

Merck Oncology Overview

ASCO 2017



MERCK

INVENTING FOR LIFE

June 5, 2017

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, NJ, USA

This presentation of Merck & Co., Inc., Kenilworth, NJ, USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s 2016 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

Merck Oncology Strategy

Extend and Improve the lives of people worldwide suffering from a wide range of cancers



Establish KEYTRUDA as foundational treatment in monotherapy and in combination across multiple tumor types



Explore combinations with standard of care and novel agents including other immune modulators



Identify patients most likely to benefit from KEYTRUDA through evaluation of biomarkers

Significant progress made in the last 5 years since KEYTRUDA entered the clinic

Broadest PD-1 / PD-L1 program

- More than 500 trials in more than 30 tumor types
- More than 300 combination trials
- Has shown activity in more than 20 tumor types

Roughly 40 ongoing registration-enabling studies

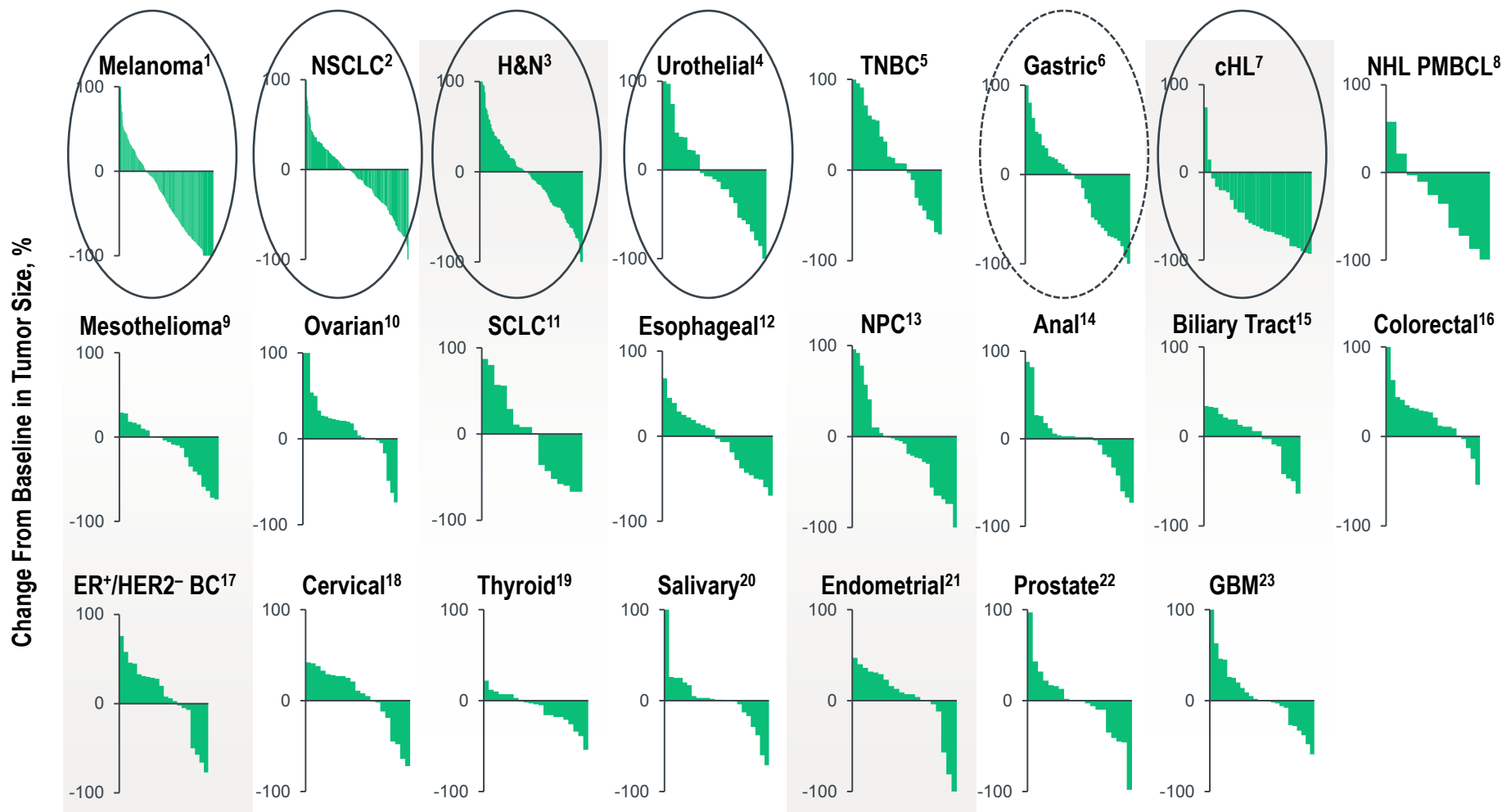
- FDA Breakthrough Designation in 8 tumors
- Approvals in 10 different indications
- First ever cancer approval based on genetic traits and not tumor location

