



Bristol-Myers Squibb

ASCO 2017

Investor Event

June 4, 2017

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BMS R&D

Dr. Tom Lynch
Chief Scientific Officer



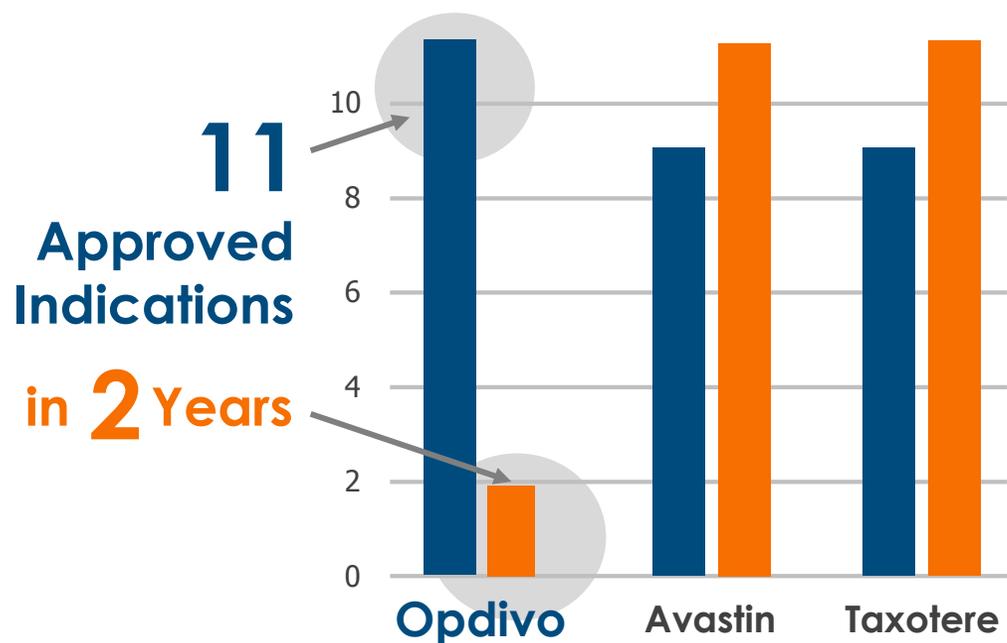
VISION FOR R&D

We are **focused, science oriented** and **data driven** – and **determined to deliver** medicines that have the potential to **transform the lives of patients**

R&D Priorities

- **Expand Opdivo/Yervoy across multiple tumors/biomarker sets**
- **Accelerate delivery of our next wave of I-O assets**
- **Understand the biology of I-O resistance**
- **Develop novel combination regimens**
- **Accelerate development of our most promising assets in CFI**
- **Focus on Business Development**

Continued Immuno-Oncology R&D Success



15 Positive Registrational Trials

5 Phase III trials stopped early due to survival benefit

15 Tumors with ongoing registrational trials

~250 Global Approvals for Opdivo

11 *New England Journal of Medicine* Publications

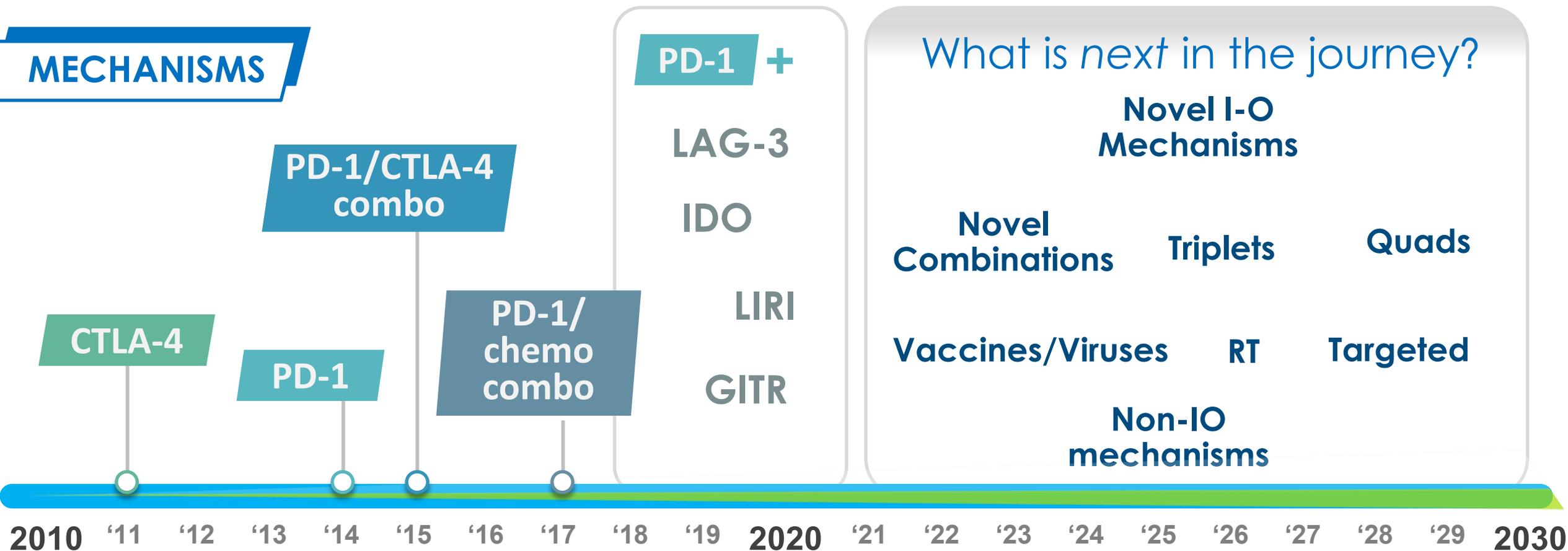
7 Breakthrough Therapy Designations

Note: All milestones since 2014

NOT FOR PRODUCT PROMOTIONAL USE

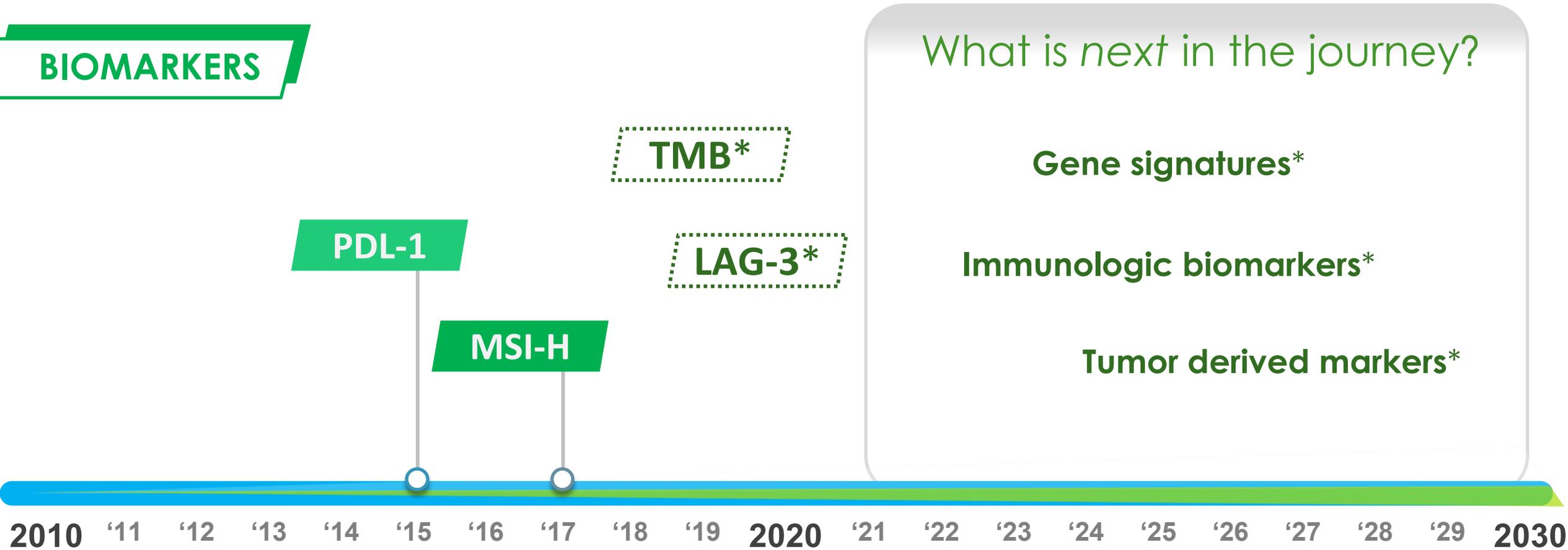
Significant progress has been made, but the journey is only just beginning

