

### **Welcome & Introductions**

Ken Frazier. Chairman and Chief Executive Officer

### **Financial & Value Creation Overview**

Rob Davis, Chief Financial Officer and Head of Global Services

### **Commercial Growth Drivers: KEYTRUDA & Beyond**

Frank Clyburn, Chief Commercial Officer

### **Animal Health Innovation**

Rick DeLuca, President, Merck Animal Health

## **Merck R&D Strategy Overview**

Dr. Roger M. Perlmutter, President, Merck Research Laboratories

## **Pipeline Opportunities**

Dr. Roy Baynes, Head of Clinical Development and Chief Medical Officer, and Mike Nally, Chief Marketing Officer

### **Future of Merck R&D: Panel Discussion**

Merck Research Laboratories Leadership: Dr. Dean Li, Dr. Fiona Marshall and Dr. Daria Hazuda

## **Q&A / Closing Remarks**

All

### **Lunch Break**

ΑII

### **Breakout Sessions**

Pipeline Deep Dive

Next Generation Discovery

International Opportunity & China





# **BROAD ONCOLOGY STRATEGY TO IMPROVE OUTCOMES FOR CANCER PATIENTS GLOBALLY**





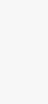








**Roy Baynes** 

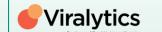




**Broadly explore** combinations to reach more patients











**Advance pipeline and** pursue strategic collaborations and acquisitions to expand portfolio

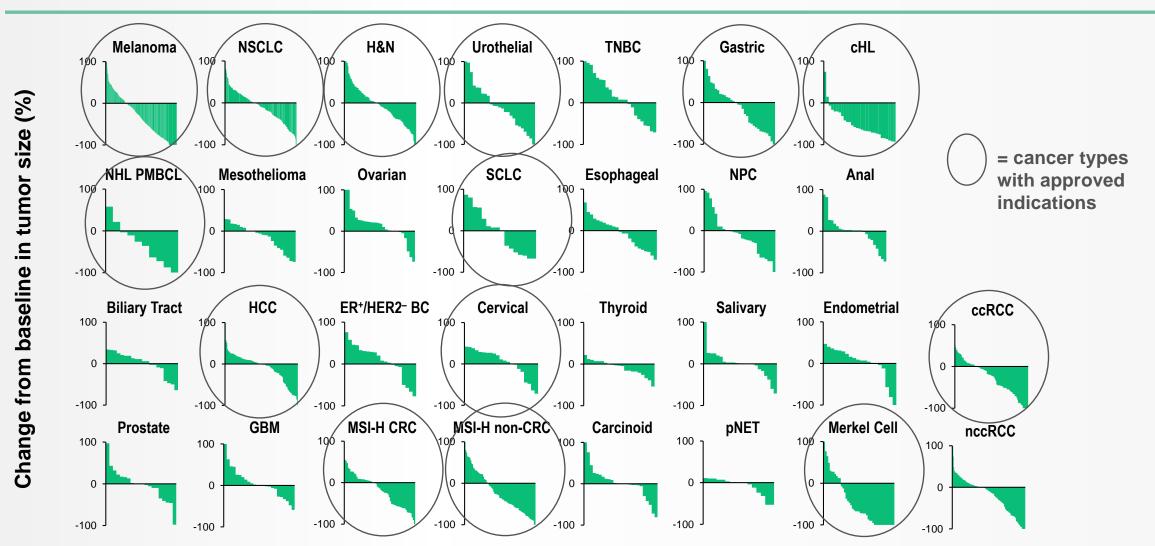




**Establish KEYTRUDA as foundational treatment** across most tumor types and stages of disease

# MERCK INVENTING FOR LIFE

## **KEYTRUDA: BROAD ACTIVITY IN >25 CANCER TYPES**







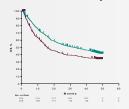




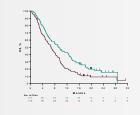
**Roy Baynes** 

# **KEYTRUDA: REPEATED OVERALL SURVIVAL** BENEFITS IN MONOTHERAPY AND IN COMBINATION

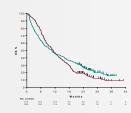




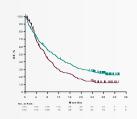
1L Esophageal. CPS ≥10 **KEYNOTE-181** Pembro vs Chemo



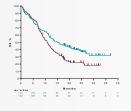
1L Gastric, CPS ≥1 KEYNOTE-062 Pembro vs Chemo