Ongoing launches around the world in multiple settings

- First PD-1 to market in the U.S.
- Only PD-1 / PD-L1 approved in 1L lung
- Launching in more than 60 markets in melanoma and 50 markets in lung

We are establishing KEYTRUDA as a new foundation for cancer treatment

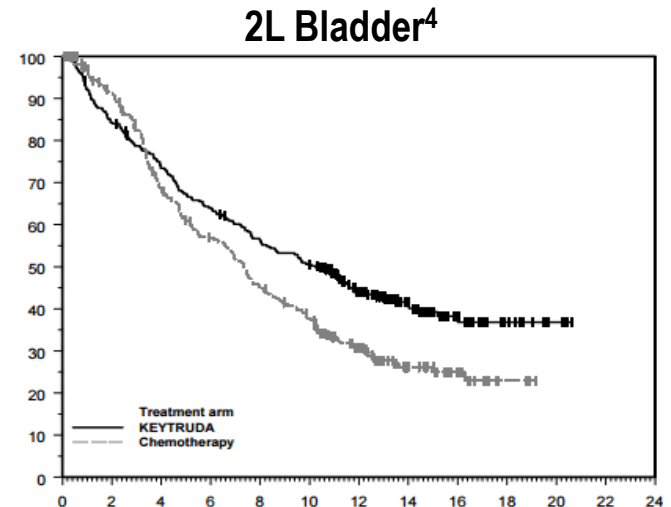
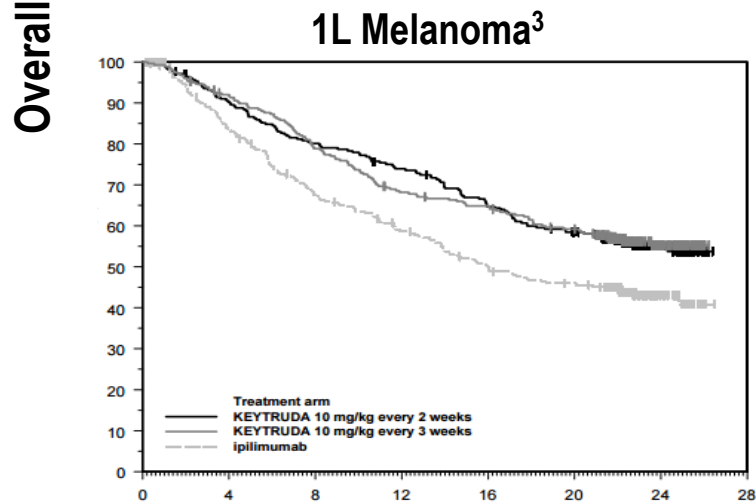
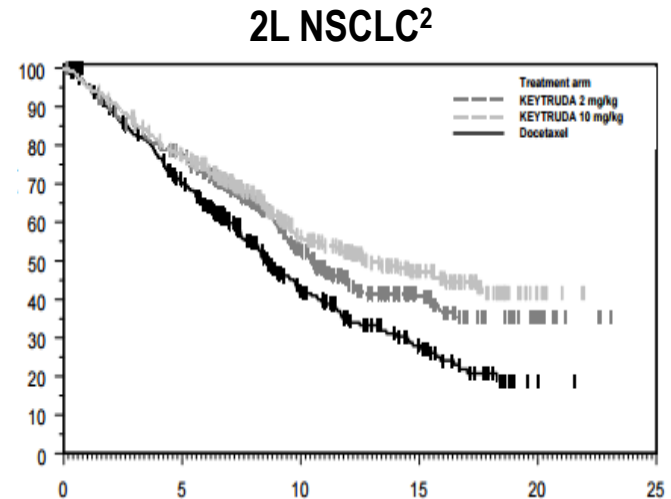
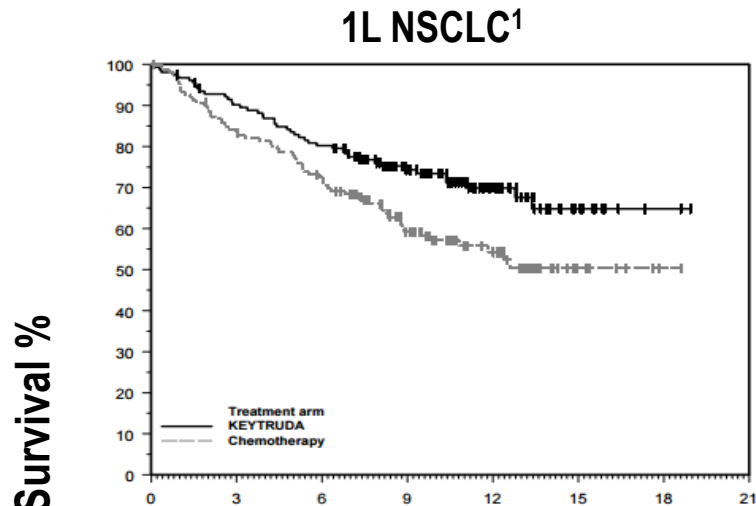
KEYTRUDA monotherapy has shown activity in more than 20 tumors resulting in approvals across 5 tumor types