MECHANISMS



Significant progress has been made, but the journey is only just beginning

BIOMARKERS



*Exploratory/unapproved biomarkers

BMS R&D Priorities in Oncology

Leveraging Translational Approaches and Innovative Trial Designs

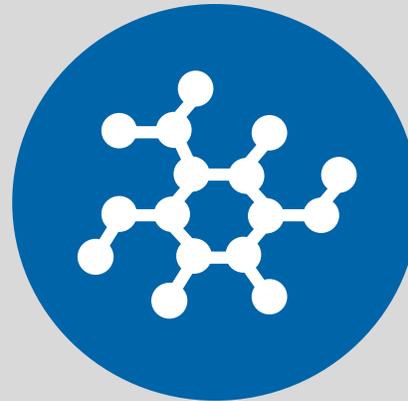
- Deliver on current O+/-Y development portfolio
- Accelerate next wave of IO agents
- Explore new combination regimens

- Improve outcomes for patients with:
 - IO sensitive tumors
 - Primary Resistance
 - Acquired Resistance

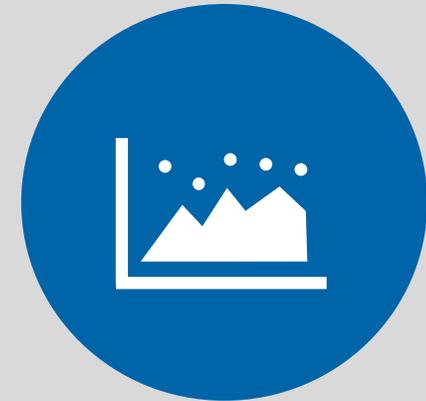
Focus On Building Key Capabilities



**Enhance Translational
Medicine Capabilities**



**Invest in Cancer
Biology**



**Invest in Data
and Analytics**

Our Industry Leading Internal Oncology Pipeline

Anti-CTLA-4 NF	Cabiralizumab (Anti-CSF1R)	Anti-LAG3
Glypican-3 ADC	Anti-GITR	IDO Inhibitor
Anti-TIGIT	Ulocuplumab (Anti-CXCR4)	PROSTVAC
Anti-CD73	Mesothelin ADC	<i>EMPLICITI</i>
Anti-OX40	Urelumab (Anti-CD137)	<i>OPDIVO</i>
HuMax-IL8	Anti-Fucosyl GM1	<i>YERVOY</i>
BET Inhibitor	Lirilumab (Anti-KIR)	<i>SPRYCEL</i>

Data as of May 10th, 2017

<i>Marketed</i> ¹
Phase III ²
Phase II
Phase I

¹ Approved in at least one major market (US, EU, JP)

² In Ph III or currently under reg. review

Oncology – Development Portfolio

Phase I		Phase II		Phase III		Approved Indications	
Anti-CTLA-4 NF Solid Tumors [^]	Mesothelin-ADC [^] Solid Tumors	<i>OPDIVO</i> * NHL (FL)	Anti-LAG3* + <i>OPDIVO</i> * Solid Tumors	<i>OPDIVO</i> * Adjuvant Melanoma	<i>OPDIVO</i> * 1L Head & Neck	<i>OPDIVO</i> * Previously treated Met Melanoma	<i>OPDIVO</i> * + <i>YERVOY</i> * BRAF wild-type Met Melanoma
Glypican-3 ADC [^] HCC	BET Inhibitor Solid Tumors	<i>OPDIVO</i> * NHL (DLBCL)	Lirilumab* Hematologic Mal.	<i>OPDIVO</i> * 2L SCLC	<i>OPDIVO</i> * + <i>YERVOY</i> * 1L Head & Neck	<i>OPDIVO</i> * 1L BRAF wild-type Met Melanoma	<i>OPDIVO</i> * + <i>YERVOY</i> * Melanoma across BRAF status
Anti-TIGIT [^] Solid Tumors	Ulocuplumab Hematologic Mal.	<i>OPDIVO</i> * MSI+ Colon	Urelumab*+ <i>OPDIVO</i> * Solid Tumors & Hematologic Mal.	<i>OPDIVO</i> * + <i>YERVOY</i> * 1L SCLC	<i>OPDIVO</i> * [#] 3L Gastric	<i>OPDIVO</i> * Melanoma across BRAF status	<i>YERVOY</i> * Metastatic Melanoma
Anti-GITR [^] Solid Tumors	Lirilumab* [^] Solid Tumors	<i>OPDIVO</i> * [#] Ovarian	Anti-Fucosyl GM1 [^] SCLC	<i>OPDIVO</i> * + <i>YERVOY</i> * 1L NSCLC	<i>OPDIVO</i> * + <i>YERVOY</i> * 1L Gastric	<i>OPDIVO</i> * Previously treated Met Squamous NSCLC	<i>YERVOY</i> * Adjuvant Melanoma
Cabiralizumab* [^] Solid Tumors	Lirilumab* + <i>EMPLICITI</i> * MM	<i>OPDIVO</i> * 2L HCC	<i>EMPLICITI</i> 1L MM Pomalido- mide Combo	<i>OPDIVO</i> * Unresectable NSCLC	<i>OPDIVO</i> * [#] + Adjuvant Gastric	<i>OPDIVO</i> * Previously treated Met Non-squamous NSCLC	<i>EMPLICITI</i> * Relapsed/Refractory MM Revlimid Combo
Anti-CD73 [^] Solid Tumors	Urelumab* + <i>EMPLICITI</i> * MM	<i>OPDIVO</i> * CNS Lymphoma	<i>YERVOY</i> Adolescent Mel	<i>OPDIVO</i> * NSCLC Neoadjuvant	<i>OPDIVO</i> * [#] 2L Esophageal	<i>OPDIVO</i> * Previously treated advanced RCC	<i>SPRYCEL</i> * 1L CML
Anti-OX40 [^] Solid Tumors	<i>OPDIVO</i> * Solid Tumors & Hematologic Mal.		<i>SPRYCEL</i> * Pediatric	<i>OPDIVO</i> * + <i>YERVOY</i> * 1L RCC	<i>OPDIVO</i> * Adjuvant Esophageal /Gastroesophageal	<i>OPDIVO</i> * Advanced Hodgkin Lymphoma	<i>SPRYCEL</i> * Refractory CML
Anti-LAG3* [^] Solid Tumors & Hematologic Mal.	<i>OPDIVO</i> * + <i>YERVOY</i> Solid Tumors	* Development Partnership <i>EMPLICITI</i> : AbbVie <i>SPRYCEL</i> : Otsuka <i>OPDIVO</i> , <i>YERVOY</i> : Ono Pharmaceutical Prostvac: Bavarian Nordic Lirilumab: Innate Pharma, Ono Pharmaceutical Urelumab, Anti-LAG-3: Ono Pharmaceutical Cabiralizumab: Five Prime Therapeutics		<i>OPDIVO</i> * 1L Glioblastoma	<i>OPDIVO</i> * + <i>YERVOY</i> * 1L Mesothelioma	<i>OPDIVO</i> * Previously treated Met Head & Neck	<i>OPDIVO</i> * Previously treated Met Urothelial
IDO Inhibitor [^] Solid Tumors	<i>OPDIVO</i> * Pediatric			<i>OPDIVO</i> * 1L HCC	<i>OPDIVO</i> * + <i>EMPLICITI</i> * Multiple Myeloma		
HuMax-IL8 Solid Tumors				<i>OPDIVO</i> * Adjuvant Bladder	<i>EMPLICITI</i> * 1L MM Revlimid Combo		
				<i>OPDIVO</i> * + <i>YERVOY</i> * 1L Bladder	PROSTVAC* ⁺⁺ Met CRPC		

