

Merck Oncology Overview

ESMO 2021



Agenda

- **Introduction** | Dr. Dean Li, President, Merck Research Labs (MRL)
- **ESMO 2021 Highlights** | Dr. Roy Baynes, SVP and Chief Medical Officer, MRL
- **Commercial Opportunities** | Jannie Oosthuizen, SVP of Oncology Human Health, Merck
- **Q&A**

Forward-looking statement of Merck & Co., Inc., Kenilworth, N.J., USA

This presentation of Merck & Co., Inc., Kenilworth, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. 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 the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care 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.

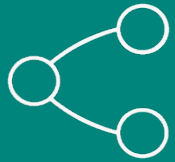
The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s 2020 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).



Dr. Dean Li

President, Merck Research Labs

Uniquely positioned to drive long-term success and oncology leadership through continued execution and momentum



Broad oncology program with deep pipeline of differentiated early- and late-stage assets



World-class scientific expertise and ability to leverage KEYTRUDA's foundational stature

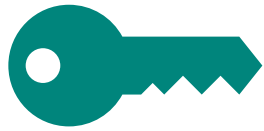


Extensive runway to advance science to reach more patients and solve for unmet need



Unmatched commercial expertise to capitalize on significant opportunities

Broad oncology strategy to improve outcomes for cancer patients globally



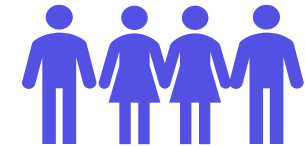
Further **establish** KEYTRUDA as foundational treatment and **expand** to additional tumor types and earlier stages of disease



Deepen responses and **extend** benefit with combinations



Advance pipeline and pursue strategic collaborations and acquisitions to broaden portfolio



Identify patients most likely to benefit from treatments

Industry's broadest immuno-oncology development program aimed to advance standard-of-care and address unmet needs



ESMO data demonstrates our leadership in early-stage disease, women's cancers and beyond

Continue to showcase **expansion into earlier stages of disease**

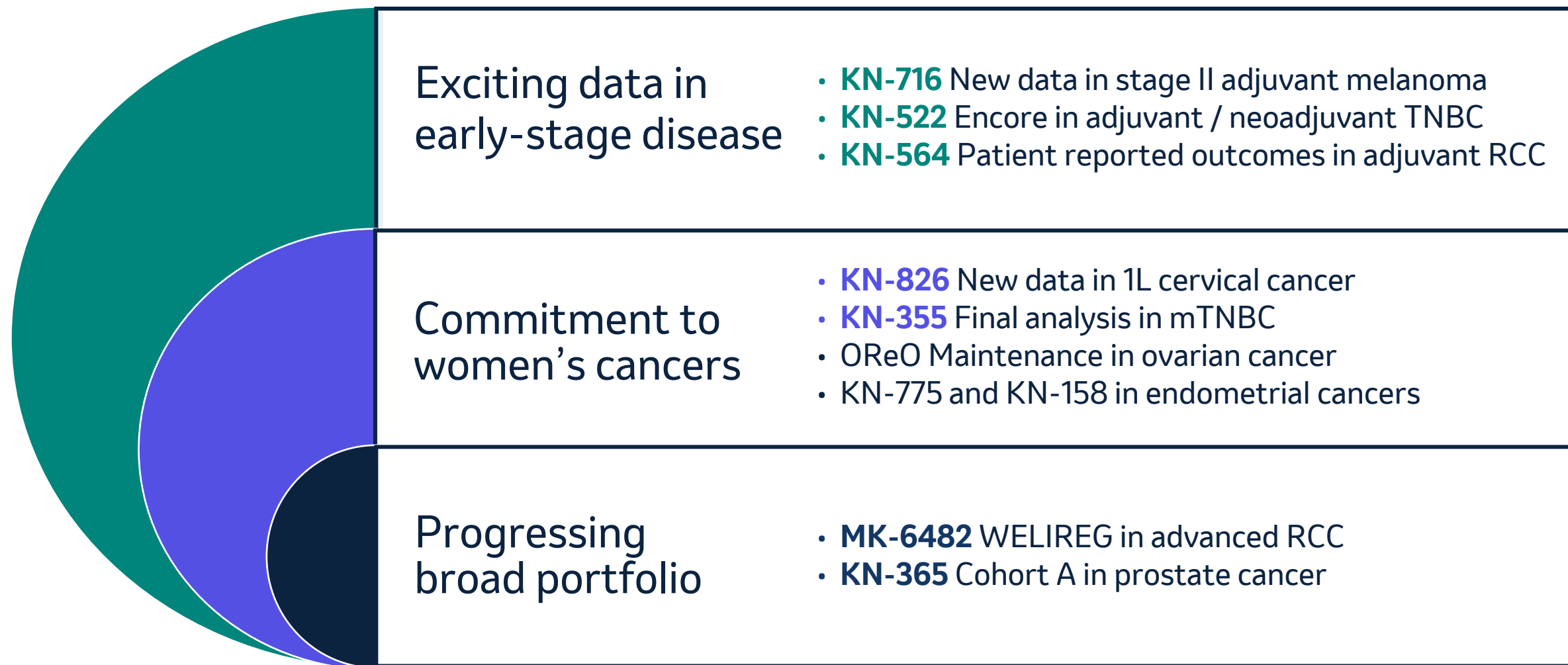
Highlight advances from our **rapidly growing portfolio in women's cancers**

Demonstrate **leadership in oncology** by highlighting the breadth and depth of **portfolio** and **pipeline**

