumor assessments per (RECIST v1.1) performed at week 8 and every 6 weeks

Minimum of 11 months of follow-up for response

Median OS follow-up was 8 months (range, 0–17.3 months)

# Baseline Demographics

<b>Nivolumab 3 mg/kg</b>	<b>N = 117</b>
<b>Median age, years (range)</b>	<b>65 (37–87)</b>
<b>ECOG PS, %</b>	
0	22
1	78
<b>Gender, %</b>	
Male	73
<b>Number of prior systemic regimens, %</b>	
2	35
≥3	65
<b>Best response to most recent prior regimen, %</b>	
CR or PR	4
SD	27
PD	61
<b>Time from completion of most recent prior regimen to treatment, %</b>	
<3 months	76
>3 months	24

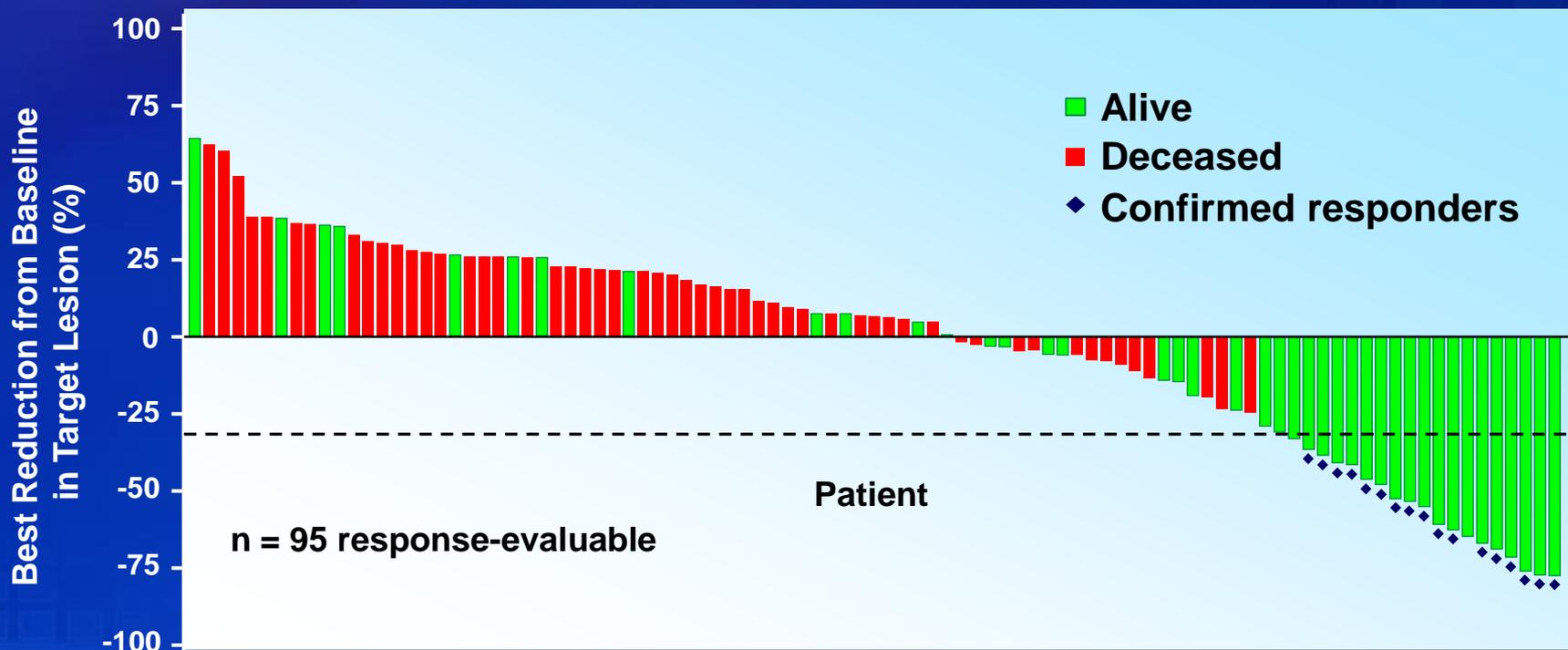
# Clinical Activity of Nivolumab

	IRC Assessed (per RECIST 1.1) <sup>a</sup>