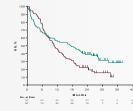
2L Bladder, Any PD-L1 KEYNOTE-045 Pembro vs Chemo



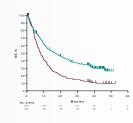
1L HNSCC, CPS ≥20 **KEYNOTE-048** Pembro vs **EXTREME** 



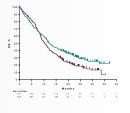
1L Gastric, CPS ≥10 **KEYNOTE-062** Pembro vs Chemo



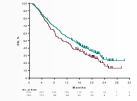
2L+ NSCLC. TPS ≥50% **KEYNOTE-010** Pembro vs Docetaxel



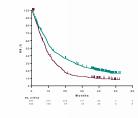
1L HNSCC, CPS ≥1 KEYNOTE-048 Pembro vs **EXTREME** 



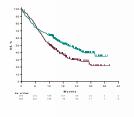
2L HCC, Any PD-L1 KEYNOTÉ-240 Pembro vs Placebo



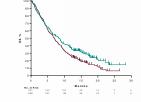
2L+ NSCLC. TPS ≥1% **KEYNOTE-010** Pembro vs Docetaxel



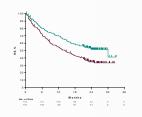
1L NSCLC, TPS ≥50% KEYNOTE-042 Pembro vs Chemo



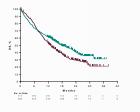
2L+ HNSCC, Any PD-L1 KEYNOTE-040 Pembro vs SOC



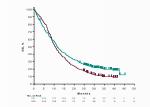
1L NSCLC. TPS ≥50% **KEYNOTE-024** Pembro vs Chemo



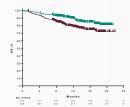
1L NSCLC, TPS ≥20% KEYNOTE-042 Pembro vs Chemo



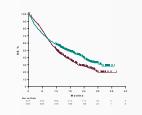
1L HNSCC, Any PD-L1 KEYNOTE-048 Pembro vs EXTREME



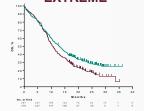
1L RCC, Any PD-L1 **KEYNOTÉ-426** Pembro + Axitinib vs **Sunitinib** 



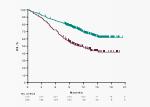
1L NSCLC. TPS ≥1% KEYNOTE-042 Pembro vs Chemo



1L HNSCC, CPS ≥1 **KEYNOTE-048** Pembro + Platinum vs **EXTREME** 



1L NSQ NSCLC, Any PD-L1 **KEYNOTE-189** Pembro + Pem/Platinum vs Placebo + Pem/Platinum



1L SQ NSCLC, Any PD-L1 **KEYNOTE-407** Pembro + Carboplatin/Taxane vs Placebo + Carboplatin/Taxane









Dr.