Dr. Roy Baynes

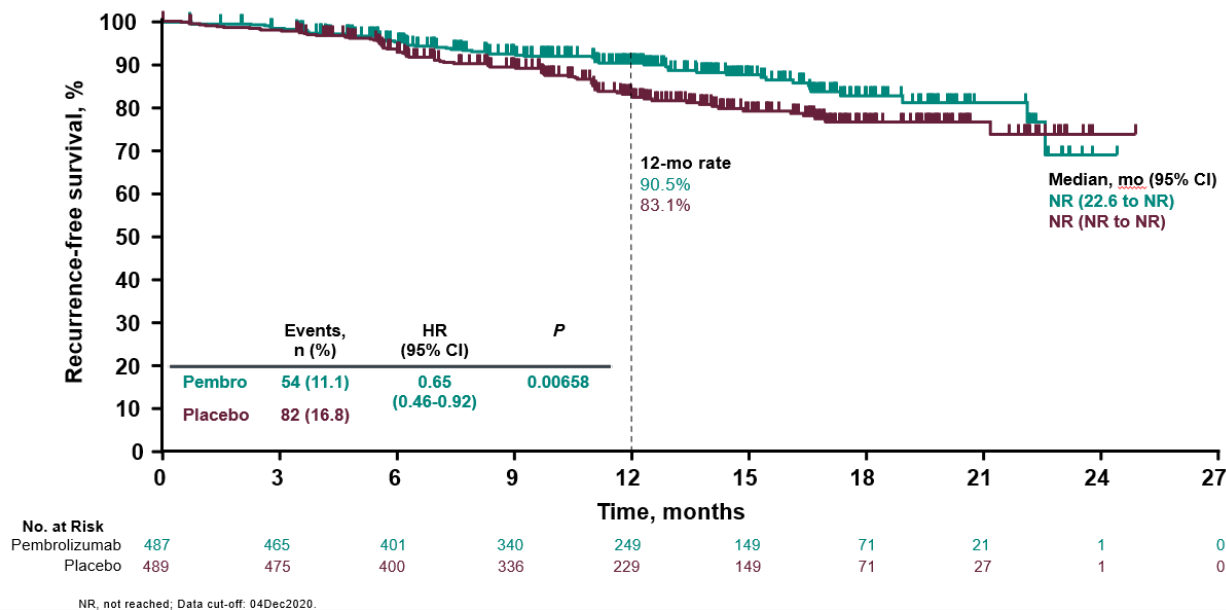
SVP and Chief Medical Officer, MRL

ESMO 2021: highlighting data in early-stage, women's cancers and across broad portfolio



KEYNOTE-716: clinically meaningful data supports potential new treatment option in stage II melanoma

Recurrence-Free Survival (Primary Endpoint)

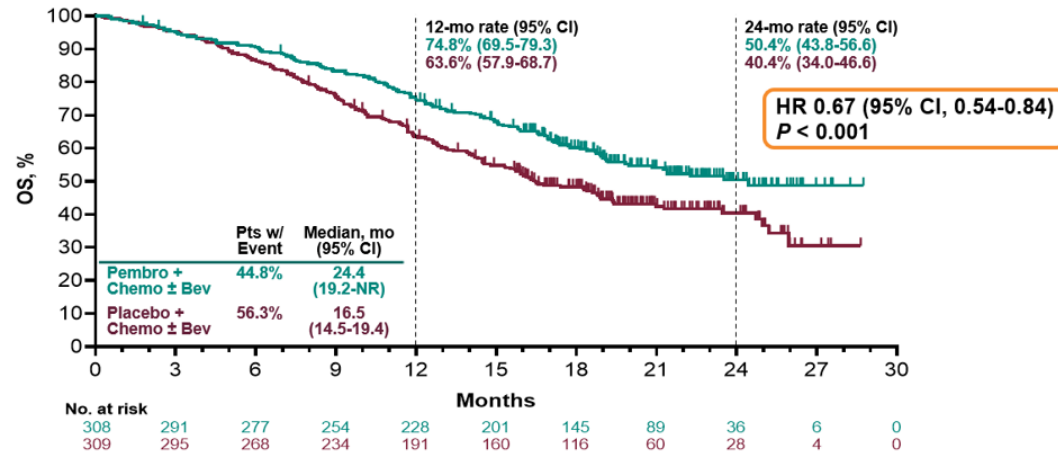


KEYTRUDA demonstrated a **35% reduction in the risk** of disease recurrence or death compared to placebo

- Represents a potential **first treatment option** in patients with resected, high-risk, stage II melanoma
- **Builds on the foundation** of efficacy and safety data already established by KEYNOTE-054 in stage III setting

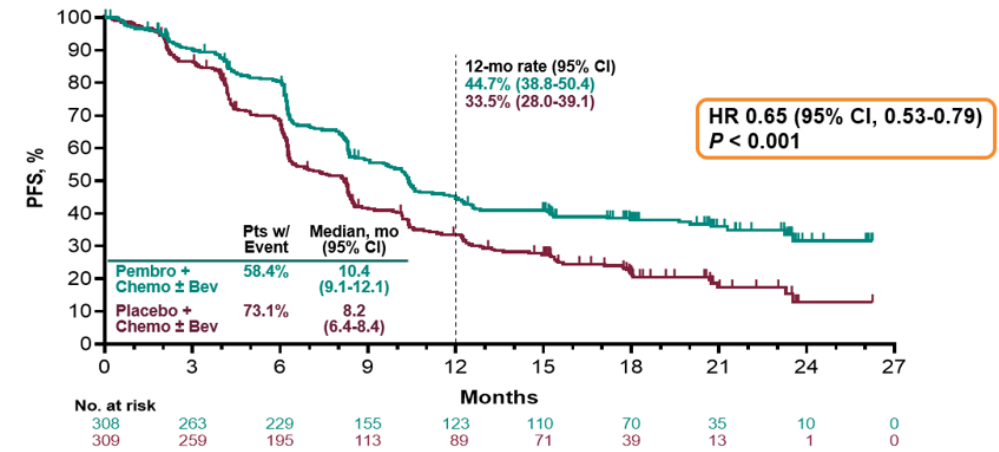
KEYNOTE-826: first and only first line cervical cancer combination regimen improving overall survival (OS), progression free survival (PFS) and objective response rate (ORR)

OS: All-Comer Population



Reduced the risk of death by 33% in the all-comers population with a median **OS of 24.4 mos** for KEYTRUDA vs. 16.5 mos with chemo