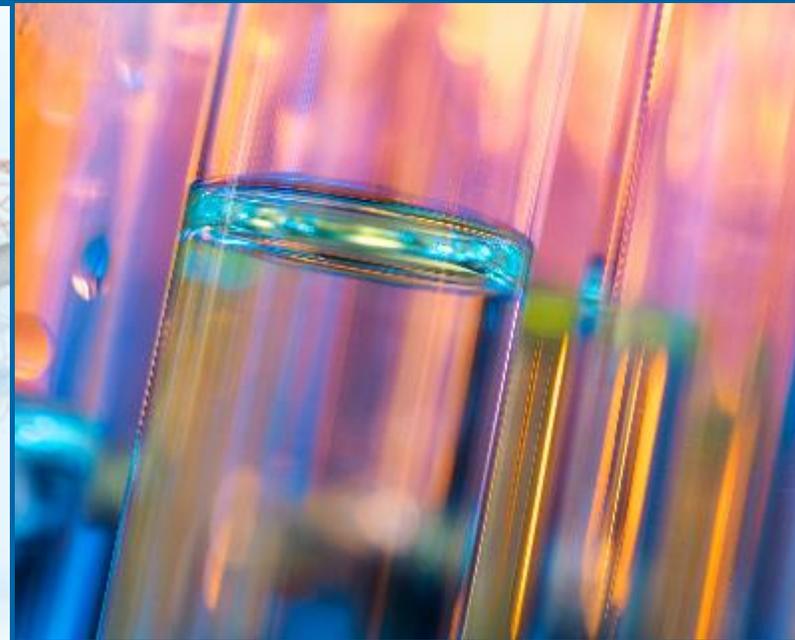
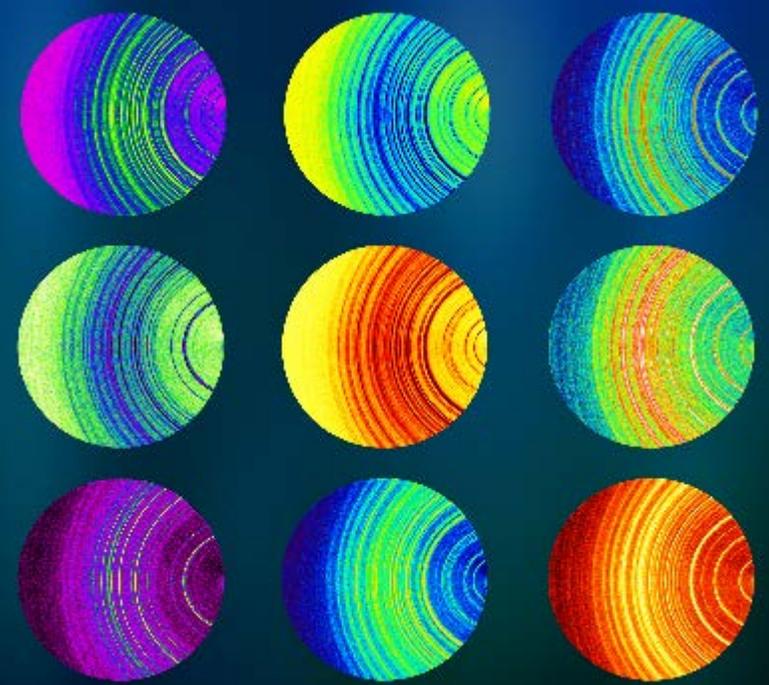
Anti-CTLA-4 NF started a Phase 1 trial and was added to this slide May 10

[^] Trial(s) exploring various combinations
[#] Partner-run study
⁺⁺ Option rights

Early Stage Pipeline Strategy

Dr. David Feltquate

Head of Early Clinical Development



The Immuno-Biology of Cancer is Complex

- Effector cells are central for tumor recognition and killing
- Other factors may modulate the activity of effector cells

IMMUNE REGULATORY and **ANTIGEN-PRESENTING CELLS** may negatively regulate or not provide necessary stimulation to the immune system

**IMMUNE
REGULATORY
& APCs**

TUMOR

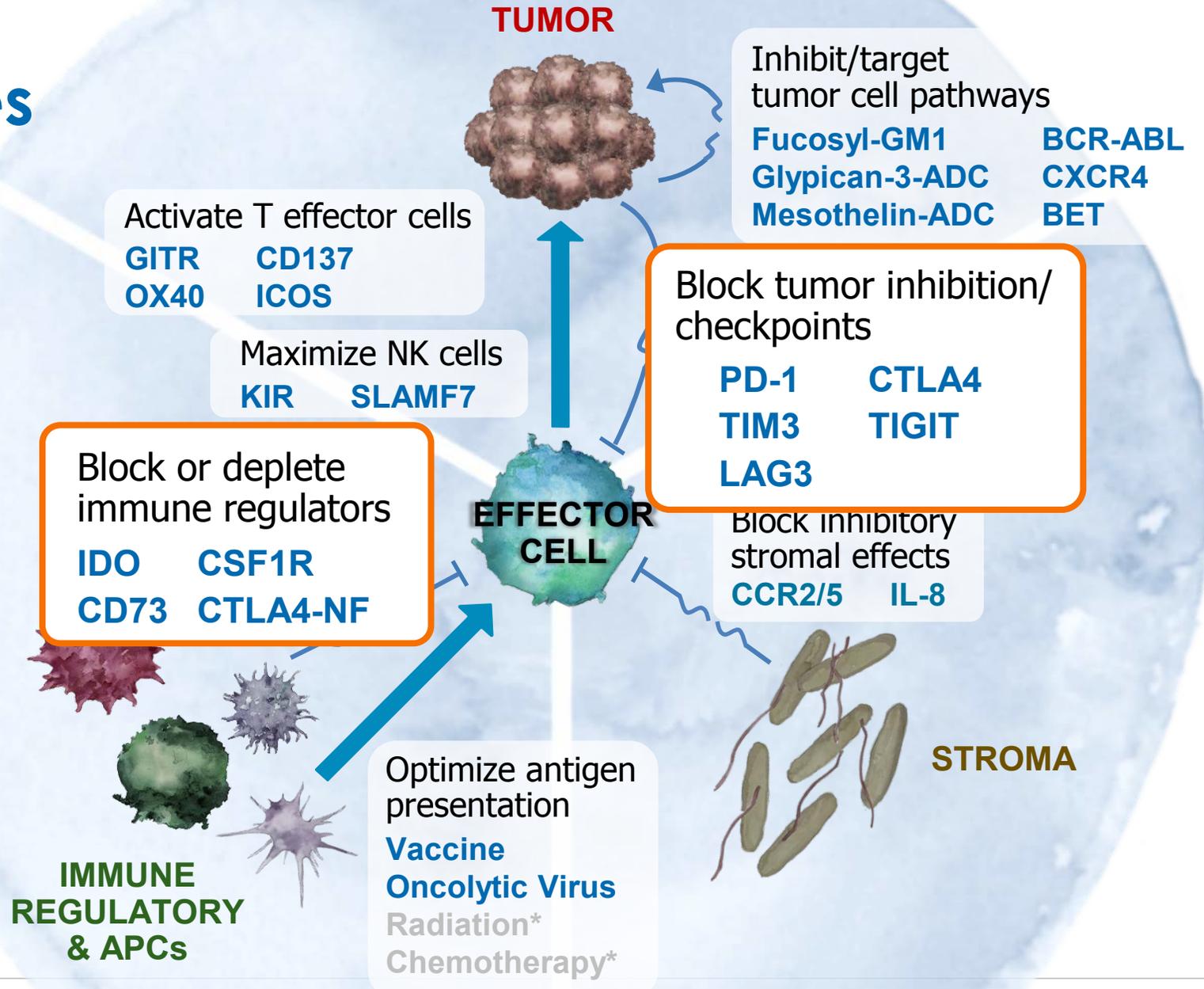
The **TUMOR** may leverage inherent mechanisms to sustain itself and evade immune destruction