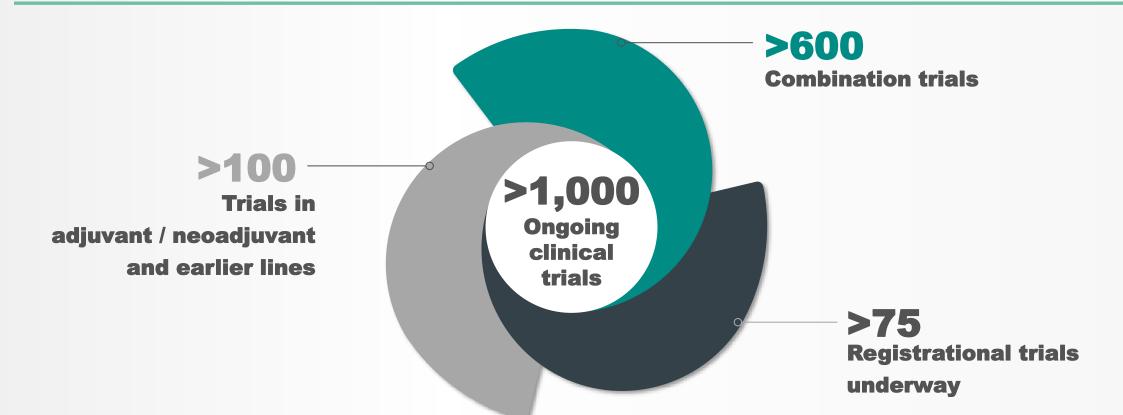
Roy

**Baynes** 



# **KEYTRUDA: STILL IN EARLY INNINGS** OF DEVELOPMENT















Continuing to build a wall of data

# **KEYTRUDA: ROBUST I-O PROGRAM IN ADJUVANT / NEOADJUVANT AND EARLIER LINES OF THERAPY**









Roy

**Baynes** 





## 2018

Adjuvant Melanoma (KN-054) **APPROVED** 

### 2021

**NSCLC Adjuvant (KN-091) HNSCC Adjuvant /** Neoadjuvant (KN-689)

## 2023

**Gastric & Esophageal Adjuvant** / Neoadjuvant (KN-585) **HNSCC Locally Advanced** (KN-412)

## 2025

Adjuvant / Neoadjuvant MIBC (KN-866) Adjuvant / Neoadjuvant MIBC (KN-905) **HCC Adjuvant (KN-937)** NSCLC Stage I/IIa (KN-867)



**TNBC Neoadjuvant /** Adjuvant (KN-522) cSCC Locally Advanced (KN-629)

### 2022

Adjuvant Melanoma (KN-716) RCC Adjuvant (KN-564) **2L NMIBC (KN-057) MIBC Locally Advanced** (KN-676)

### 2024

**NSCLC Neoadjuvant (KN-671)** 

### 2026+

**TNBC Adjuvant (KN-242)** cSCC Locally Advanced (KN-630) ER+ / HER2- Breast Cancer Adjuvant / Neoadjuvant (KN-756)



## Many registrational trials with readouts over the coming years

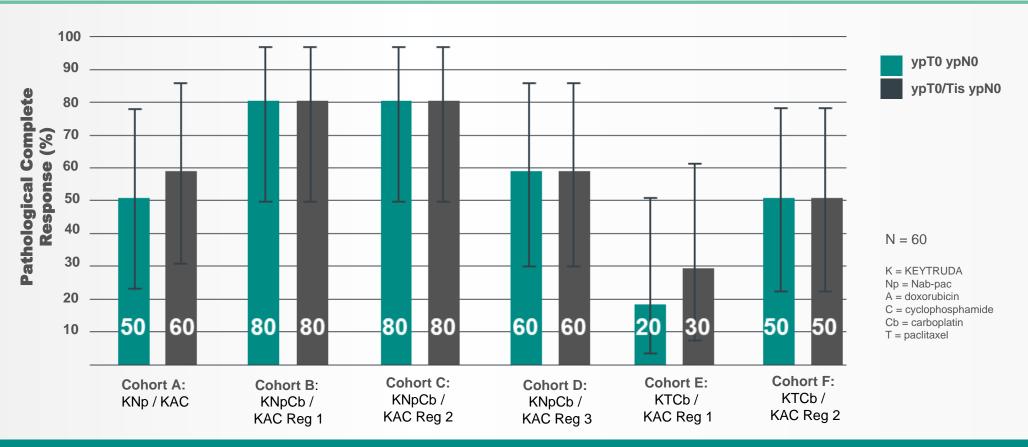








# **KEYTRUDA: EARLY EVIDENCE IN BREAST CANCER; 10 ONGOING TRIALS**



**Encouraging results from KEYNOTE-173 show promise** in adjuvant / neoadjuvant settings

# **KEYTRUDA: EARLY STAGE PROSTATE CANCER** DATA INFORM PHASE 3 DEVELOPMENT PROGRAM







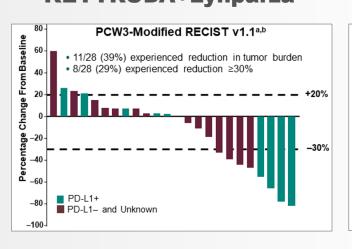




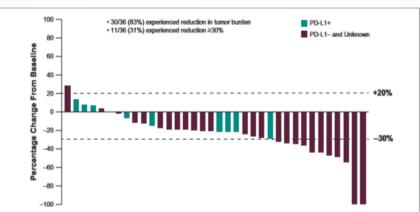
Roy

**Baynes** 

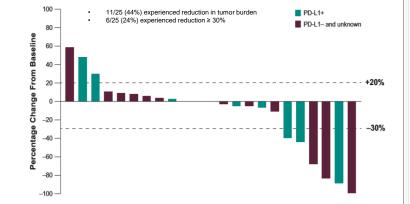
## **KEYNOTE-365 Cohort A KEYTRUDA+Lynparza**