PFS: All-Comer Population



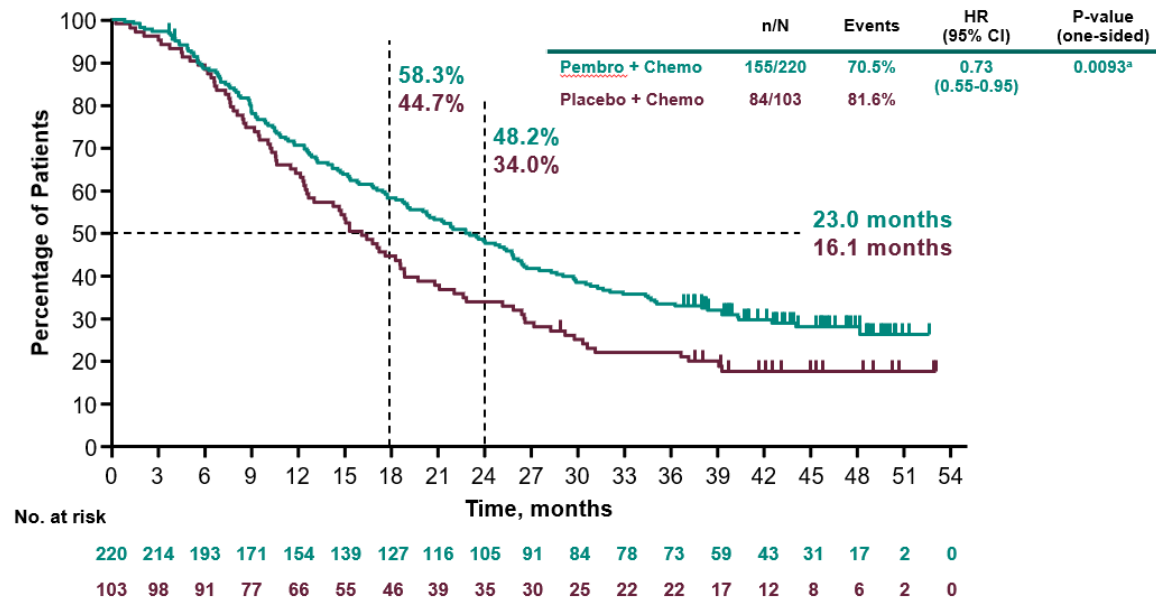
Response assessed per RECIST v1.1 by investigator review.
Data cutoff date: May 3, 2021.

Improved PFS by 35% in the all-comers population with a median **PFS of 10.4 mos** for KEYTRUDA vs. 8.2 mos with chemo

KEYTRUDA + chemotherapy with or without bevacizumab demonstrated **significant benefit** in **all populations** including PD-L1 CPS ≥ 1 and CPS ≥ 10 with potential to be the **new standard of care** for women with persistent, recurrent, or metastatic cervical cancer

KEYNOTE-355: results support new standard of care treatment regimen in first line metastatic TNBC

Overall Survival: PD-L1 CPS ≥10

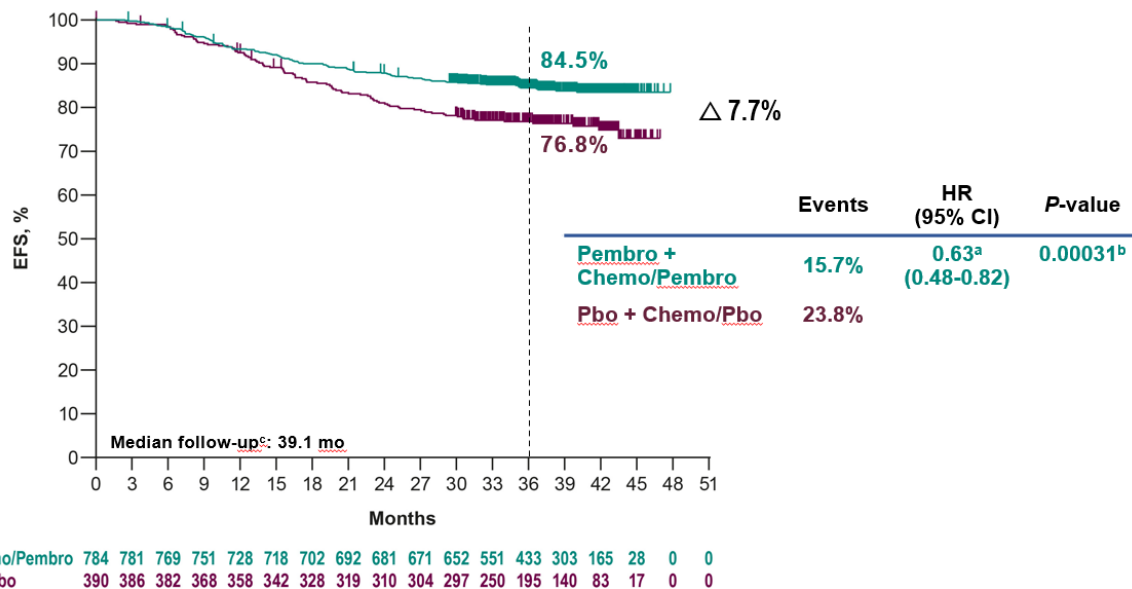


KEYTRUDA + chemotherapy resulted in **statistically significant** and **clinically meaningful** improvements in both **OS** and **PFS** versus chemotherapy alone

- **Reduced the risk of death by 27% (HR=0.73)**
- **Increase of 6.9 months** in median OS
- Addressing **unmet medical need** with the potential to **extend lives** of certain patients with this aggressive cancer

KEYNOTE-522: first phase 3 study with immunotherapy to demonstrate positive event free survival (EFS) results in high-risk early-stage TNBC