1. Daud A et al. ASCO 2015; 2. Garon EB et al. ESMO 2014; 3. Seiwert T et al. ASCO 2015; 4. Plimack E et al. ASCO 2015; 5. Nanda R et al. SABCs 2014; 6. Bang YJ et al. ASCO 2015; 7. Moskowitz C et al. ASH 2014; 8. Zinzani PL et al. ASH 2015; 9. Alley EA et al. AACR 2015; 10. Varga A et al. ASCO 2015; 11. Ott PA et al. 2015 ASCO; 12. Doi T et al. ASCO 2015; 13. Hsu C et al. ECC 2015; 14. Ott PA et al. ECC 2015; 15. Bang Y-J et al. ECC 2015; 16. O'Neil B et al. ECC 2015; 17. Rugo HS et al. SABCs 2015; 18. Frenel JS et al. ASCO 2016; 19. Mehner JM et al. ASCO 2016; 20. Cohen R et al. ASCO 2016; 21. Ott PA et al. ASCO 2016; 22. Hansen AR et al. ESMO 2016; 23. Reardon D et al. SNO 2016.

Gastric: sBLA accepted for Priority Review with PDUFA date of September 22, 2017

KEYTRUDA has also demonstrated improvements in overall survival...



Time in Months

...with many additional registration-enabling studies in monotherapy and combination currently underway

ONGOING REGISTRATION-ENABLING TRIALS

Melanoma

Adjuvant (KN054)
1L + T-Vec (Amgen)
1L + IDO-1 (Incyte)

Head and Neck

1L + chemo/cetuximab (KN048)
2L (KN040)
2L Nasopharyngeal (KN122)
Locally Advanced (KN412)

Triple Negative Breast

1L + Chemo (KN355)
2L+ (KN086)
2L/3L (KN119)
TNBC Adj (KN242)
Neoadjuvant (KN522)

Lung

1L NSCLC (KN042)
1L + pem / carbo non sq NSCLC (KN189)
1L + paclitaxel sq NSCLC (KN407)
Adjuvant NSCLC (KN091)
1L + chemo SCLC (KN604)

Hematological Malignancies

rrHL (KN204)
2L NHL rrPMBCL (KN170)
1L MM + len/dex (KN185)
3L rrMM + pom/dex (KN183)

Renal Cell

1L (KN427)
Adjuvant (KN564)
1L + Axitinib (KN426)
1L + Lenvatinib (Esai)

Gastrointestinal

1L Gastric + chemo (KN062)
2L Gastric (KN061)
3L Gastric (KN059)*
2L Esophageal (KN181)
3L Esophageal (KN180)
1L CRC MSI-high (KN177)
3L CRC MSI-high (KN164)