## **KEYNOTE-365 Cohort B KEYTRUDA+Docetaxel**



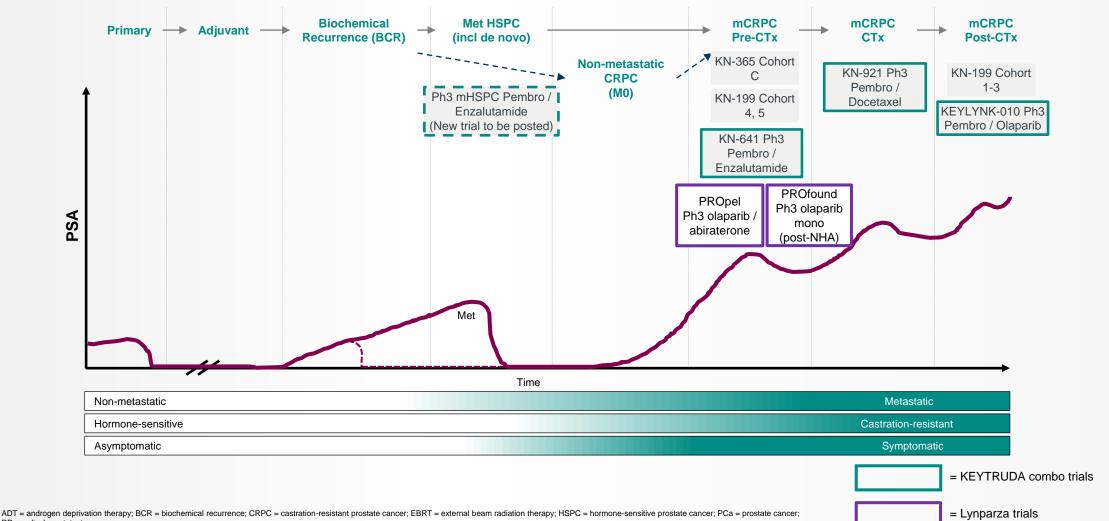
## **KEYNOTE-365 Cohort C KEYTRUDA+Enzalutamide**





# **BROADEST PROSTATE CANCER PROGRAM WITH MULTIPLE PH 3 TRIALS ADDRESSING 40% OF PATIENTS**





RP = radical prostatectomy.













<sup>\*</sup>CI indicates estimated ARCHES approval as of 4Q 2019













# LYNPARZA: SHOWING EFFICACY BEYOND **WOMEN'S CANCERS**

Pancreatic

cancer

- 1L, nonBRCA, KEYTRUDA combo (KEYLYNK-001) • 1L Maintenance BRCA+ (SOLO-1) - Approved
- 1L Maintenance, All Comers Combo + Bev (PAOLA-1)
- PSR, All Comers Combo + Cediranib (GY004)
- PRR, All Comers Combo + Cediranib (GY005)
- 2L+ PSR (SOLO2/Study19) Approved
- 3L+ PSR, gBRCA Treatment (SOLO3)



- cancer
- mBC, gBRCA (OlympiAD) Approved
- HER2- Adjuvant, gBRCAm (OlympiA)

- mCRPC, All Comers (KEYLYNK-010)
- mCRPC, HRRm (PROfound)
- mCRPC, All Comers Combo + Abiraterone (PROpel)



- 1L NSQ NSCLC (KEYLYNK-006)
  - 1L SQ NSCLC (KEYLYNK-008)

Luna

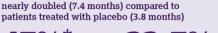
cancer

Median PFS for patients treated with olaparib 1L Maintenance qBRCA nearly doubled (7.4 months) compared to (POLO)