<b>ORR, % (n) [95% CI]</b>	<b>15 (17) [9, 22]</b>
<b>Disease control rate, % (n)</b>	<b>40 (47)</b>
<b>Median DOR, months (range)</b>	<b>NR (2+, 12+)</b>
<b>Ongoing responders, % (n)</b>	<b>76 (13)</b>
<b>Median time to response, months (range)</b>	<b>3 (2, 9)</b>
<b>Median PFS, months (95% CI)</b>	<b>2 (2, 3)</b>
<b>PFS rate at 1-year, % (95% CI)</b>	<b>20 (13, 29)</b>

<sup>a</sup>July 2014 DBL

NR = not reached; ORR = objective response rate; DOR = duration of response;  
PFS = progression free survival

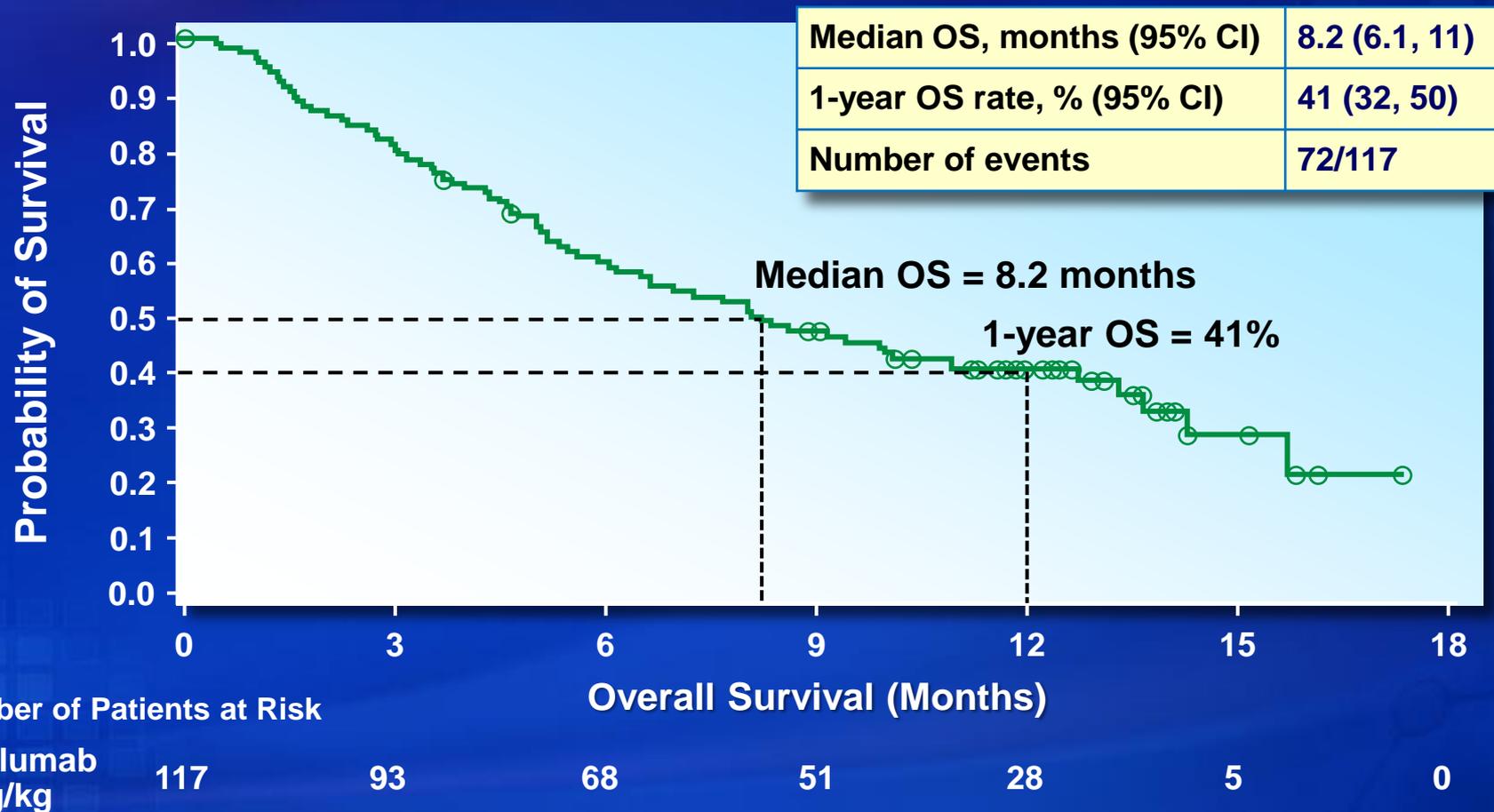
# Response and Survival Status By Best Reduction in Target Lesion (IRC Assessed)<sup>a</sup>