**EFFECTOR
CELL**

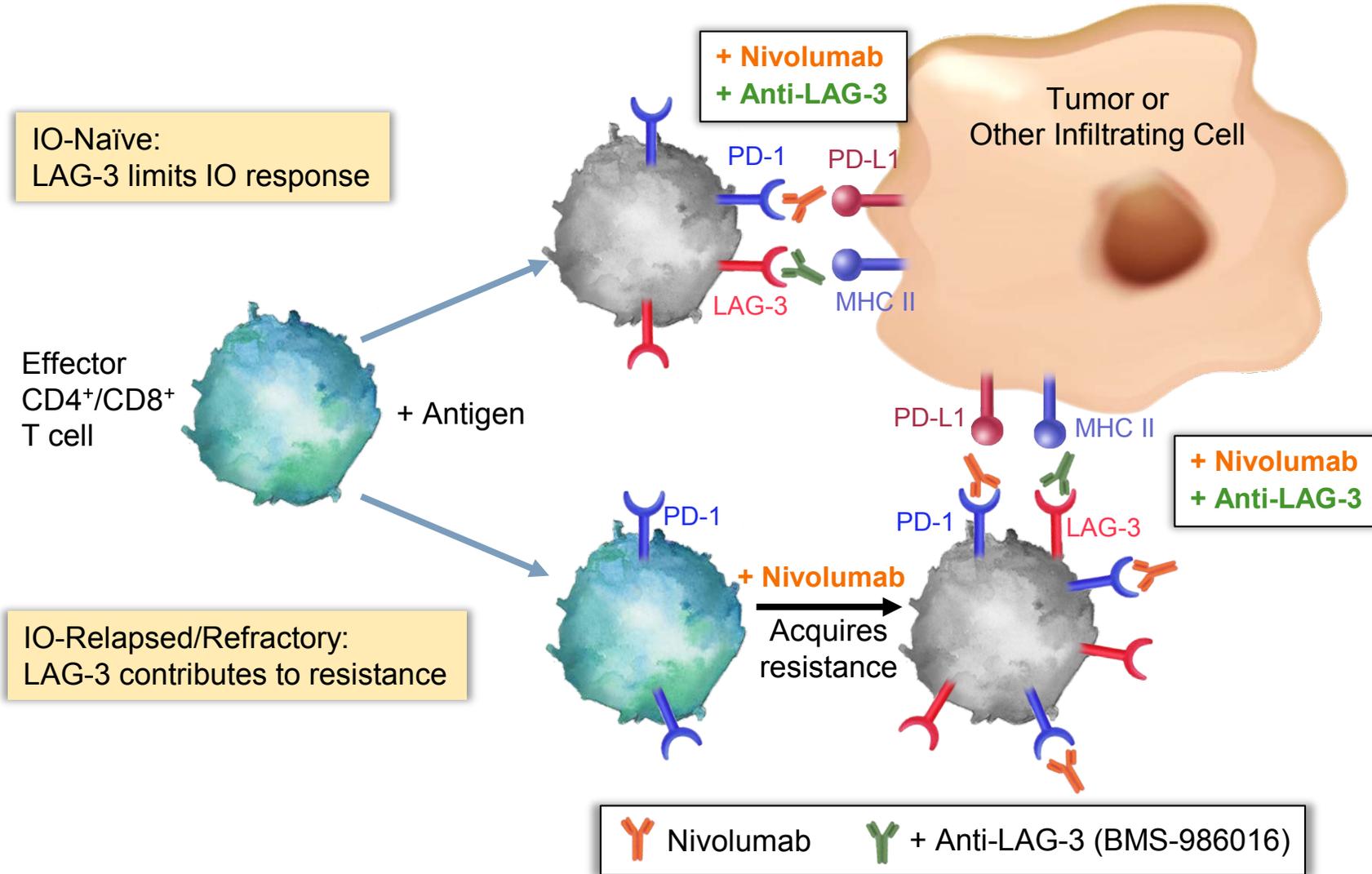
The **STROMA** comprises a variety of cell types that may suppress immune function via expression of cell surface or soluble inhibitory molecules, including metabolites

STROMA

Our Portfolio has multiple approaches in each of these categories



Role of LAG-3 in T-Cell Exhaustion and Anti-PD-1 Resistance: Rationale For Anti-LAG-3 and Anti-PD-1 Combination Therapy



In therapy-naïve patients, constitutive LAG-3 expression may limit the anti-tumor activity of PD-1 pathway blockade.

In patients exposed to PD-1 pathway blockade, adaptive upregulation of LAG-3 expression may lead to treatment resistance and tumor progression.

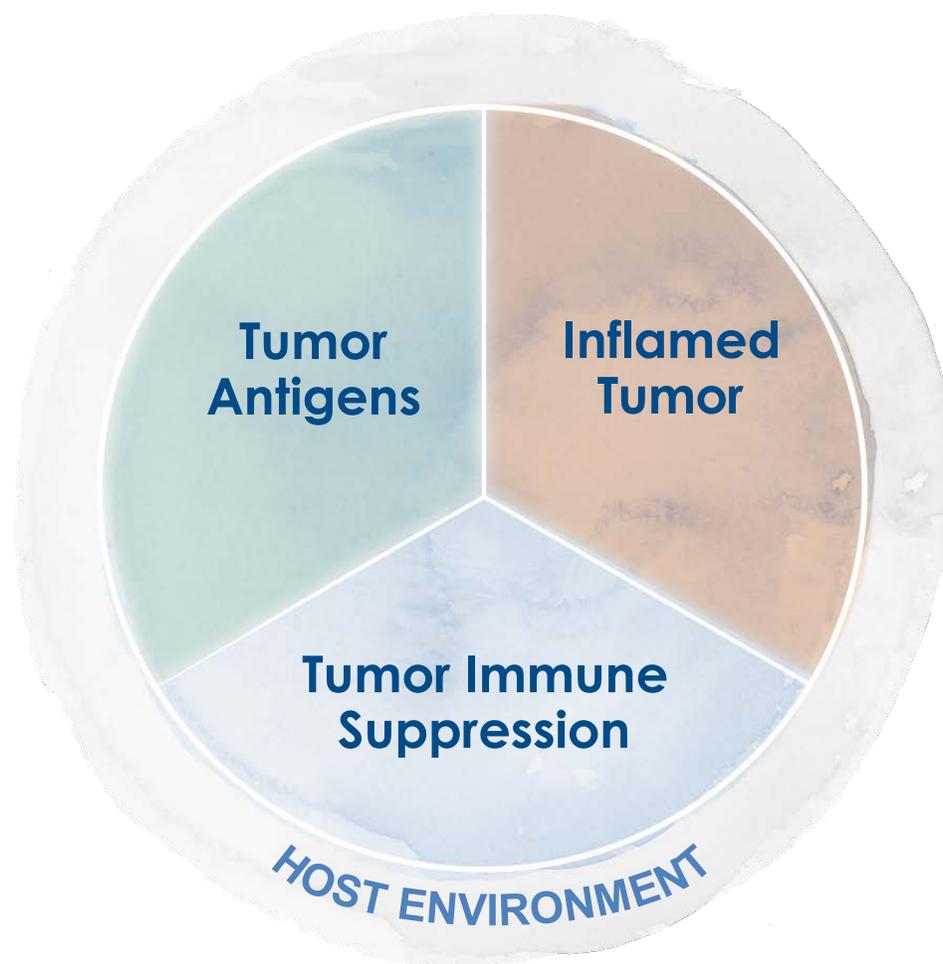
Developing Biomarkers to Predict Better Outcomes

Tumor Antigens

- Tumor Mutation Burden (TMB)
- Microsatellite Instability / Mismatch Repair Deficiency
- T cell Receptor Profiling

Tumor Immune Suppression

- Tim-3
- LAG-3
- Suppressive Immune Cells (e.g. T-regs)



Inflamed Tumor Microenvironment

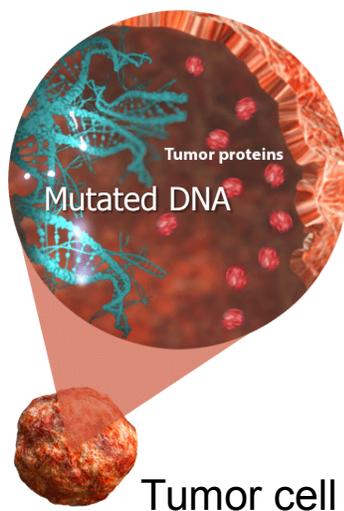
- PD-L1
- Tumor Inflammatory Signature (TIS)
- T cell Infiltration

Host Environment

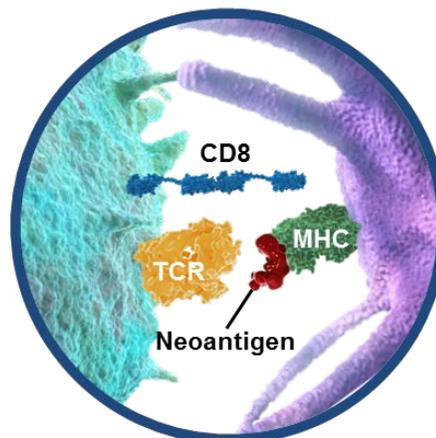
- Microbiome Markers

Tumors with high mutation burden are a rational target for I-O therapy

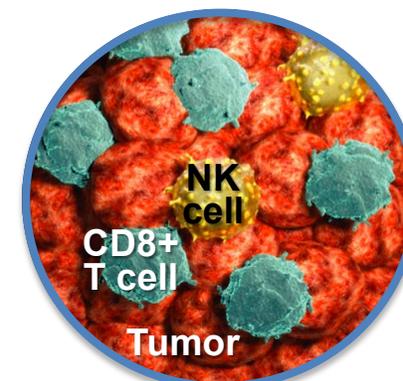
Tumor cells with high TMB...^{1,2}



...may have high neoantigen load...^{1,2}



...which can lead to high tumor immunogenicity and increased T-cell reactivity and anti-tumor response²⁻⁵



The high immunogenicity of tumors with high mutation burden makes them a rational target for treatment with I-O therapies^{1,2}