progression or death, compared to placebo

\*HR 0.53 [95% CI 0.35-0.82], p=0.0038





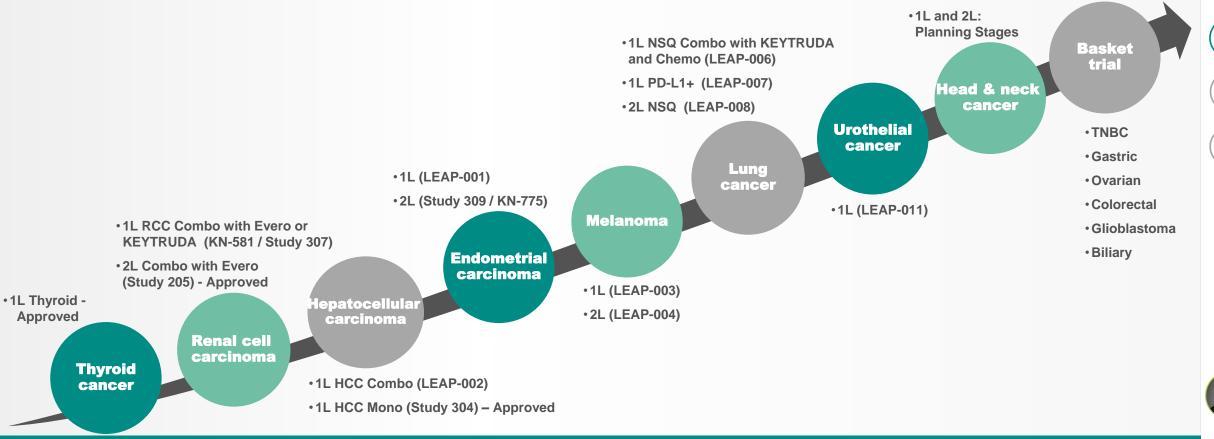


**Tumor** 



## Demonstrating potential in prostate cancer, pancreatic cancer and more

# **LENVIMA: POTENTIAL ACROSS BROAD** RANGE OF TUMOR TYPES











Dr. Roy **Baynes** 

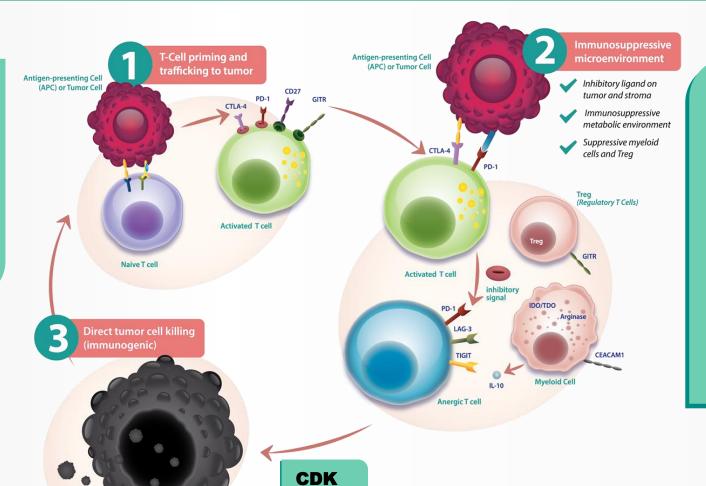


# 13 trials studying KEYTRUDA in combination with Lenvima spanning >13 tumor types

# MERCK INVENTING FOR LIFE

# EXTENSIVE ONCOLOGY PIPELINE COVERING ALL ASPECTS OF THE TUMOR ENVIRONMENT

CD27
CTLA4
CVA21
Other cancer
vaccines and viruses
PCVs
RIG-I
STING



**ERK** 

CCR5
CXCR2
GITR
IDO/TDO
ILT3
ILT4
IL10
LAG-3
PD-1
PD-1/LAG-3 bi-specific
Pi3K-delta
TGFβ

**TIGIT** 

TLR4









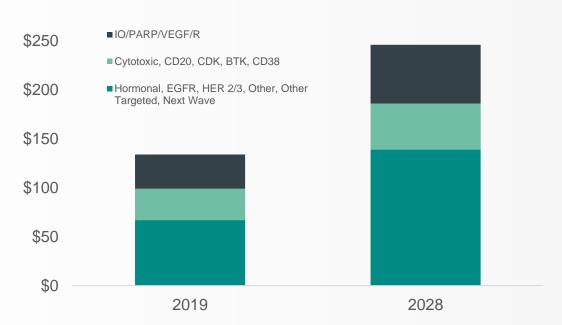


# **ESTABLISHING LEADERSHIP IN GROWING ONCOLOGY MARKET**

- Largest I-O clinical development program in the industry
- Sizable long-term opportunity in new tumor types, including TNBC and prostate cancer
- Broad combination program with Lynparza, Lenvima and others
- Significant long-term opportunities in adjuvant / neoadjuvant settings