EFS at Interim Analysis 4

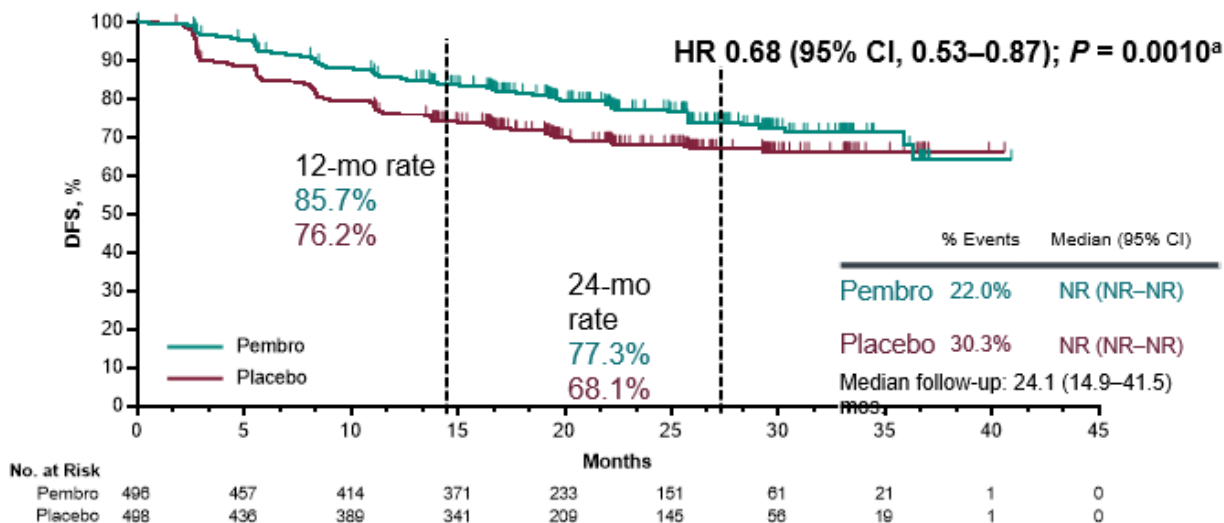


KEYTRUDA + chemotherapy significantly prolonged EFS, reducing the risk of EFS events by 37%

- **Favorable trend for OS** with final results pending
- Benefit consistent across **all subgroups**
- Results serve as the basis for the **recent FDA approval of KEYTRUDA** for patients with high-risk, early-stage TNBC
- KEYTRUDA + chemotherapy as part of a neoadjuvant/ adjuvant regimen has the **potential to change the treatment paradigm**

KEYNOTE-564: first positive phase 3 study of adjuvant immunotherapy in RCC

Disease-free survival in ITT population

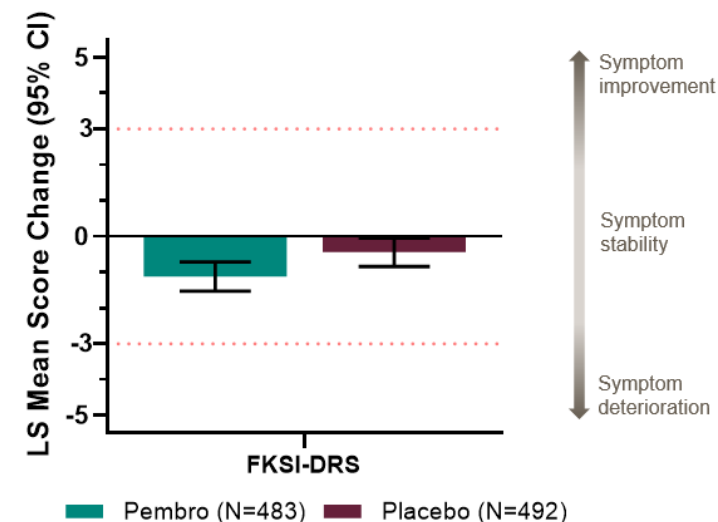


^aCrossed prespecified p-value boundary for statistical significance of 0.0114.

ITT population included all randomized participants. NR, not reached. Data cutoff date: December 14, 2020.

Summary of FKSI-DRS scores

Change from Baseline to Week 52



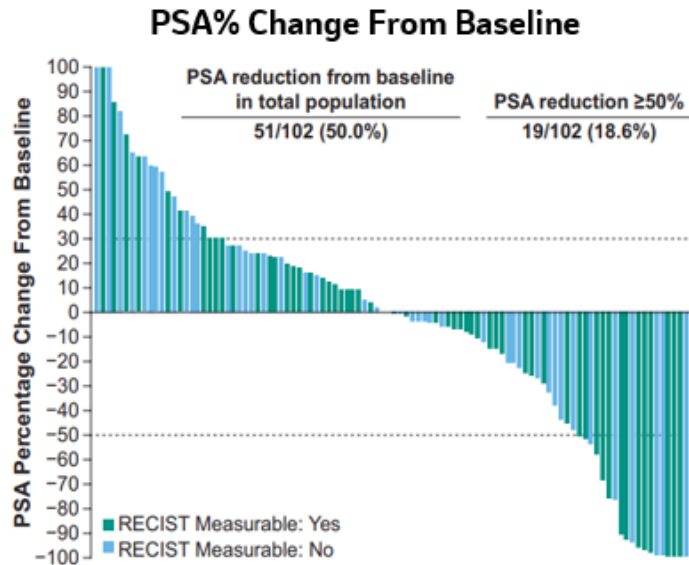
Updated ESMO data on KN-564 PRO shows no clinically meaningful differences in health-related QoL or symptom scores

KEYTRUDA following surgery **reduced risk** of recurrence or death by **32%** compared to placebo for patients with RCC

- Favorable trend in **OS** with a **46% reduction** in the risk of death with KEYTRUDA compared to placebo (HR=0.54 [95% CI, 0.30–0.96]; $p=0.0164$)
- Potential new standard of care in the adjuvant setting