<sup>a</sup>Based on July 2014 DBL; 22/117 treated patients are not displayed due to lack of evaluable on-study assessments; 18/22 died  
 Dashed horizontal reference line indicates the 30% reduction consistent with a RECIST v1.1 response

- ◆ In addition to the 17 responders, 4 patients had non-conventional responses that were not included in the IRC-assessment
  - Three of the 4 patients with non-conventional responses are alive at the time of analysis (OS of 12+, 13+, 14+ months)

# Overall Survival: All Treated Patients<sup>a</sup>



◆ Median follow-up for OS: 8 months (range, 0–17 months)

<sup>a</sup> Based on July 2014 DBL

Symbols represent censored observations. OS = overall survival

# ORR by PD-L1 Expression (IRC Assessed)

- ◆ 76 evaluable samples<sup>a</sup>

Subgroups		ORR, % (n/N)
Overall		15 (17/117)
PD-L1	≥1%	20 (9/45)
	<1%	13 (4/31)
	≥5%	24 (6/25)
	<5%	14 (7/51)
	Indeterminate/NE <sup>b</sup>	30 (3/10)

<sup>a</sup> Based on a July 2014 DBL

<sup>b</sup> No quantifiable PD-L1 expression

NE = not evaluable

# Nivolumab Safety Summary\*

Category	Nivolumab 3 mg/kg (N = 117)	
	Any Grade	Grade 3–4
Total patients with an event, %	74	17
Fatigue	33	4
Decreased appetite	19	0
Asthenia	12	0
Rash	11	1
Nausea	15	0
Diarrhea	10	3

\* Of the adverse events included in the table, no events were grade 5

- ◆ **Grade 3 treatment-related pneumonitis was reported in 4 patients (3%)**
- ◆ **Two treatment-related deaths (1 hypoxic pneumonia and 1 ischemic stroke) in patients with multiple comorbidities and concurrent progressive disease**

# Checkmate-063 Key Takeaways

- ◆ **Highly refractory patient population with no treatment alternatives**
  - 65% had already failed 3+ lines
  - 61% with progressive disease as best response to most recent prior therapy
- ◆ **Clinically meaningful and durable efficacy**
  - 1 yr OS of 41% and ORR of 15% per RECIST 1.1
  - Durable responses with 76% ongoing at time of analysis (minimum 11 months follow-up)
- ◆ **Clinical activity in PD-L1+ and PD-L1- patients**
- ◆ **Safety profile consistent with previous studies and managed with well established safety guidelines**