## Global oncology market potential (\$B)





Source: EvaluatePharma















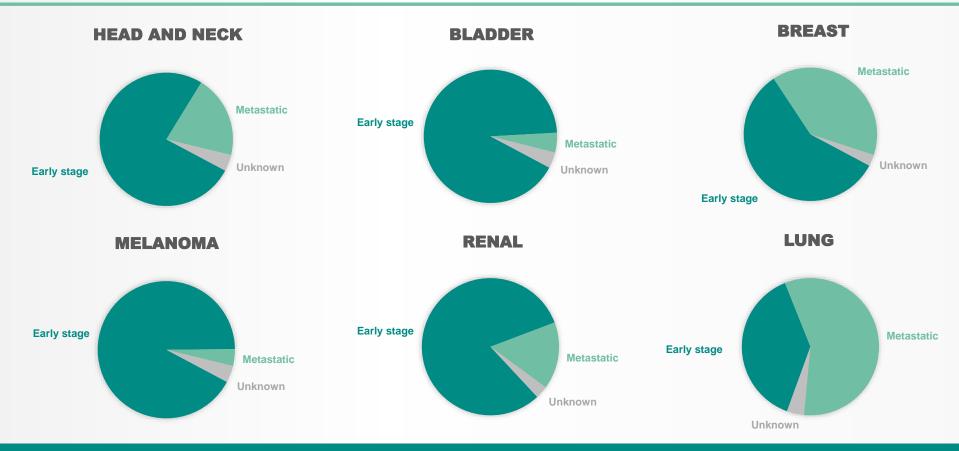






Mike Nally

# **EARLY STAGE - INCLUDING ADJUVANT / NEOADJUVANT - REPRESENTS SIGNIFICANT PORTION OF CANCER PREVALENCE**



18 registrational trials across these tumor types and more, representing meaningful growth opportunity

# **ADDRESSING TUMOR TYPES WITH HIGHEST** INCIDENCE, INCLUDING BREAST AND PROSTATE

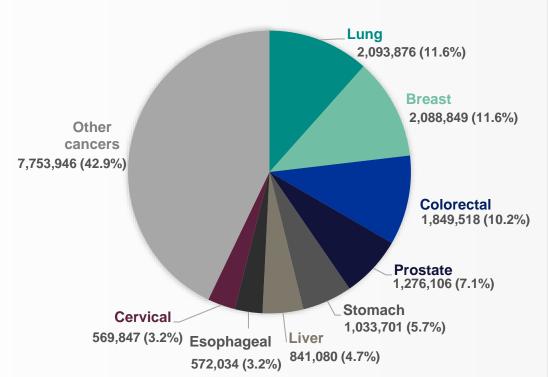
## **Breast cancer market expected** to grow to \$38B by 20281

- TNBC represents 10-15% and ER+/HER2- represents ~65% of all breast cancers
- Program addresses different stages of disease and lines of therapy

## **Prostate cancer market expected** to grow to \$15B by 20281

- mCRPC represents 20% and mHSPC represents 20% of all prostate cancers
- Broadest I-O development program addressing all stages of mCRPC and moving into mHSPC

## Global incidence of top tumor types





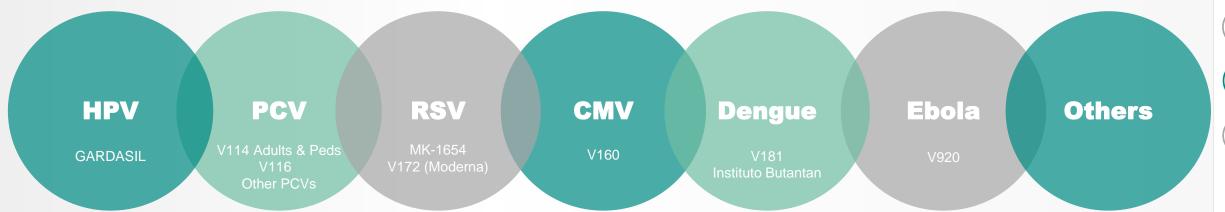




Mike Nally



# **EXTENSIVE VACCINES PIPELINE TARGETING DISEASES WITH SIGNIFICANT UNMET NEED**



- Supporting global appeals to eliminate cervical cancer by improving access to **GARDASIL**
- Increasing gender-neutral vaccination

- Need for prevention of residual disease
- 13 Phase 3 trials across adults and pediatrics for V114
- Major unmet medical need in infants and elderly
- Leading nongenetic cause of neurologic disability
- Identified by CDC / FDA and others as area of critical need
- Major cause of hemorrhagic fever and death
- Partnership with Instituto Butantan allows early access to Phase 3 study results
- Licensing application under review at FDA, EMA, WHO and African countries
- Addressing key areas of unmet need with broad early vaccine pipeline