1. Schumacher TN, Schreiber RD. *Science*. 2015;348(6230):69-74.

2. Kim JM, Chen DS. *Ann Oncol*. 2016;27(8):1492-1504.

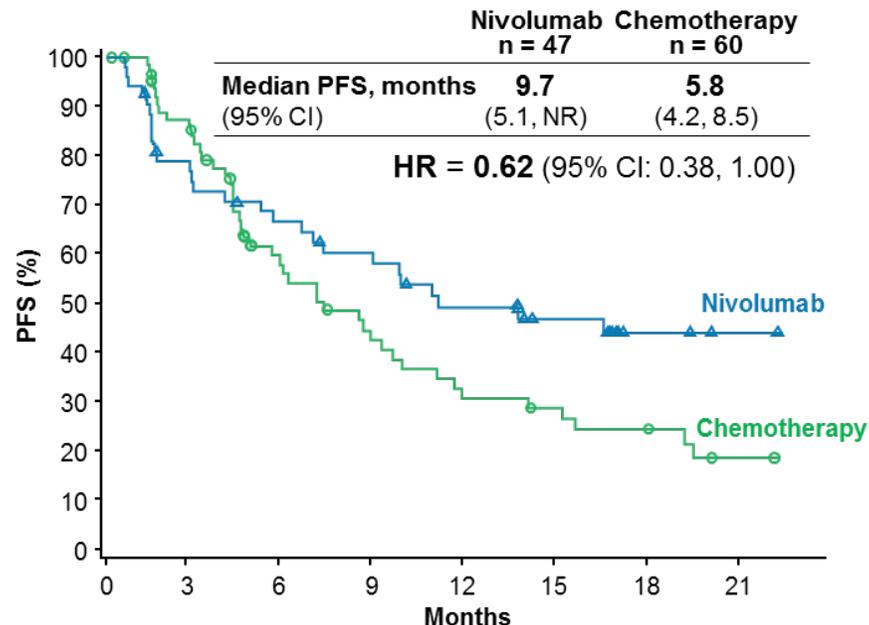
3. Lontos M et al. *Ann Transl Med*. 2016; 4(14):264. 4. Sharma P, Allison JP. *Science*. 2015;348(6230):56-61. 5. Giannakis M et al. *Cell Rep*. 2016;15:857-865.

Tumor Mutational Burden

Tumor cells with high TMB may have high neoantigen load, which can lead to high tumor immunogenicity and increased T-cell reactivity and anti-tumor response

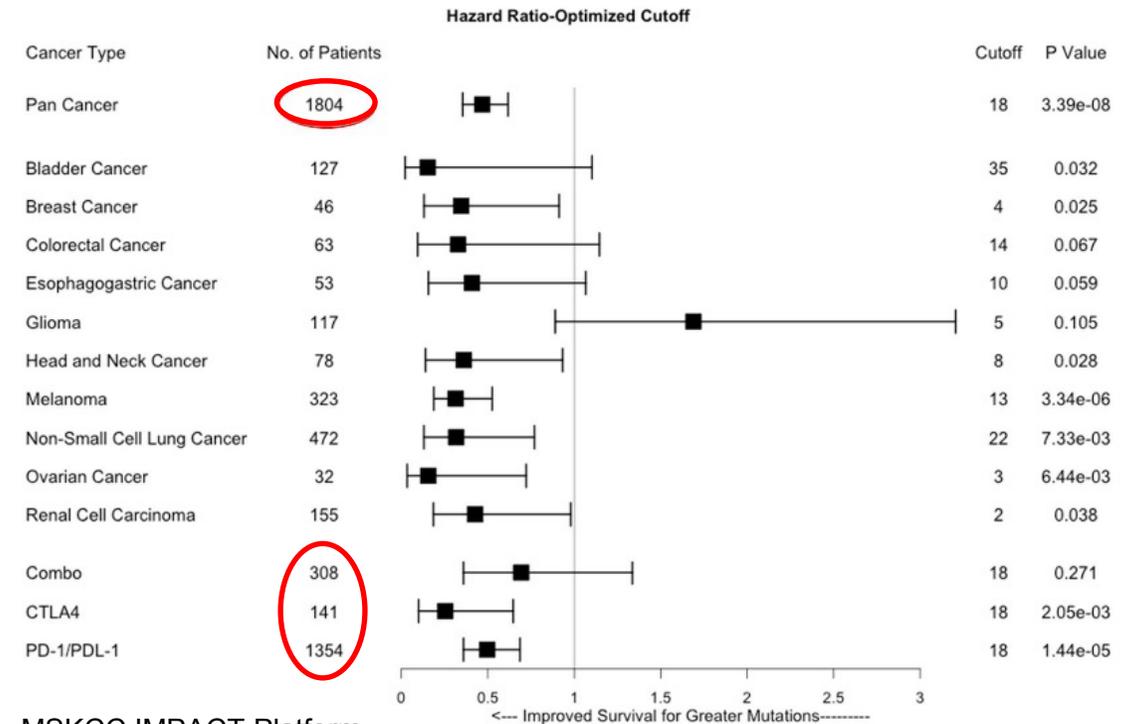
Data from Checkmate-026

High TMB



No. at Risk	0	3	6	9	12	15	18	21
Nivolumab	47	30	26	21	16	12	4	1
Chemotherapy	60	42	22	15	9	7	4	1

Pan-Cancer Analysis of Mutational Load and ICB Response



MSKCC IMPACT Platform

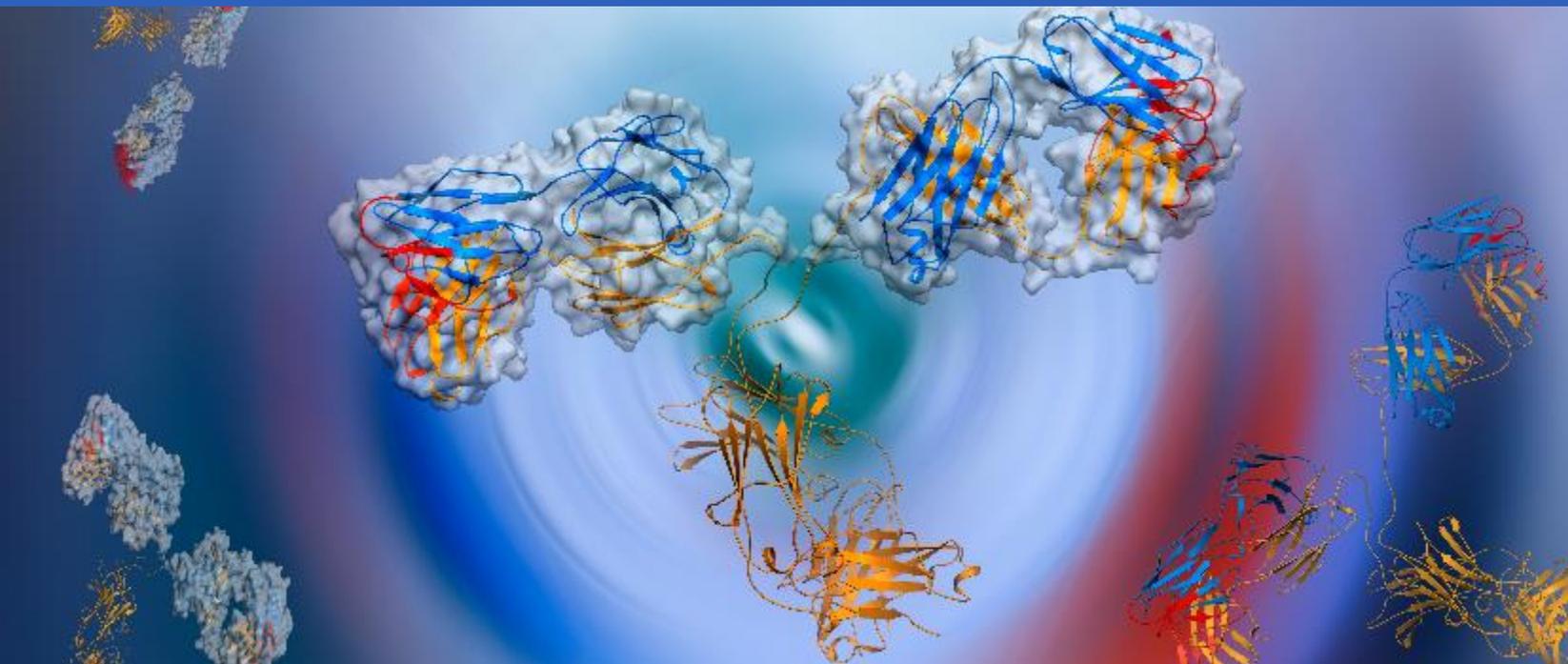
Presented by Timothy Chan at 2017 ASCO-SITC Clinical Immuno-Oncology Symposium

