

Merck ASCO Event June 6, 2016



### 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 2015 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).



### Agenda

- Strategy Overview
- Combination Strategy
- Biomarker Strategy
- Closing and Q&A



### **Merck's Strategy in Oncology**

### Improve long-term disease control and survival across a wide range of cancers



Establish KEYTRUDA as a foundation for the treatment of cancer in monotherapy and in combinations



Identify patients most likely to benefit from KEYTRUDA



### **KEYTRUDA Program Accomplishments to Date**

#### In 5 years since entering clinical development

- ✓ First anti-PD-1 to market in the U.S.
- ✓ Approvals in melanoma and 2L PD-L1+ NSCLC
- ✓ Demonstrated overall survival
  - vs. ipilimumab in melanoma
  - vs. docetaxel in 2L PD-L1+ NSCLC
- ✓ Filed in Head and Neck Cancer (U.S.); Priority Review granted
- ✓ Launching in >50 markets globally
- ✓ Clinical activity in more than 20 different tumor types
- ✓ More than 30 registration-enabling studies ongoing
- ✓ 4 FDA Breakthrough Designations





# ASCO 2016: Continuing to Demonstrate Breadth and Depth of the Potential for KEYTRUDA

#### >80 Abstracts

Data in ~20 tumor types

Overall Survival data in Melanoma and NSCLC

Long-term follow-up in Head and Neck Cancer

Early evidence from ~10 combinations

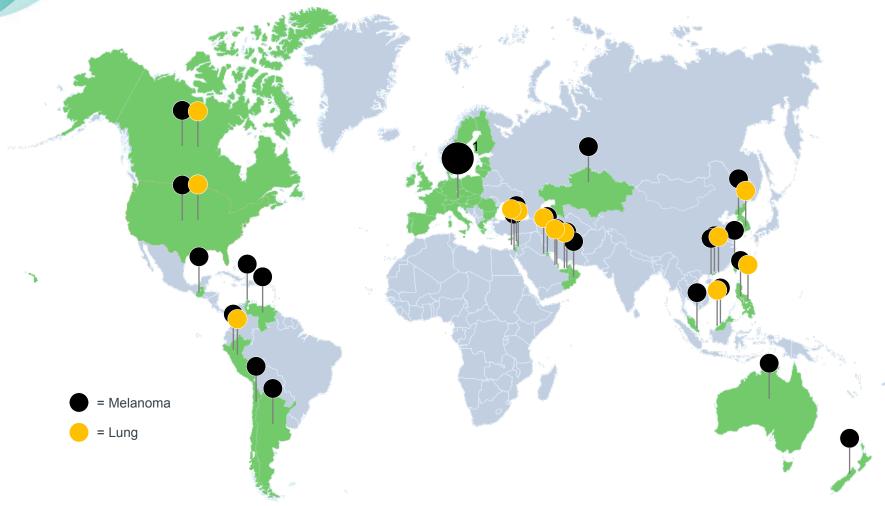
#### 1 Abstract

KEYNOTE-001 Melanoma

ASCO 2013 ASCO 2016



#### Global Opportunity: Launching In More than 50 Markets



<sup>1.</sup> Europe: markets depicted on map with dots include France, Germany, Spain, Italy, UK & Switzerland. Additional 24 EU markets shaded green include Slovakia, Czech, Hungary, Finland, Estonia, Latvia, Lithuania, Poland, Denmark, Sweden, Norway, Austria, Netherlands, Belgium, Luxembourg, Portugal, Slovenia, Croatia, Malta, Bulgaria, Romania, Greece, Ireland, and Cyprus.





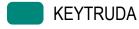
#### The Broadest Program of Any Anti-PD-1/PD-L1 Drug