Bladder

1L + Chemo (KN361)
2L NIBC (KN057)

Hepatocellular

2L (KN224)
2L (KN240)

Other

2L Ovarian (KN100)
2L Prostate (KN199)

Primary completion date within the next 18 months as per clinicaltrials.gov as of 5/30/2017

*Study supported a sBLA currently under review

ASCO 2017: Findings from more than 50 abstracts across 16 different types of cancer were presented



Lung

- KEYNOTE-021G: + Pemetrexed and Carboplatin as 1L – Poster
- KEYNOTE-024: vs. Chemo as 1L NSCLC (TPS \geq 50%) Update – Oral



GU & GI

- KEYNOTE-052: 1L bladder – Oral
- KEYNOTE-045: 2L bladder – Oral
- KEYNOTE-059: 3L gastric – Oral



Breast

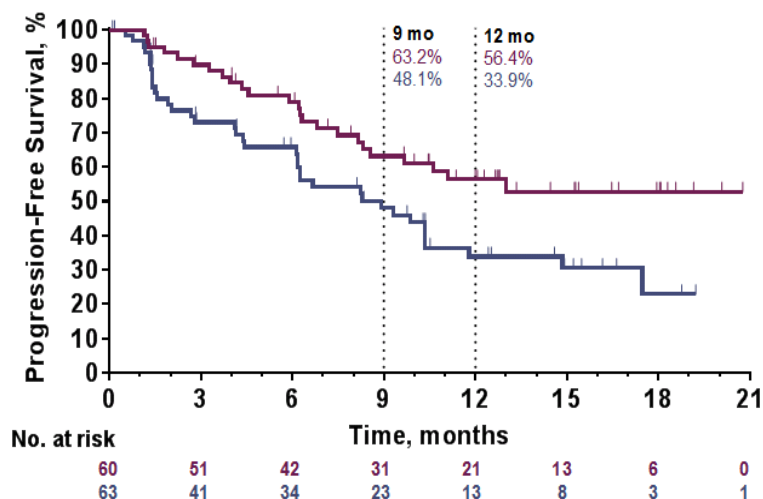
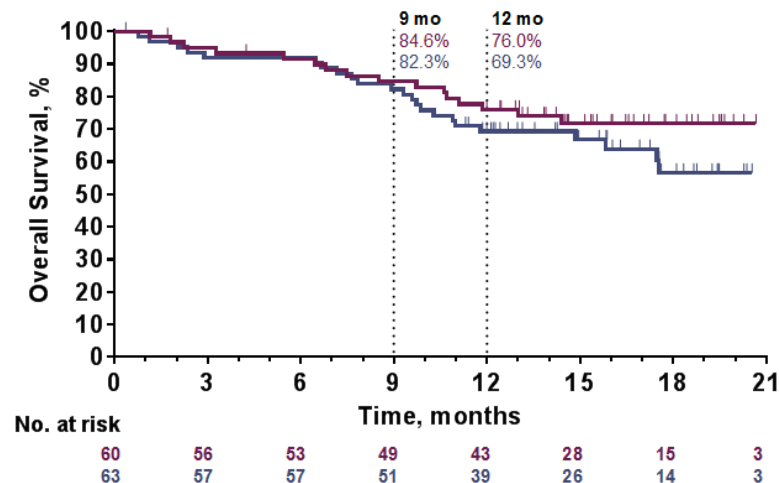
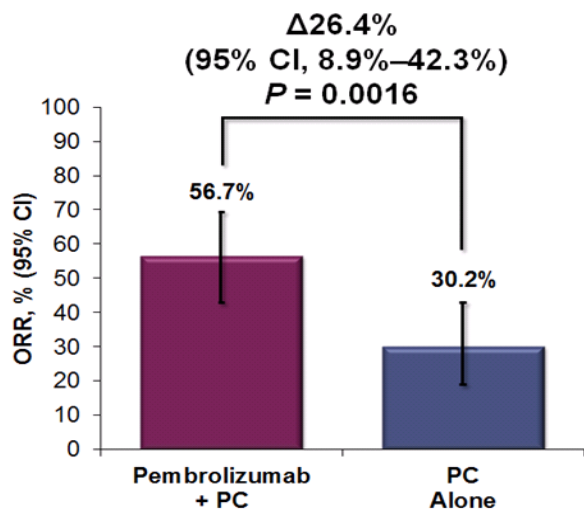
- KEYNOTE-173: Neoadjuvant TNBC – Oral
- I-SPY 2 TRIAL: Neoadjuvant TNBC & HR+ – Oral