# Key Upcoming Nivolumab Events

## Data Presentations:

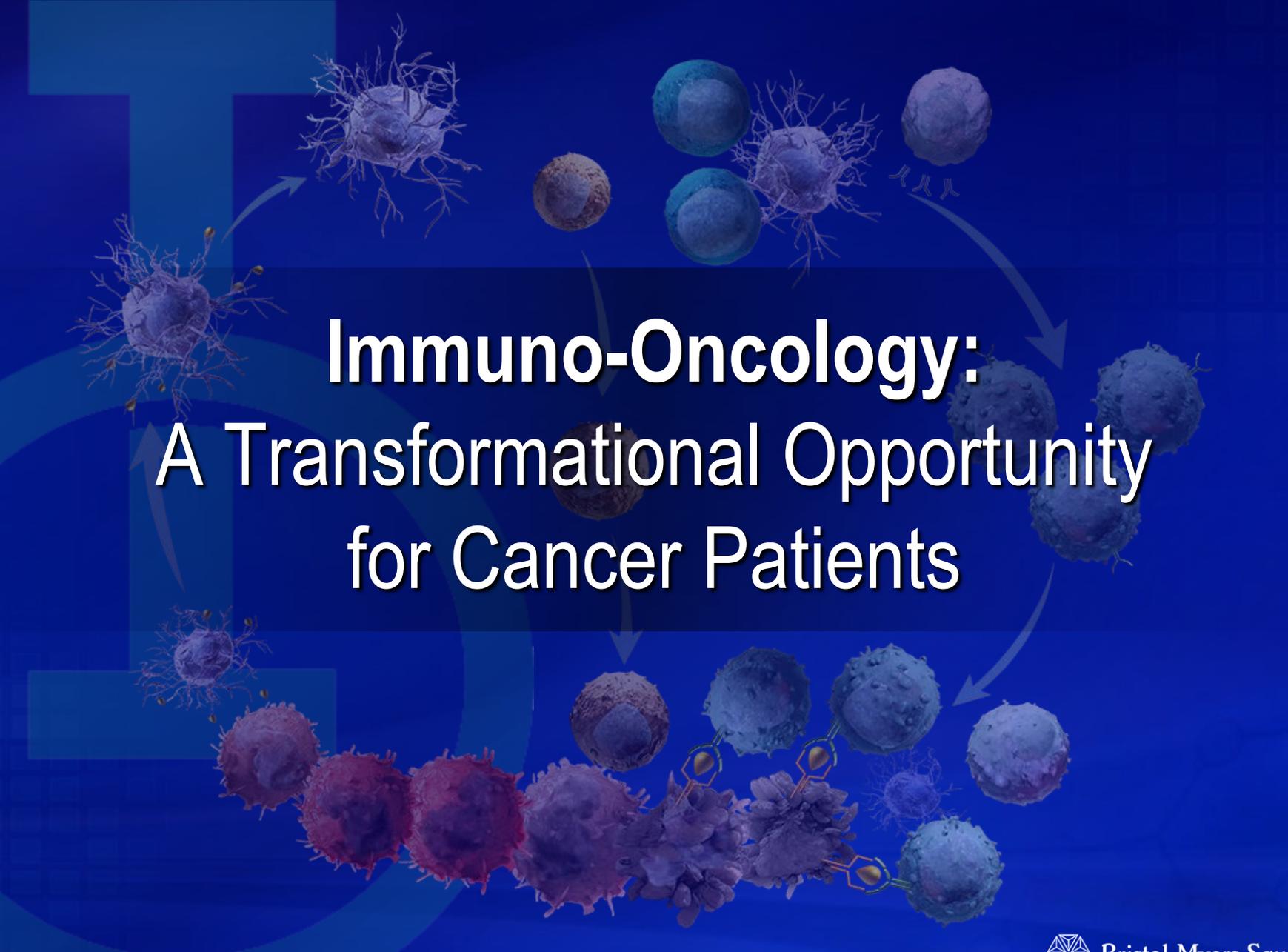
- ◆ Checkmate -066: Phase 3 vs. DTIC in 1<sup>st</sup> Line Melanoma (SMR Nov 13-16)
- ◆ Checkmate -039: Phase I in Hematologic Malignancies (ASH Dec 6-9)

## Regulatory Filings:

- ◆ Checkmate -063: completion of rolling submission by year end

## New Study Starts:

- ◆ Phase 3 Lung Combination with Yervoy



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