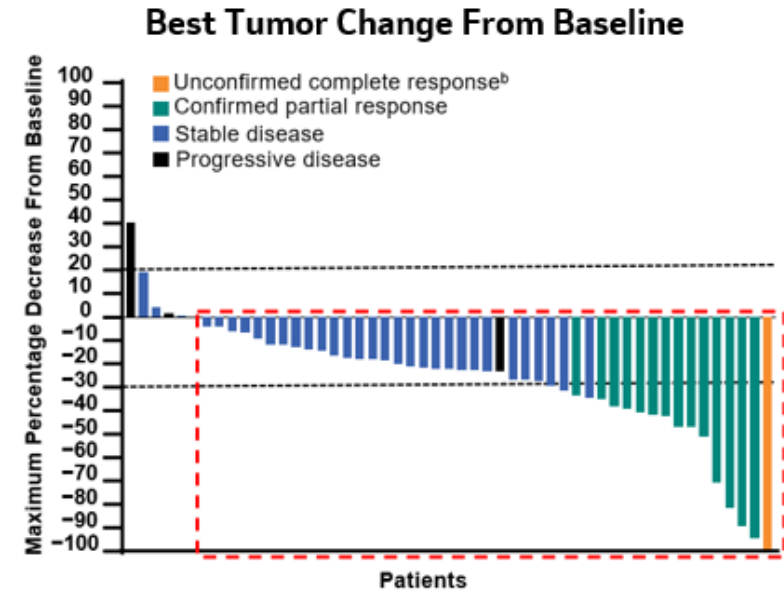
Building on our broad oncology portfolio with expansive phase 3 prostate program and novel mechanisms

PROSTATE: KN-365 cohort A



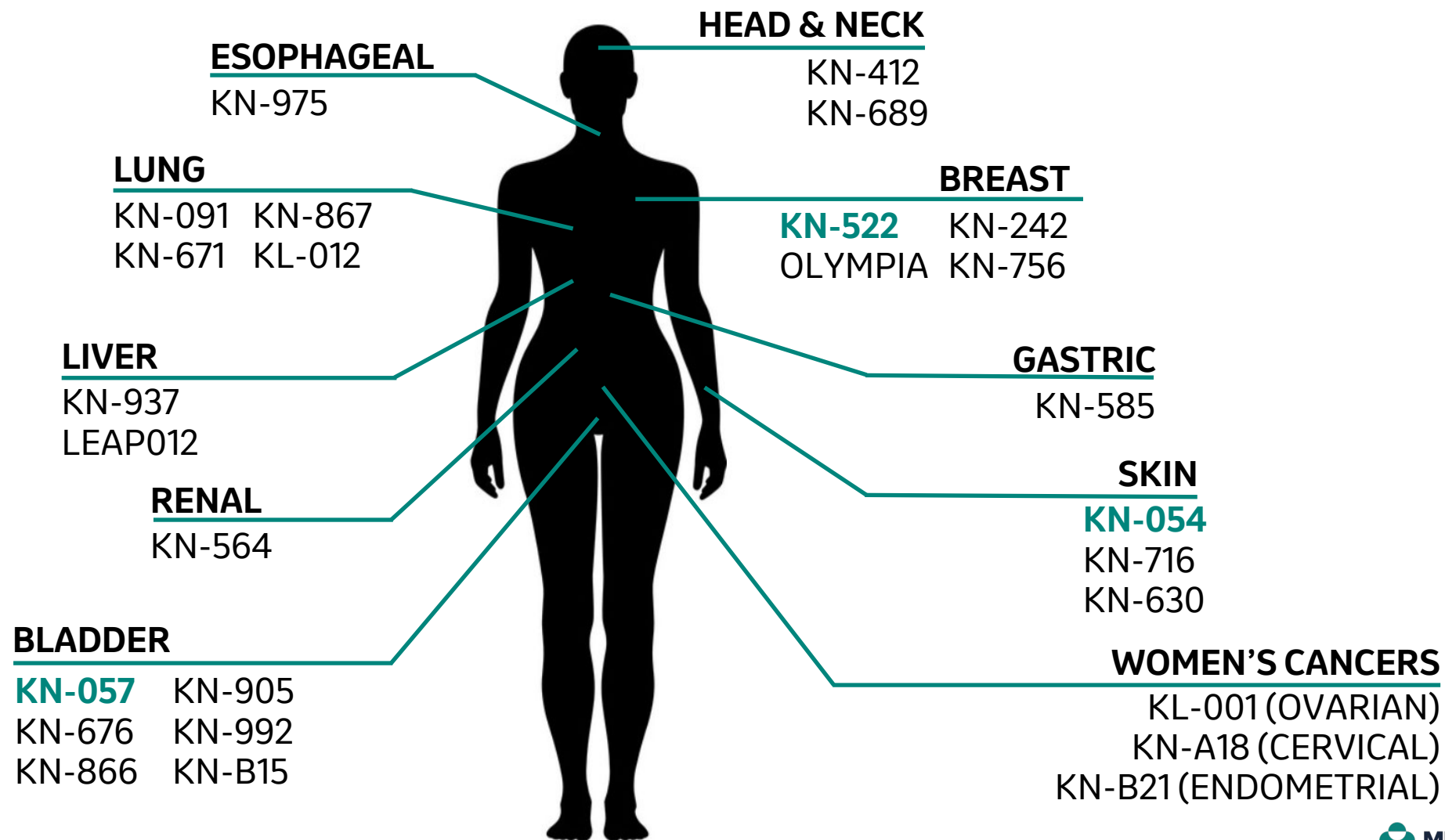
- **58.6% of patients** experienced **reduction** in target **lesion size** among patients with RECIST-measurable disease
- Minimum of 11.4 months follow-up
- **Promising rPFS and OS data** support further evaluation of KEYTRUDA + olaparib

WELIREG: MK-6482-003 (encore)



- **86.5% of patients** experienced a **reduction** in target **lesion size**
- Median follow-up of 15.4 months, belzutifan + cabozantinib showed **promising activity** in **all patients** with previously treated aRCC
- ORR consistent across IMDC risk categories
- Median PFS, 16.8 months

Potential foundational early-stage disease program across many tumor types



Transforming cancer treatment with multiple agents and approaches across array of tumors

Breast Cancer

**Notable
advancements** with
diverse assets

KN-522: adj / neoadj TNBC
KN-355: mTNBC
Tukysa: mHER2+
LIV-1: ADC in mTNBC

Women's Cancers

Broad profile across
many tumors

KN-826 / KN-A18: Cervical
KN-775 / KN-158:
Endometrial
KL-001: Ovarian
Lynparza Ovarian -multiple
lines - OReO - rechallenge
GARDASIL: HPV Vaccine