Lung

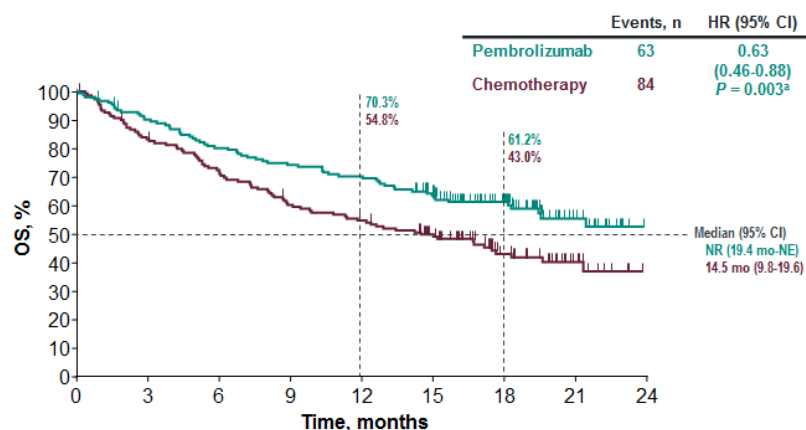
- KEYNOTE-021G: + Pemetrexed and Carboplatin as 1L – Poster
- KEYNOTE-024: vs. Chemo as 1L NSCLC (TPS \geq 50%) Update – Oral

KEYNOTE-21G: Beginning to show trend to OS benefit with further follow-up (not statistically significant)



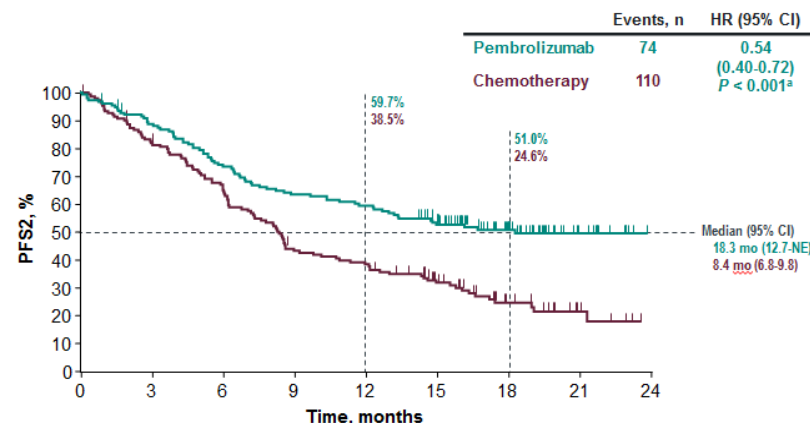
- KN-021G approved based on significant improvement in ORR and PFS
- Trend toward OS benefit is emerging despite the high rate of crossover (75%)

KEYNOTE-024: OS benefit continues through 2-years & exploratory analysis of PFS2 shows KEYTRUDA as initial therapy provided overall better disease control



Overall Survival

- Continued to show OS benefit over chemo as 1L therapy for mNSCLC with PD-L1 TPS $\geq 50\%$
- Despite a 10% increase in the crossover rate from the primary analysis, **there remained a high degree of separation of the OS curves**