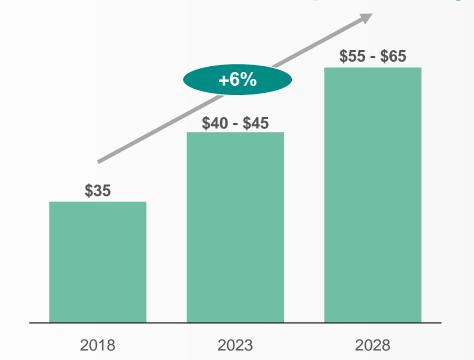


# **GROWING GLOBAL DEMAND FOR VACCINES** PROVIDES SUSTAINABLE MARKET OPPORTUNITY

## **Growth over the next decade** driven by:

- Increasing Coverage: Driving penetration of inline products in high income markets (U.S./EU)
- Globalization: Expanding markets and increasing penetration for inline and future pipeline products
- Innovation: Launching pipeline products

## Global vaccines market potential (\$B)<sup>1</sup>













# UNIQUE PNEUMOCOCCAL PORTFOLIO TARGETING PROTECTION IN ADULTS AND CHILDREN













## **PNEUMOVAX 23**

## Foundation of adult prevention

Unique combination of serotype coverage and cost effectiveness

### V114

## **Advancing protection** across pediatric and adult populations

**Expanded serotype** coverage to potentially address the highest burden of pneumococcal disease



Awarded Breakthrough Therapy Designation in Pediatric and Adult Populations

## V116

## **Targeted approach** to adult prevention

Focus on potential to broaden protection in adult population

## **OTHER PCVs**

## **Aiming for broadest** protection for pediatric population

Potential to establish long-term leadership in pediatric market

**FOUNDATION** 

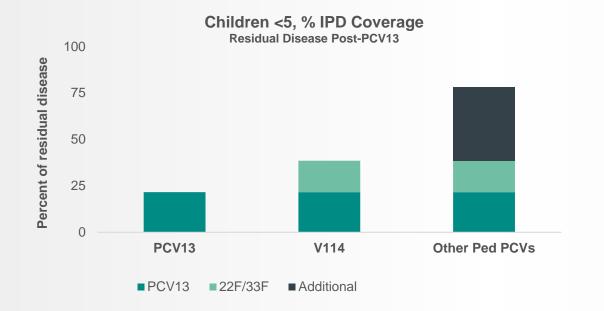
## **NEXT-GENERATION PNEUMOCOCCAL PIPELINE**



# PNEUMOCCOCAL MARKET EXPECTED TO REMAIN LARGE WITH SIGNIFICANT ADDITIONAL OPPORTUNITY

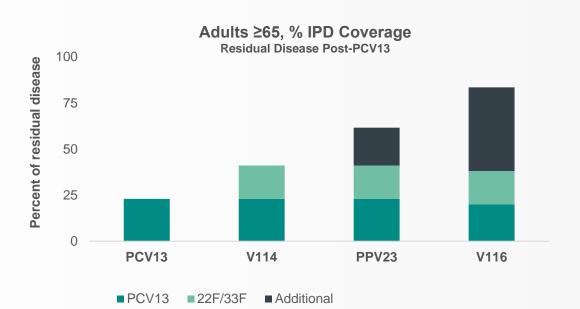
### **PEDIATRICS**

- Represent two-thirds of market
- Even with vaccine progress, still close to 500,000 deaths annually in children <5 years old around the world



### **ADULTS**

 Significant remaining opportunity driven by aging population, limited National Immunization Programs and low vaccination rates (~400,000 hospitalization per year in the U.S.)





















# **MULTIPLE PROGRAMS TARGETING A MARKET OF OVER \$10B GLOBALLY**



- Most common respiratory pathogen in infants with >50,000 hospitalizations each year in the U.S. alone and >3 million hospitalizations globally
- RSV infection occurs in up to 10% of adults 65 and over in the U.S. each year, resulting in >175,000 hospitalizations
- Total RSV market estimated to be >\$5 billion



- #1 non-genetic cause of hearing loss in infants in the U.S.
- 0.3 2.0% global prevalence of congenital cytomegalovirus
- >\$3 billion market size expected globally
- V160 has potential to be first in class

Dengue

- 400 million dengue infections annually with 4 billion patients at risk worldwide
- >\$3 billion market size across travel and endemic segments
- V181 data suggests potential for all 4 dengue serotypes to be covered by 1 dose