Prostate Cancer

Robust phase 3
program¹

KN-365A: Ph II
KN-921: K+D mCRPC
KN-641: K+E abi exp
KN-991: K+E mHSPC
PROpel: 1L mCRPC
PROfound: 1L-2L mCRPC
KL-010: K+L 3L mCRPC

Renal Cell Carcinoma

Expansive set of
treatment options

KN-564: adjuvant
KN-426: K+axitinib
KN-581: K+Lenvima
Lenvima: 2L+
WELIREG:
VHL associated RCC
Monotherapy: sporadic RCC
2L-4L
Combination therapies
across lines of treatment

¹KN-921: KEYTRUDA+docetaxel; KN-641: KEYTRUDA+enzalutamide; KN-991: KEYTRUDA+enzalutamide
PROpel: Lynparza+abiraterone; PROfound: Lynparza; KL-010: KEYTRUDA+Lynparza



Jannie Oosthuizen

President, Global Oncology

Driving global leadership across a broad portfolio of commercial assets

KEYTRUDA[®]
(pembrolizumab) Injection 100 mg

Foundational cancer
treatment

Lynparza[®]
olaparib
tablets 150 mg

Market-leading
PARPi

LENVIMA[®]
(lenvatinib) capsules | 10 mg and 4 mg

Broad-based
TKI

TUKYSA[®]
tucatinib
50 mg | 150 mg tablets

Highly-selective
small-molecule TKI¹

WELIREG[™]
(belzutifan)

First-in-class HIF-2 α
Inhibitor

45

Approved
Indications

25

Tumor
Types +
MSI-H, TMB

>1M

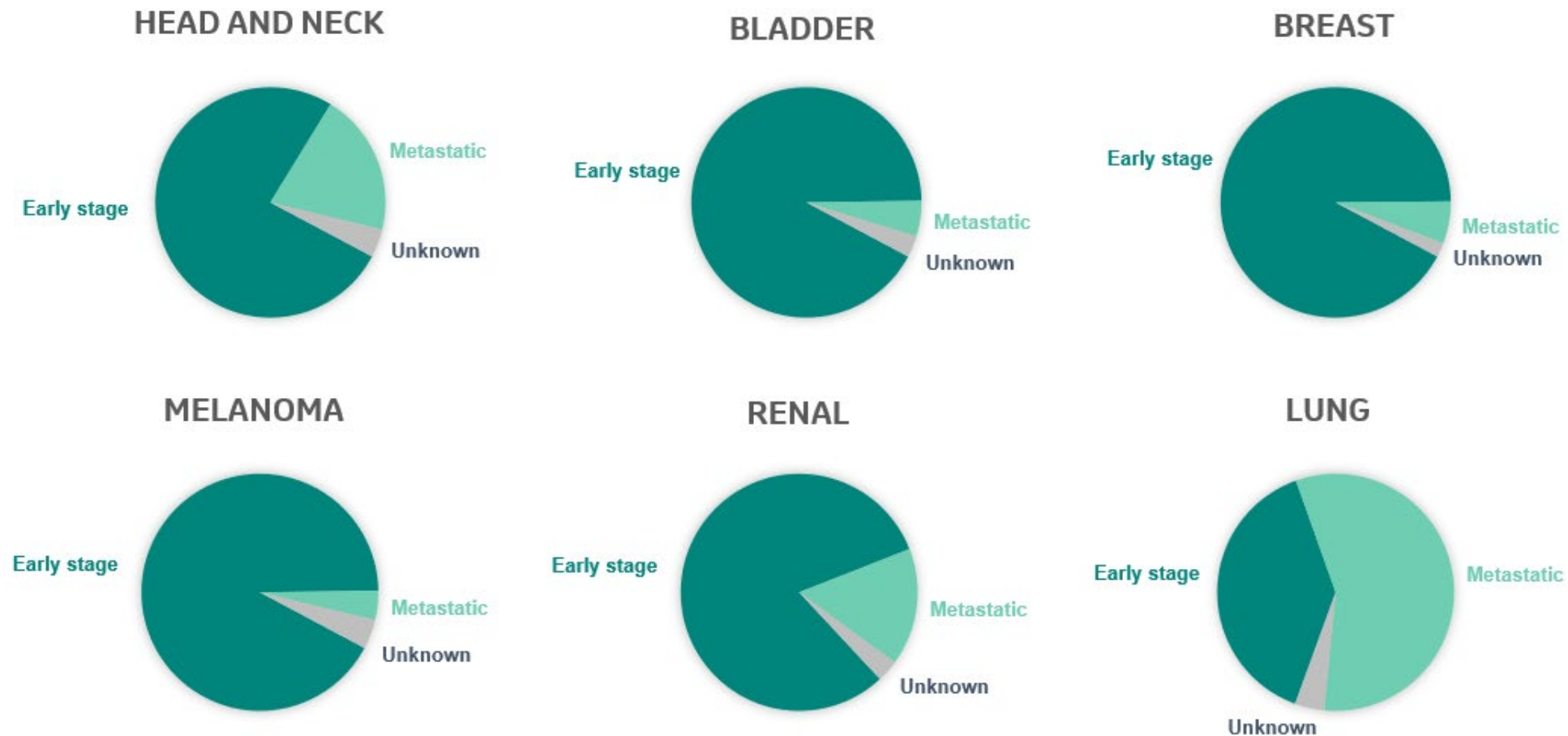
Patients treated
with Merck Oncology
Products²

Lynparza, Lenvima and Tukysa are in partnership

¹Tukysa is currently available in ex-US markets

² Patients treated with commercially available product as of Sep 2021

Significant opportunities in early-stage treatment across cancer types where prevalence is high



Meaningful opportunity to **improve patient outcomes** with **earlier** diagnosis and treatment