PFS2

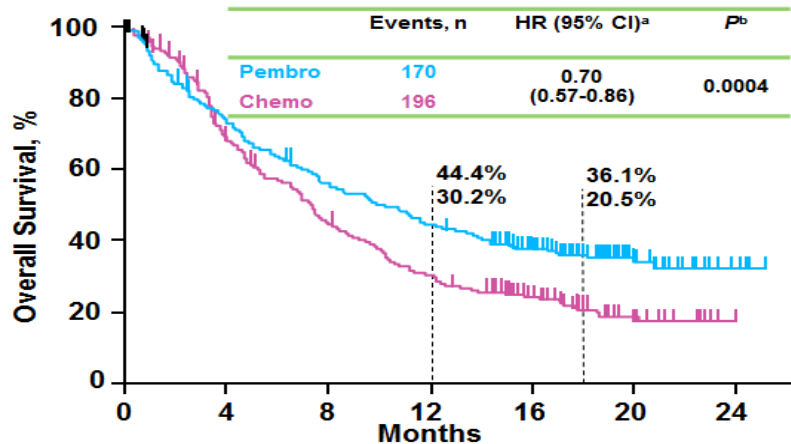
- PFS2 was substantially improved for patients in the pembro arm vs the chemo arm
- Patients whose tumors have PD-L1 TPS $\geq 50\%$ have better survival if **beginning treatment with pembro** rather than platinum-doublet chemo



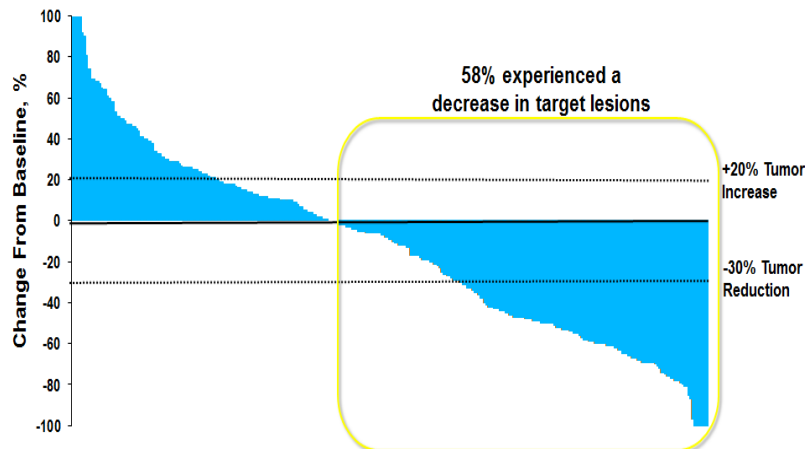
GU & GI

- KEYNOTE-045: 2L bladder – Oral
- KEYNOTE-052: 1L bladder – Oral
- KEYNOTE-059: 3L gastric – Oral

KEYNOTE-045 & KEYNOTE-052: Approved in U.S. for treatment of urothelial cancer in 2L based on OS & in cisplatin-ineligible patients (1L) based on ORR

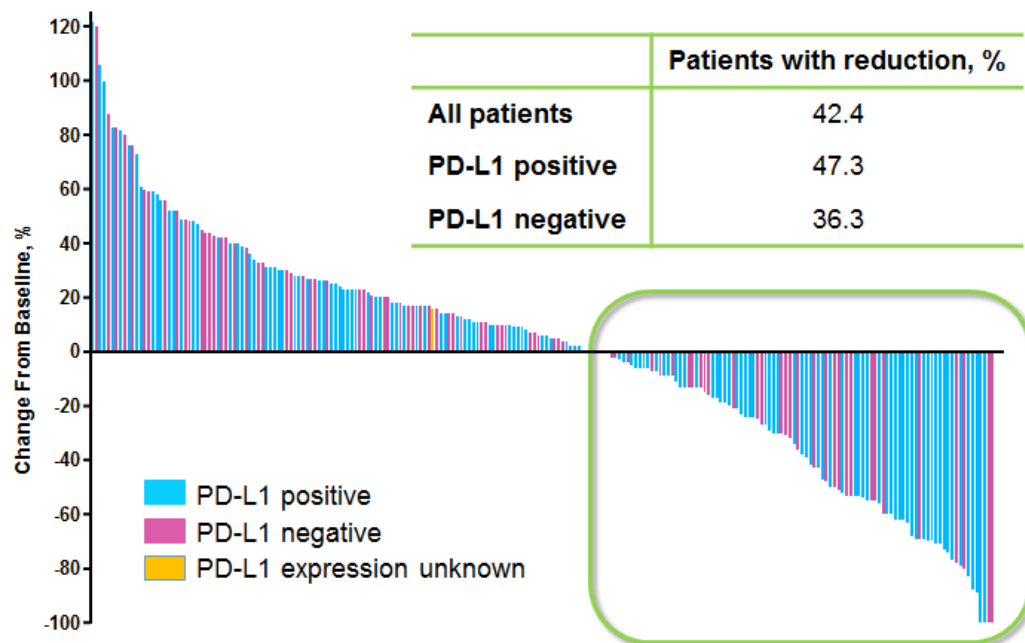


- KEYNOTE-045: Only PD-1 / PD-L1 to show OS in 2L setting [HR = 0.70 OS (p-value 0.0004)]