# **30 YEARS OF HIV INNOVATION CONTINUES**

1980s

1990s

**2000s** 

**2010s** 

2020+

1983

HIV is discovered

1989

Role of protease published -**AZT launches** 

1996



1998



2000

ACHAP1 Partnership with **Botswana and Bill** and Melinda Gates Foundation



2017



2018





### **CONTINUING TO INNOVATE**

MK-8591: Investigational NRTTI for the treatment and prevention of HIV

Many additional mechanisms in early development









# MK-8591: UNIQUE PHARMACOLOGY ENABLING POTENTIAL LONG DURATION THERAPY

**Long-Duration Oral** & Implantable

Oral

Monthly	Implantable	Daily	Weekly	Elimination
Continue to simplify HIV care	Radical simplification of HIV care	Maximize simplicity, potency and tolerability	Free patients from daily dosing	Aspiring to cure
Potential to reduce risk of HIV infection ↓↓↓ Dosing frequency ↑↑↑ Adherence		Daily dosing for antiretroviral suppression	↓↓ Dosing frequency ↑↑ Adherence	Sustained viral response or cure

**PREVENTION [PrEP]** 

**TREATMENT** 

**CURE** 

# **HIV REMAINS A PARAMOUNT WORLDWIDE HEALTH THREAT**

36.9M

Number of people living with HIV

**1.8M** 

**People** newly infected with HIV in 2017

940K

AIDSrelated deaths in 2017









# MERCK INVENTING F











# MK-8591: UNIQUE ATTRIBUTES ALIGN WELL WITH **UNMET NEED**

**MK-8591** 

Simple, efficacious regimens that support lifelong therapy with high QoL

## **HIV UNMET NEED**

**Extended coverage for** missed doses (forgiveness)

**Pill fatigue** 

**Reduced toxicity** 

**Easy, effective** options for PrEP

# **GEFAPIXANT (MK-7264): EXPLORING ROLE OF P2X3** PATHWAY IN DISORDERS OF SENSORY PATHOLOGY

**Blocking** 

receptors

normal

sensory

function

may restore

**P2X3** 

**Development focused on the role** of P2X3 receptor mediated signaling in:

 Unexplained or refractory chronic cough

- Visceral pain syndromes
- Altered sympathetic function

**Sensory Pathology** P2X3 Blockade · Headache/migraine Hypertension · Pathologic cough Bronchoconstriction Breathlessness · Sleep apnea · IBS-C/D Urinary urgency · Bladder/pelvic pain · Endometrial-related pain Neuropathic pain · Muscle pain · Itch

Pathologies currently being explored

**Pathologically** sensitized afferents send aberrant signals of disease



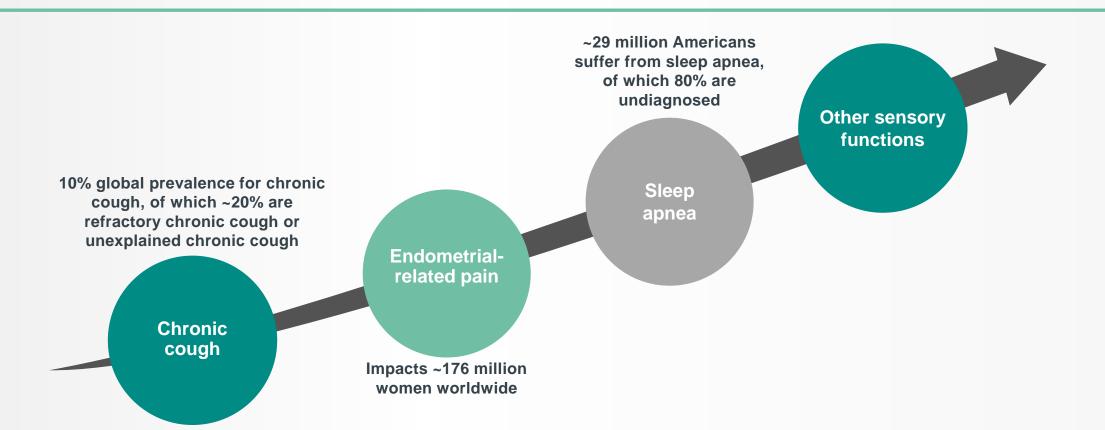






# MERCK INVENTING FOR LIFE

# GEFAPIXANT (MK-7264): OPPORTUNITY FOR BROAD APPLICABILITY













## Potential pipeline in a product

# **DIVERSE PIPELINE WITH STRONG GROWTH** POTENTIAL THROUGH NEXT DECADE

















**Broadest I-O program** with strong pipeline of oncology products to drive long-term leadership



**VACCINES** 

**Durable business with** extensive portfolio, and pipeline and global growth opportunity



Innovative pipeline targeting areas of significant unmet need