More than 270 trials in more than 30 tumors; more than 100 combination trials

#### **EARLY DEVELOPMENT** REGISTRATION Melanoma **GITR (MK-4166) Head and Neck** 1L (KN006) • 1L + chemo/cetuximab (KN048) 2L (KN002) 2L (KN040) **GITR (MK-1248)** Adjuvant (KN053/054) • 3L (KN055) • 1L + T-Vec (Amgen) 2L Nasopharyngeal (KN122) 1L + IDO-1 (Incvte) LAG-3 (MK-4280) **NSCLC Hematological Malignancies** • 1L (KN024) IL-10 (MK-1966) • 3L HL (KN087) • 1L (KN042) • rrHL + brent. ved. (KN204) • 1L + pemetrexed (KN189) • 2L NHL rrPMBCL (KN170) **CEACAM1 (MK-6018)** • 1L + chemo (KN407) 1L MM + len/dex (KN185) • 2/3L (KN010) 2L rrMM + pom/dex (KN183) Adjuvant (KN091) CDK 1,2,5,9 (MK-7965) **Bladder Gastrointestinal BET-Bromodomain (MK-8628)** • 1L (KN052) 1L Gastric + chemo (KN062) • 2L NIBC (KN057) • 2L Gastric (KN061) • 2L (KN045) • 3L Gastric (KN059) PI3K Delta (MK-1822) 2L Esophageal (KN181) **Triple Negative Breast** 3L Esophageal (KN180) • 2L+ (KN086) 1L CRC MSI-high (KN177) • 3L CRC MSI-high (KN164) • 2L/3L (KN119) **Multiple Preclinical Programs** Hepatocellular Other

• 2L (KN224)

2L (KN240)



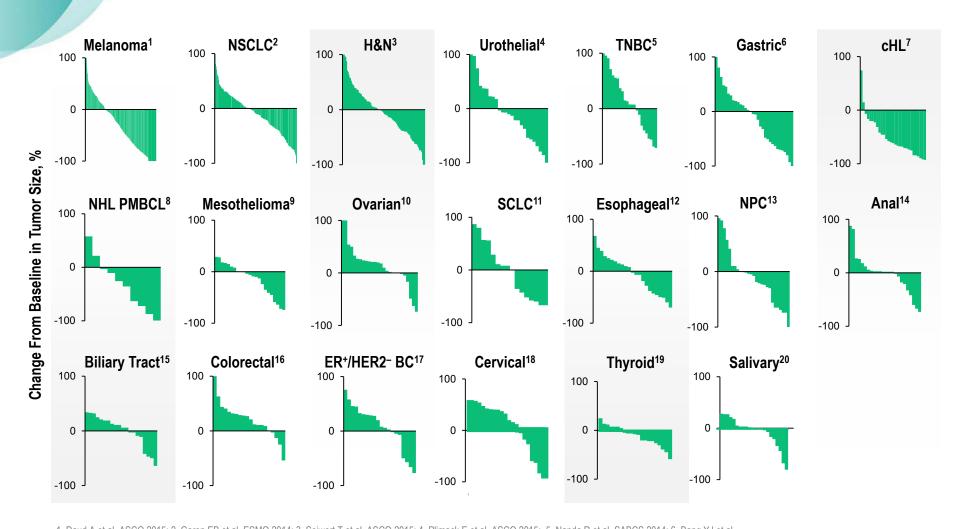




• 1L Ovarian (KN100)

• 2L Prostate (KN199)