- KEYNOTE-052: ORR of 29% in all patients

KEYNOTE-059, cohort 1: Promising antitumor activity in patients with advanced gastric cancer progressing after ≥ 2 prior lines of therapy



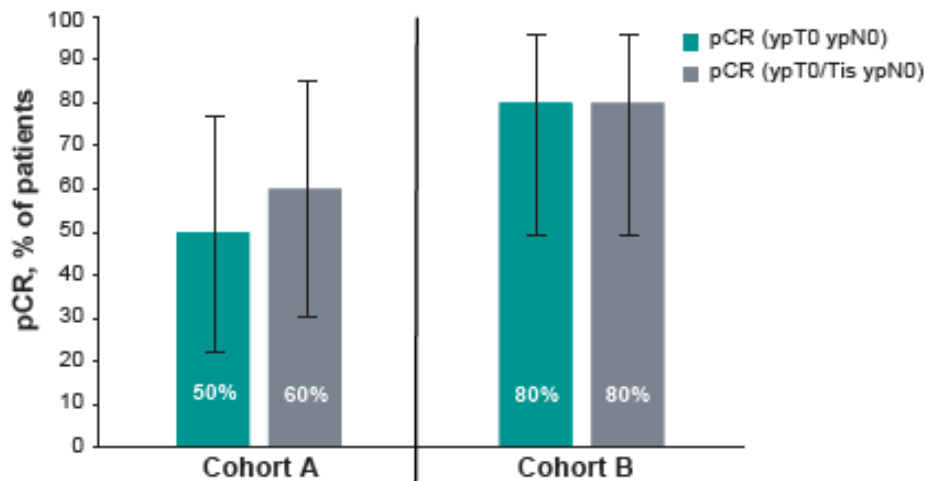
- 11.6% ORR in total patient population (N=259)
 - 15.5% ORR in PD-L1 positive patients
 - 6.4% in PD-L1 negative patients
- sBLA accepted for Priority Review with PDUFA date of September 22, 2017



Breast

- KEYNOTE-173: Neoadjuvant TNBC – Oral
- I-SPY 2 TRIAL: Neoadjuvant TNBC & HR+ – Oral

KEYNOTE-173 & I-SPY 2 TRIAL: Early promise of chemo-combo in breast cancer



- KEYNOTE-173: Promising preliminary data add to the growing body of evidence for KEYTRUDA activity in breast cancer

Signature	Estimated pCR rate (95% probability interval)		Probability pembro is superior to control	Predictive probability of success in phase 3
	Pembro	Control		
All HER2-	0.46 (0.34 – 0.58)	0.16 (0.06 – 0.27)	> 99%	99%
TN	0.60 (0.43 – 0.78)	0.20 (0.06 – 0.33)	>99%	>99%
HR+/HER2-	0.34 (0.19 – 0.48)	0.13 (0.03 – 0.24)	>99%	88%

- I-SPY 2 TRIAL: Nearly tripled pCR rate for HR+/HER2- patients and tripled pCR rate for TNBC patients

The Bayesian model estimated pCR rates appropriately adjust to characteristics of the I-SPY 2 population. The raw pCR rates (not shown) are higher than the model estimate of 0.604 in TNBC.

Tremendous progress so far in establishing KEYTRUDA as an important cancer treatment across many tumor types, with much more to come...