Key Takeaways

- A broad and detailed understanding of the complexities of tumor immunobiology is critical
- Translational medicine will be needed to match the right patients with the right medicines
- We expect the oncology landscape to continue to become more segmented
- BMS has a strategically and rationally developed internal portfolio of clinical stage assets

BMS Immuno-Oncology Overview

Dr. Fouad Namouni
Head of Oncology Development



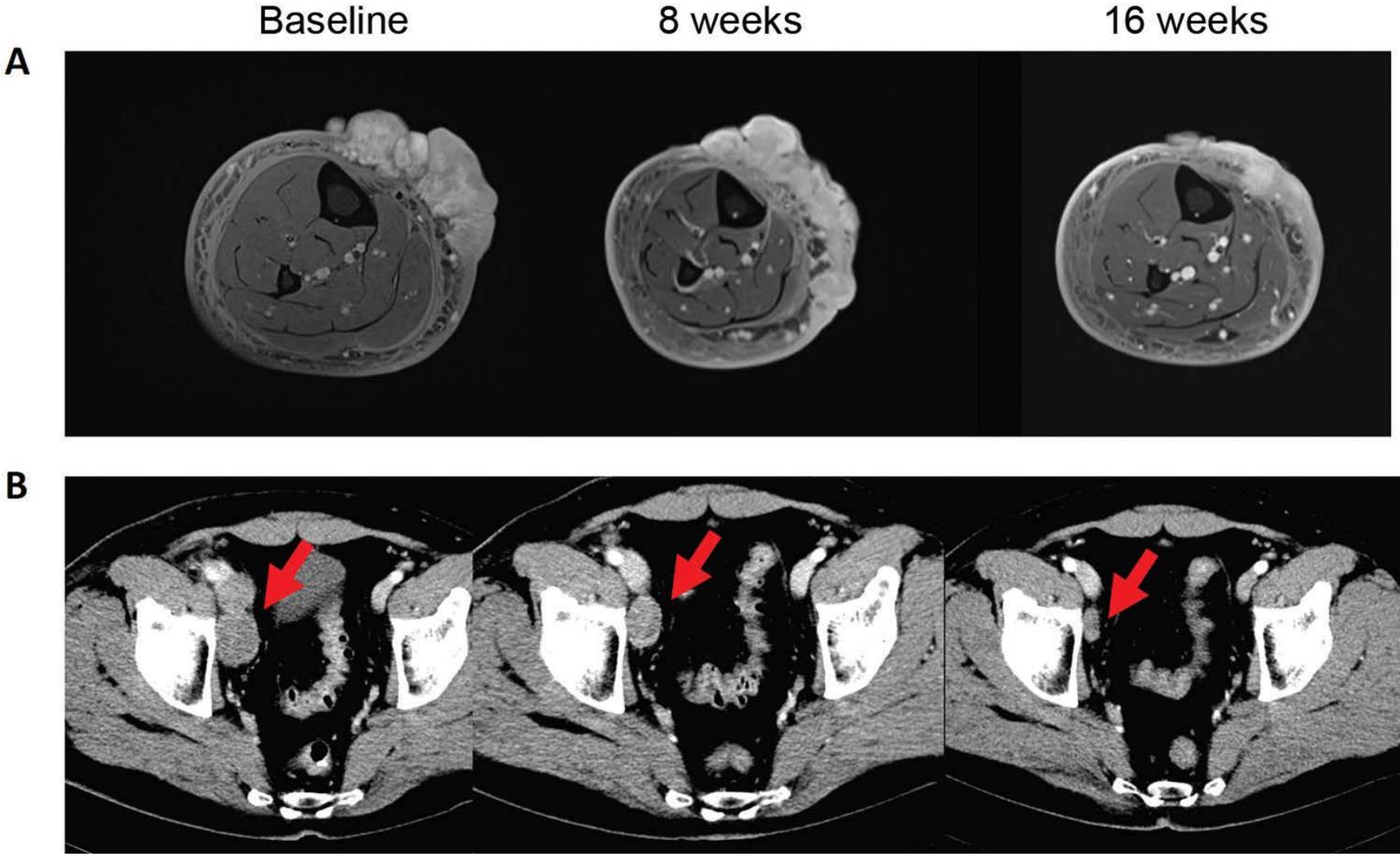
Takeaways – ASCO 2017

- Emergence of initial next-generation of IO agents (IDO, LAG-3) to complement existing checkpoint inhibitors
 - Potential to increase initial response, treat IO refractory patients.
- Potential new biomarkers may better select patients (e.g. LAG-3 expression, TMB)
- Important progress in showing the benefits of Opdivo +/- Yervoy
 - New data across lung cancer (NSCLC, mesothelioma, SCLC), adjuvant melanoma and HCC

Key Data: ASCO 2017

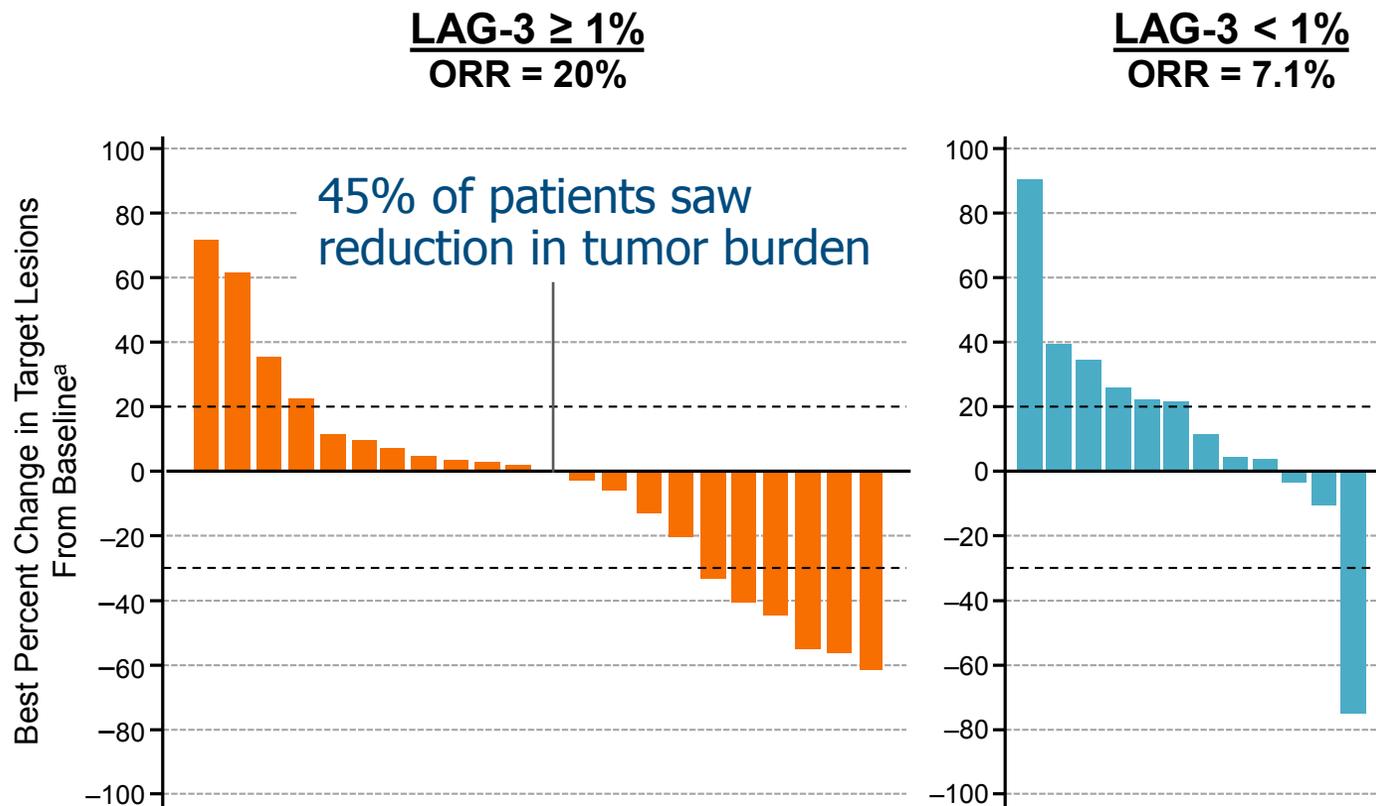
Study	Key Results
LAG-3 (Post-IO melanoma)	<ul style="list-style-type: none"> First IO asset to demonstrate efficacy in IO refractory patients with potential biomarker to select patients more likely to respond.
GITR (PK/PD)	<ul style="list-style-type: none"> Well tolerated (consistent with Opdivo single agent); increased proliferation of NK, CD8 and activation of effector and central memory cells
ECHO-204 (Melanoma, H&N, Ovarian)	<ul style="list-style-type: none"> Favorable initial efficacy in 1L melanoma and 1L H&N
Checkmate-012 (1L NSCLC)	<ul style="list-style-type: none"> First presentation of 2 year OS data with Opdivo + yervoy in 1L NSCLC; two year OS rates were 49%, 58% and 62% in all treated patients, $\geq 1\%$ PD-L1 and $\geq 50\%$ PD-L1 expression
Checkmate-142 (MSI-H CRC)	<ul style="list-style-type: none"> 55% ORR and 88% 1 year OS for combination of Opdivo/Yervoy in MSI-H CRC
Checkmate-032 (SCLC)	<ul style="list-style-type: none"> Durable responses observed for Opdivo+/-Yervoy in an expansion cohort; full data June 5th
IFCT-1501 (Mesothelioma)	<ul style="list-style-type: none"> Only I-O data in ASCO press program; embargo lifts June 5
Checkmate-040 (soraf naïve and experienced HCC)	<ul style="list-style-type: none"> Continued survival and durable objective responses in sorafanib naïve and experienced HCC
Checkmate-204 (Melanoma, Brain Mets)	<ul style="list-style-type: none"> Clinically meaningful efficacy for melanoma patients with brain mets
ECOG-1609 (Melanoma)	<ul style="list-style-type: none"> Evidence that 3mg/kg comparable DFS to 10mg/kg for adjuvant melanoma
JHU Neo-adjuvant study (Neo-adjuvant NSCLC)	<ul style="list-style-type: none"> Data to be presented June 5th; biomarkers and PD-1 blockade in neo-adjuvant setting