Transforming the treatment landscape across women's cancers



Breast

- **1st anti-PD-1** to demonstrate pCR and EFS in early stage TNBC [KN-522]
- **First IO** approved in early stage TNBC [KN-522]
- **Only IO** to demonstrate OS in mTNBC [KN-355]
- **1st PARP** to demonstrate survival in HER2-adj breast cancer [OlympiA]
- **1st PARP** approved in HER2- mBC [OlympiAD]



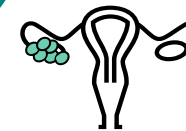
Endometrial

- **1st cancer therapy** approved for use based on a biomarker regardless of tumor type [KN-158]
- **1st IO+TKI** to demonstrate survival in endometrial cancer [KN-775]
- **1st IO+TKI** approved in endometrial cancer [KN-146]



Cervical

- **1st IO** approved in cervical cancer (2L) [KN-158]
- **1st IO** to demonstrate OS in 1L cervical cancer [KN-826]
- **1st vaccine** to prevent HPV-related cervical cancer

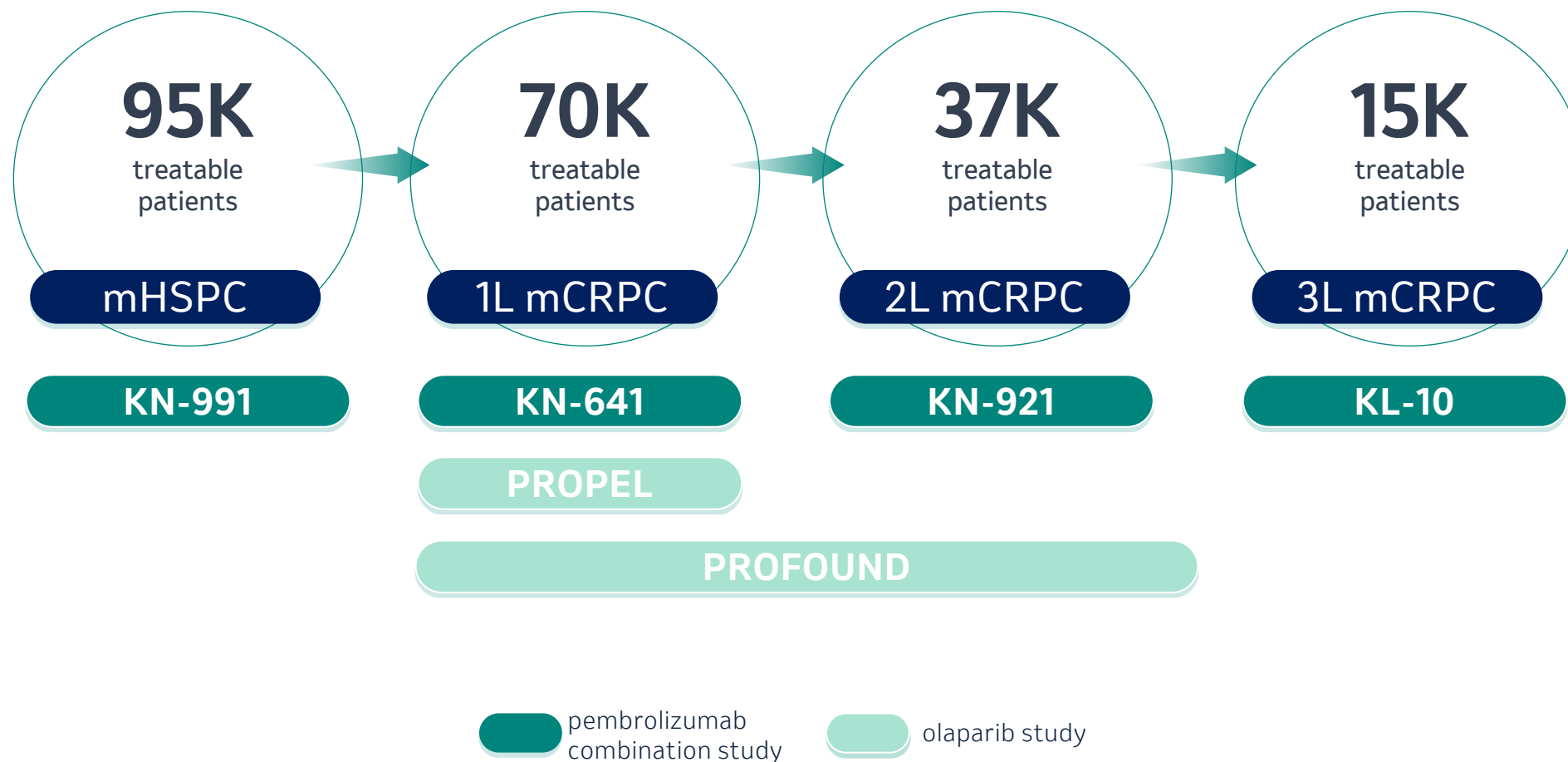


Ovarian

- **1st PARPi** approved in ovarian cancer [SOLO-1]