✓ Melanoma
✓ NSCLC

Wave 1

✓ Head and Neck
✓ Bladder
Gastric*
TNBC
✓ Colorectal
✓ Hodgkin Lymphoma
✓ MSI-High

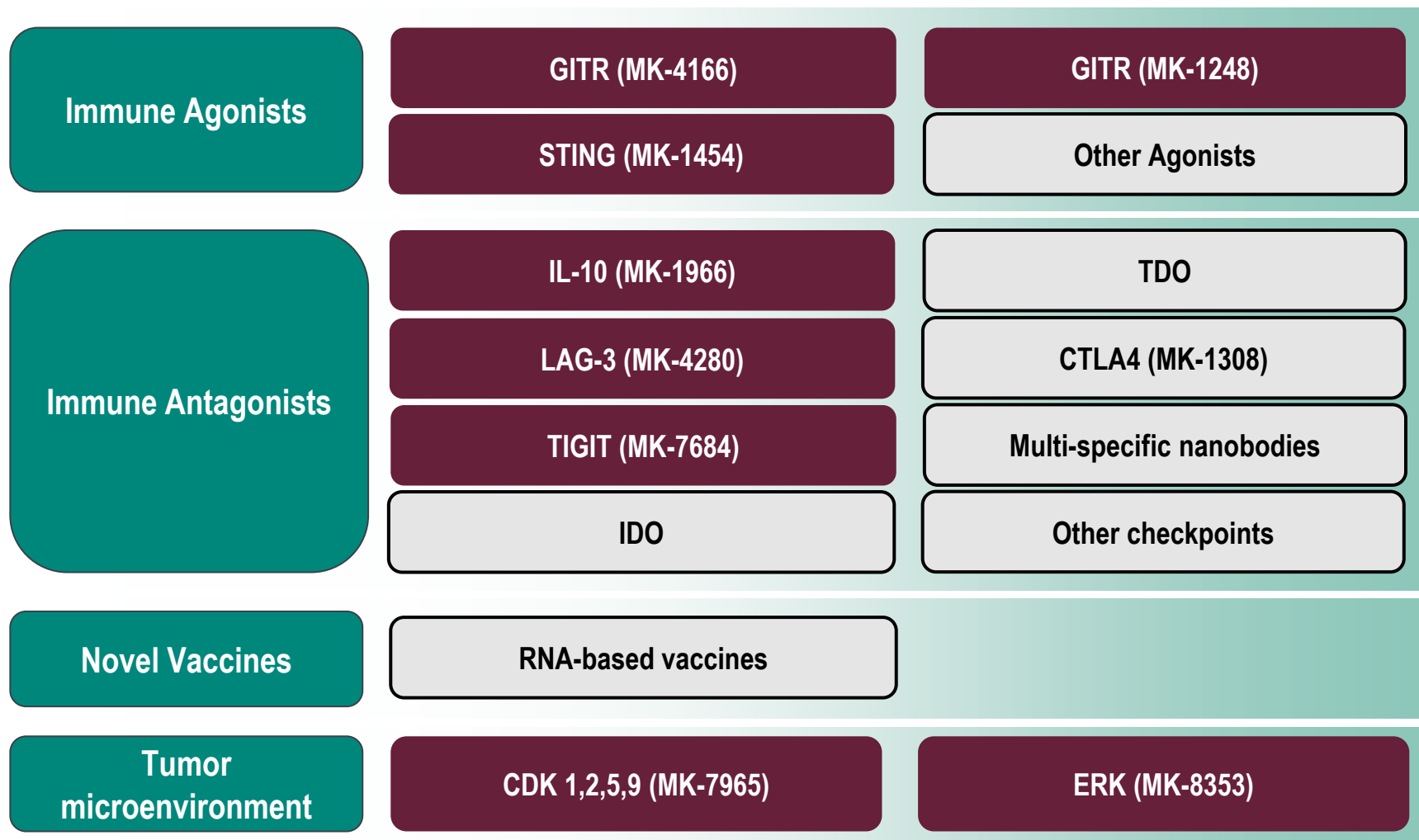
Wave 2

Esophageal
Renal
Ovarian
Prostate
Multiple Myeloma
Non-Hodgkin Lymphoma
Hepatocellular
Other Thoracic Malignancies
Gynecological Malignancies
Rare Tumors

Wave 3

Investigating Over 30 Tumor Types in Multiple Lines of Therapy

We have established an internal oncology pipeline focused on agents that could further enhance KEYTRUDA activity



 Clinical Programs

 Preclinical Programs

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Explore combinations with standard of care and novel agents including other immune modulators



Identify patients most likely to benefit from KEYTRUDA through evaluation of biomarkers



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Q&A