Anti-LAG-3 + Nivo in Advanced BRAF Wild-Type Melanoma Refractory to Nivo Monotherapy



Block Tumor Inhibition/Checkpoints: Anti-LAG3 May Overcome Anti-PD1 Resistance

Best Change From Baseline in Target Lesion Tumor Burden



- 8/48 patients analyzed had unknown LAG-3 status – data not shown

^aSix patients had clinical progression prior to their first scan and are not included in the plot. ^bOne patient had an unconfirmed best response of SD.

- Efficacy of anti-LAG3+Opdivo in heavily pretreated Melanoma patients who failed prior anti-PD1 therapy
- 76% of patients had 2 more prior systemic therapies including PD1+/-CTLA4
- LAG3+ appears to be a useful biomarker to enrich for potential benefit
- Safety profile similar to Opdivo monotherapy: 45% of patients experienced AEs (9% Gr3/4)

LAG3: First Demonstration of Efficacy in IO Relapsed/ Refractory Patients

- Potential for increased benefit in patients expressing LAG-3 biomarker
- Data consistent with mechanistic hypothesis of LAG-3 – potential application in other tumor types and settings

Next Steps:

- Expanding IO refractory melanoma cohort (up to 150 pts)
- Embark on broad development program across tumors in
 - PD-1 Resistant segments
 - IO Naïve segments
- Development of LAG-3 expression as a biomarker

Tumor Metabolism: IDO

Advancing BMS IDO:

- Differentiated PK/PD profile presented at AACR this year
- Initial efficacy data Opdivo/BMS-986205 in solid tumors expected at SITC
- CA017-003 expanded to include Opdivo/Yervoy/IDO
- Initiate several registrational trials across multiple tumors including NSCLC

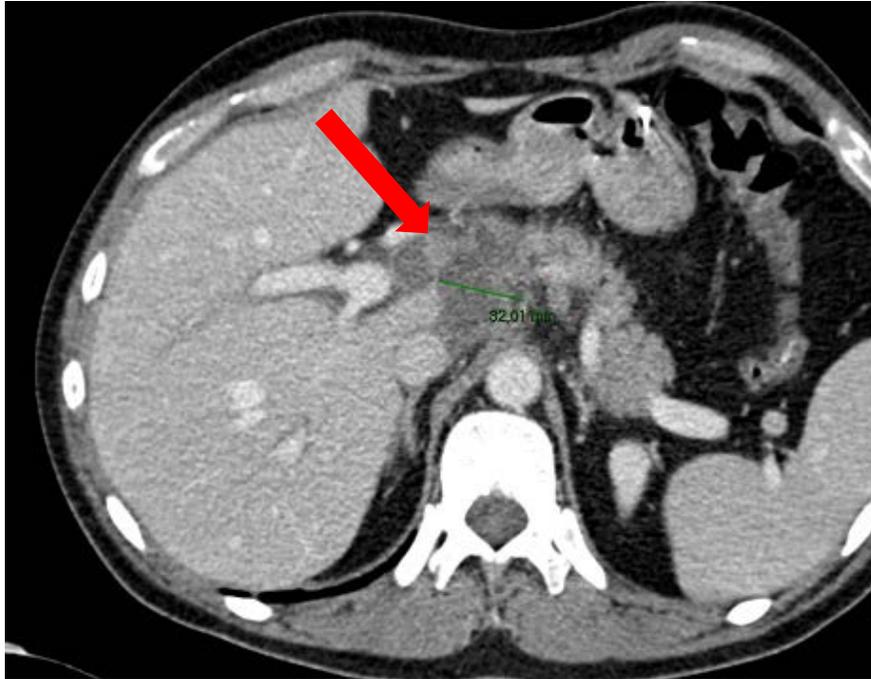
Expanding Collaboration with INCY:

- Opdivo/epacadostat shows encouraging signals in melanoma, H&N*
- Collaboration expanded to include Ph III studies in 1L NSCLC across PD-L1 spectrum, 1L H&N; expansion of ECHO-204 in IO refractory melanoma

*See abstract; full dataset presented on Monday June 5th

Activate T-effector Cells: GITR

Clinical Response in Difficult to Treat Tumors



Scan image shows a response to GITR + Opdivo in a Patient With nasopharyngeal Cancer after progression on Anti-PD-1 Therapy



Images provided by Neeltje Steeghs, The Netherlands Cancer Institute, Amsterdam, The Netherlands.

Safety profile similar to Opdivo monotherapy (70% of patients experienced an AE with 16% at Gr3/4)

Maximize NK Cells: Lirilumab

SITC 2016 data Liri+Opdivo suggested increased ORRs vs Opdivo monotherapy with a safety profile similar to Opdivo monotherapy:

- 24% ORR all-comers; 41% ORR in PDL1+
 - 71% patients experienced AEs (15% Gr3/4)

Study expanded to include:

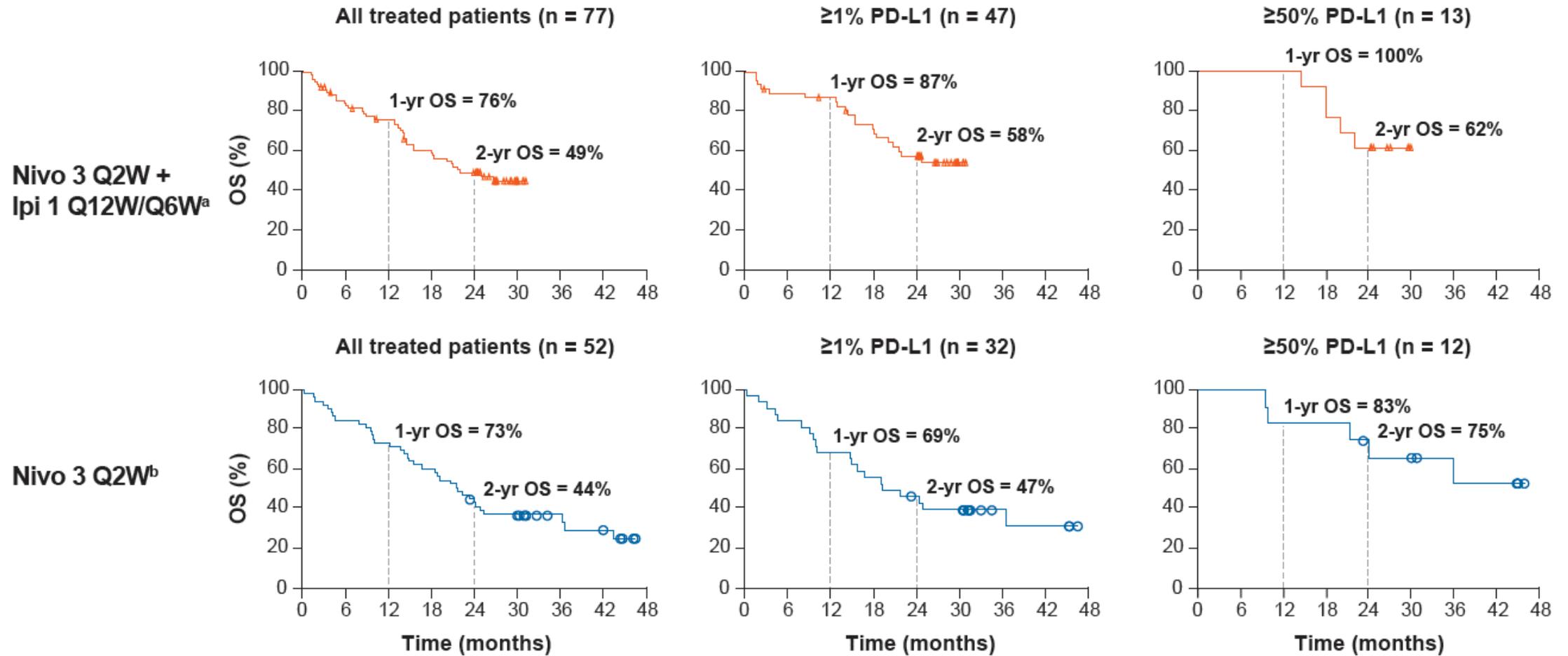
- Randomized cohort of Liri+Opdivo vs Opdivo in H&N in PD-L1+ patients
- Liri+Opdivo in squamous histologies
- Liri+Opdivo+Yervoy in H&N