#### **Keytruda Monotherapy Has Shown Activity in 20 Tumors**

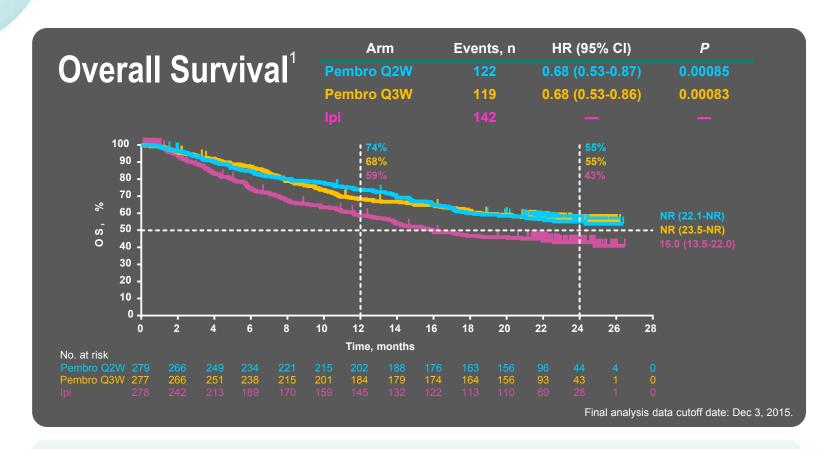


<sup>1.</sup> Daud A et al. ASCO 2015; 2. Garon EB et al. ESMO 2014; 3. Seiwert T et al. ASCO 2015; 4. Plimack E et al. ASCO 2015; 5. Nanda R et al. SABCS 2014; 6. Bang YJ et al. ASCO 2015; 7. Moskowitz C et al. ASH 2014; 8. Zinzani PL et al. ASH 2015; 9. Alley EA et al. AACR 2015; 10. Varga A et al. 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. Mehnert JM et al. ASCO 2016; 20. Cohen R et al. ASCO 2016.





## ASCO Monotherapy Data Demonstrate Overall Survival In Ipilimumab-Naive Melanoma



Improve long-term disease control and survival across a wide range of cancers





### Improving Efficacy with Selective Combination Therapy

More than 100 combination trials ongoing

### **Combination Strategy**

**Standard Therapies** 

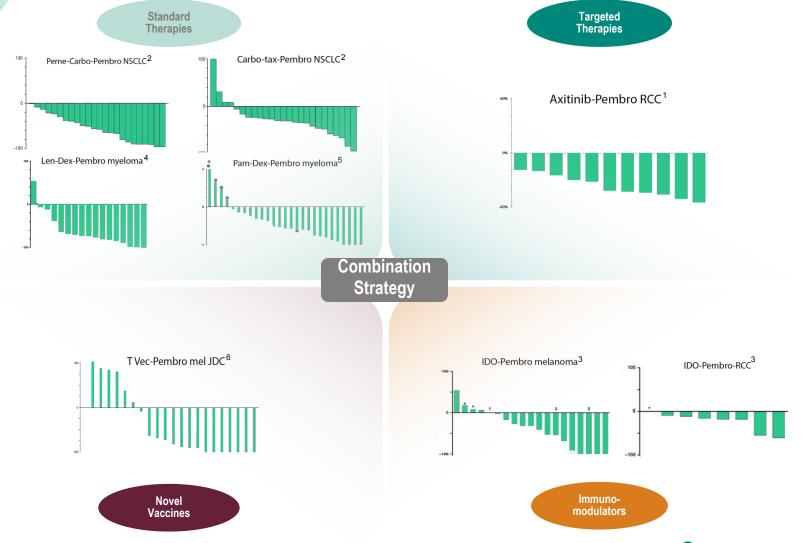
Targeted Therapies

Immunomodulators Novel Vaccines





### **KEYTRUDA-Based Combinations Show Potential for Enhanced Activity In Many Tumor Types**

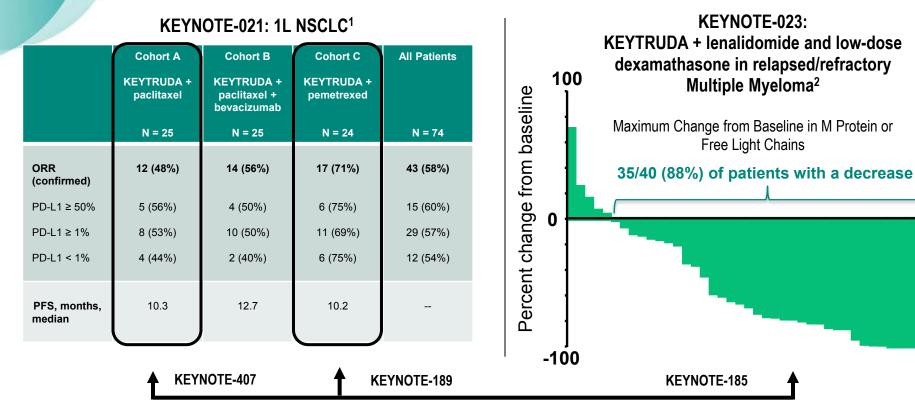


<sup>1.</sup> Data on file; 2. Papadimitrakopoulou V et al. ASCO 2015; 3. Gangadhar T et al. SITC 2015; 4. San Miguel L et al. ASH 2015.



<sup>5.</sup> Badros A et al. ASH 2015; 6. Long GV et al. SMR 2015.