Comprehensive Development Strategy in Lung Malignancies

NSCLC	Early Stage	OPDIVO + Yervoy
	Locally Advanced	OPDIVO + Chemo + RT
	Advanced/Metastatic	<ul style="list-style-type: none"> • OPDIVO Monotherapy • OPDIVO + <ul style="list-style-type: none"> • IDO • Yervoy +/- Chemo • Chemo
SCLC	Limited	OPDIVO Monotherapy OPDIVO + Yervoy
	Extensive	OPDIVO Monotherapy OPDIVO + Yervoy
Mesothelioma		OPDIVO Monotherapy OPDIVO + Yervoy

- Biomarker driven patient segmentation
- Scope for next wave combinations to potentially improve outcomes
- Need to effectively treat IO Resistant Patients

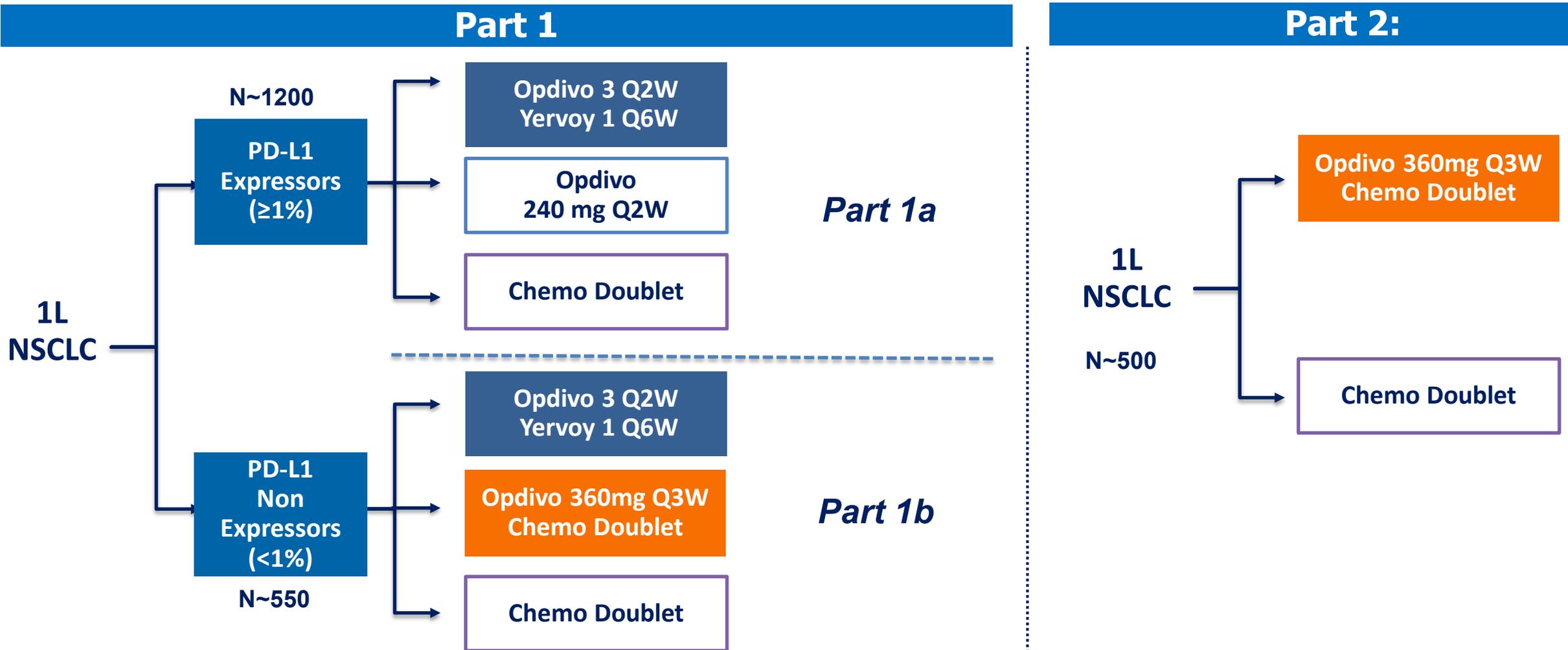
CheckMate-012: Opdivo + Yervoy in 1L NSCLC



^aData based on an April 2017 database lock; ^bData from the nivolumab monotherapy cohort based on a September 2016 database lock (median follow-up 22 months)¹¹ are provided for context; Ipi = ipilimumab; Nivo = nivolumab

Opdivo + Yervoy remained tolerable; no new safety concerns or treatment-related deaths were reported with longer follow-up

Checkmate 227: Three Phase III Trials in one NSCLC program



Part 1 – Chemo doublet options include: NSQ: pem/cis, pem/carbo; SQ: gem/cis, gem/carbo.

Part 2 – Chemo doublet options include: NSQ: pem/carbo, pem/cis; SQ: carbo/taxol.

Checkmate 568: Innovative Trial Design

Part 1

1L NSCLC



Opdivo 3 Q2W
Yervoy 1 Q6W

N~400

Part 2:

Safety lead in with at least 9 weeks follow up on study

N~30

Opdivo 360mg Q3W
Yervoy 1mg/kg Q6W
+ 2 cycles Chemo

Randomized Cohort

1L NSCLC

N~420

Opdivo 360mg Q3W
Yervoy 1mg/kg Q6W
+ 2 cycles Chemo

Opdivo 360mg Q3W
Yervoy 1mg/kg Q6W

Chemo Doublet

Chemo doublet options include: NSQ: pem/carbo, pem/cis; SQ: carbo/paclitaxel

Opdivo & Yervoy Portfolio Will Yield Significant Data

Tumor	Phase 2	Phase 3	Expected Timing*
HCC	CM-459 – Opdivo (1L)		2H 2017
Colon	CM-142 – Opdivo (2/3L MSI High)		ASCO 2017
GBM	CM-548 – Opdivo+SOC (1L)		2H 2018
Head & Neck	CM-651 – Opdivo + Yervoy (1L)		1H 2018
	CM-714 – Opdivo + Yervoy (1L Extr. Inel)		1H 2018
Bladder	CM-275 – Opdivo (2L)		Approved
Myeloma	CM-602 – Opdivo + Elo + SOC		2H 2018
RCC	CM-214 – Opdivo + Yervoy (1L)		2H 2017
Melanoma	CM-511 – Opdivo + Yervoy (1L)		2H 2017*
	CM-238 – Opdivo (Adjuvant)		2H 2018
SCLC	CM-331 – Opdivo (2L)		1H 2018
	CM-451 – Opdivo + Yervoy (1L)		1H 2018
NSCLC	CM-227 – Opdivo + Yervoy (1L) I-O, I-O/I-O, I-O/chemo		1H 2018
	CM-078 – Opdivo (2L / Asia)*		1H 2018
	CM-568 – Opdivo + Yervo + Chemo (1L)		TBD
Mesothelioma	MAPS2 IFCT-1501 – Opdivo +/- Yervoy		ASCO 2017

Timing shown represents primary completion dates except 451, 214, and 651 which match JPM disclosures. *511 Differs from clinicaltrials.gov



Bristol-Myers Squibb

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