#### **ASCO Data Demonstrate Further Progress with Combinations**



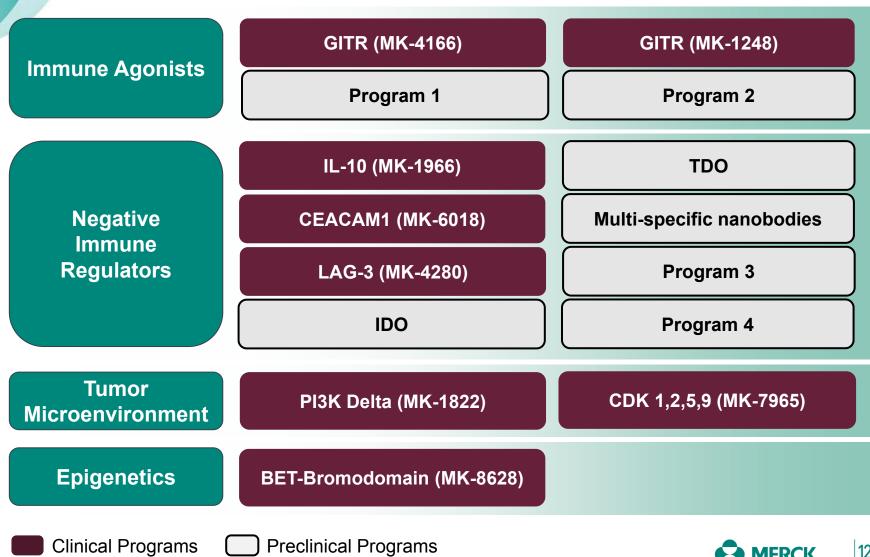
**Advanced to Phase 3** 

Establish KEYTRUDA as a foundation for the treatment of cancer in monotherapy and in combinations





#### **Internal Pipeline Further Enables Combination Strategy**





#### **Biologic Rationale for Predictive Biomarkers**

Ligand Expression on Tumor

Immunogenic Microenvironment

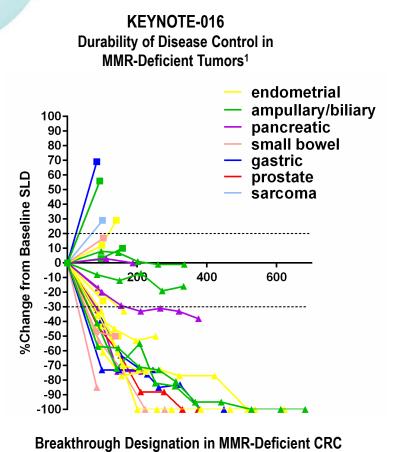
Increased Antigen
Presentation Due
to High DNA
Mutation Load

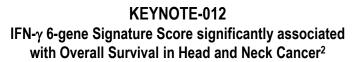
PD-L1 and PD-L2 Expression

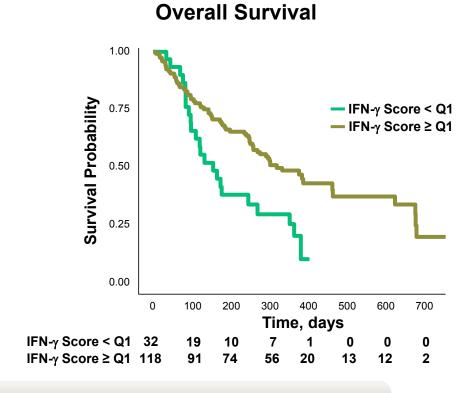
Immune-Related Gene Expression (GEP) Signature DNA Mismatch Repair Deficiency, DNA Polymerase Mutation



# ASCO Data Demonstrate the Potential Importance of Patient Selection Through PD-L1, MMR-Deficiency, and IFN-γ Markers







Identify patients most likely to benefit from KEYTRUDA





#### What to Expect From Merck Oncology in 2016

- ✓ Additional internally-owned programs to enter the clinic
- ✓ Filings in additional tumor types
- Anticipated approval in Head and Neck Cancer (U.S.)
- Anticipated approvals from KEYNOTE-010 filings in 2L PD-L1+ NSCLC
- Results from 1L NSCLC Study, KEYNOTE-024
- Additional novel combination data





Q&A