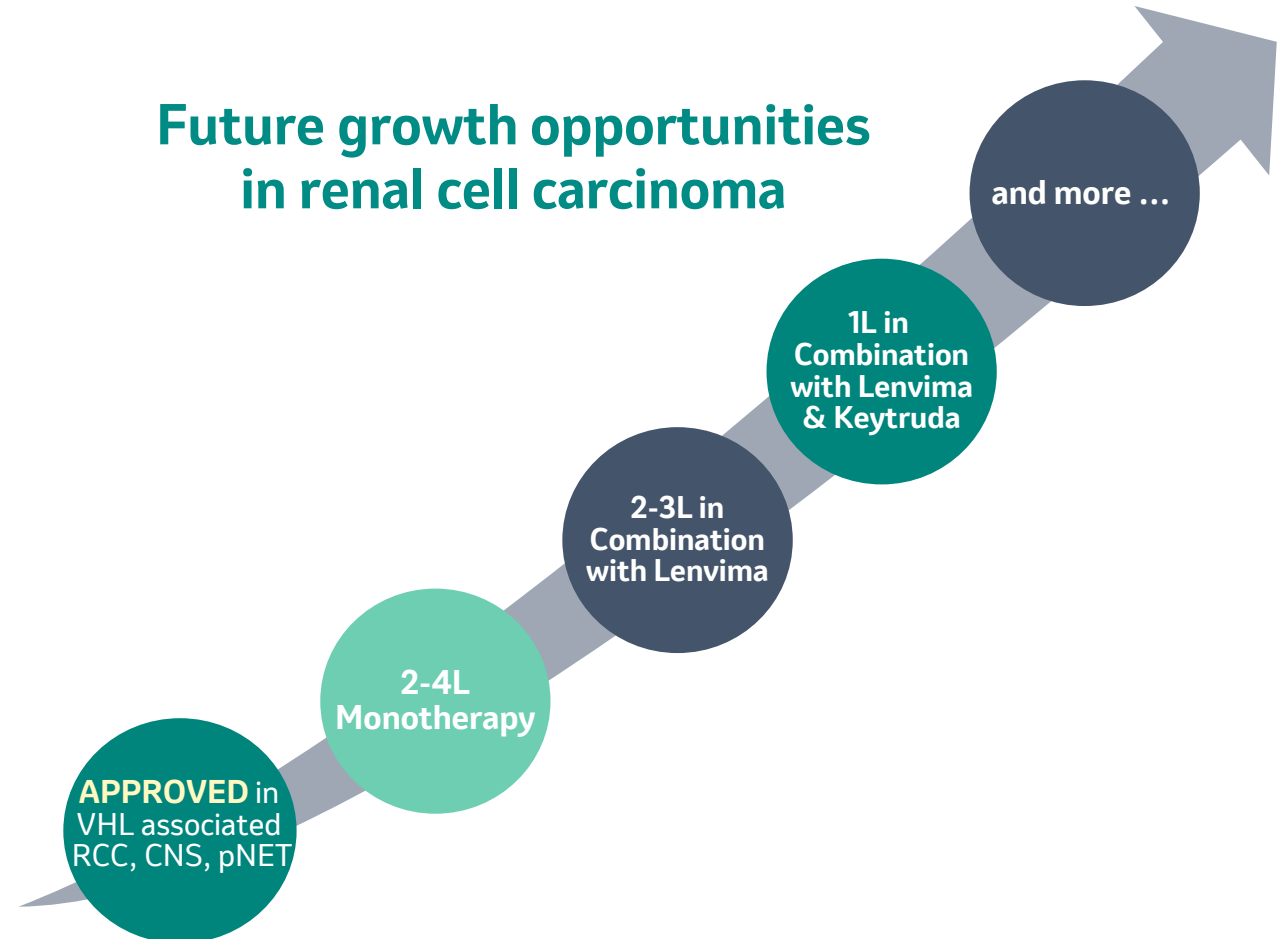
Potential for
~15 launches
over the next 4 years
Addressing **high incidence** and
significant **unmet medical need**

Building on our broad oncology portfolio with expansive phase 3 prostate program



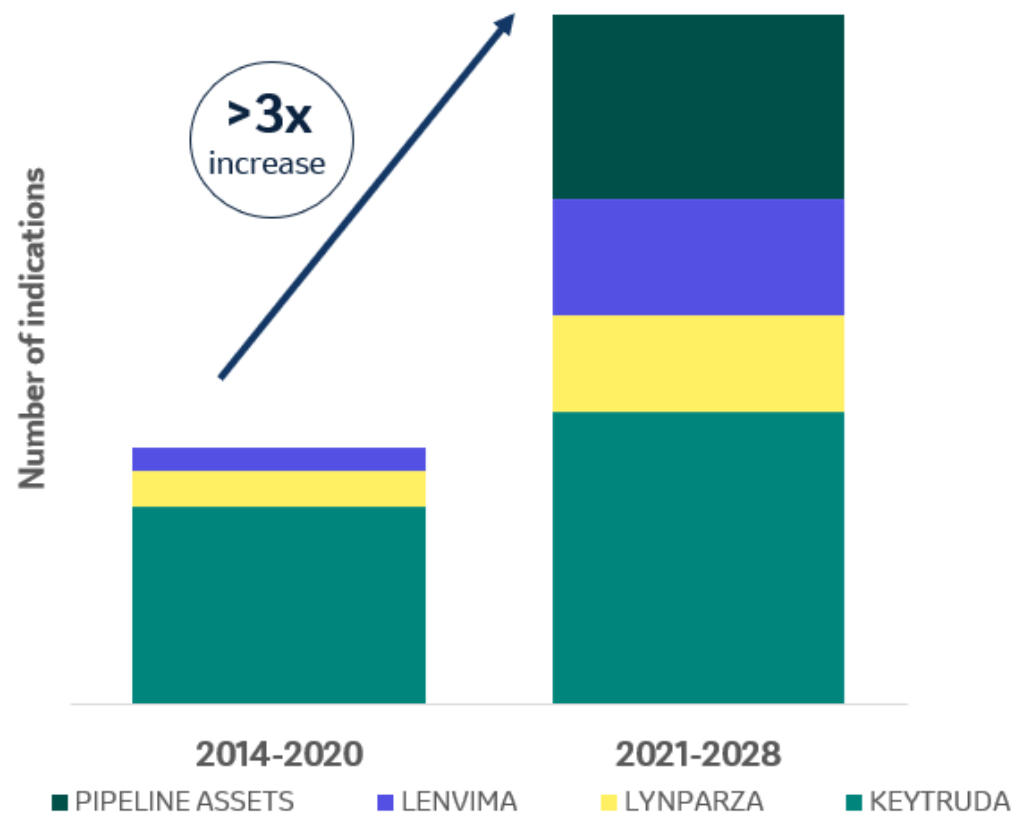
WELIREG: first-in-class molecule with potential for success in RCC

- **First-in-class** molecule targeting a gene transcription factor, based on **Nobel Prize-winning science**
- Result of successful **business development** along with **clinical and commercial execution**
- **3 pivotal clinical trials** in progress assessing efficacy alone and in combination with TKI & IO in advanced renal cell carcinoma

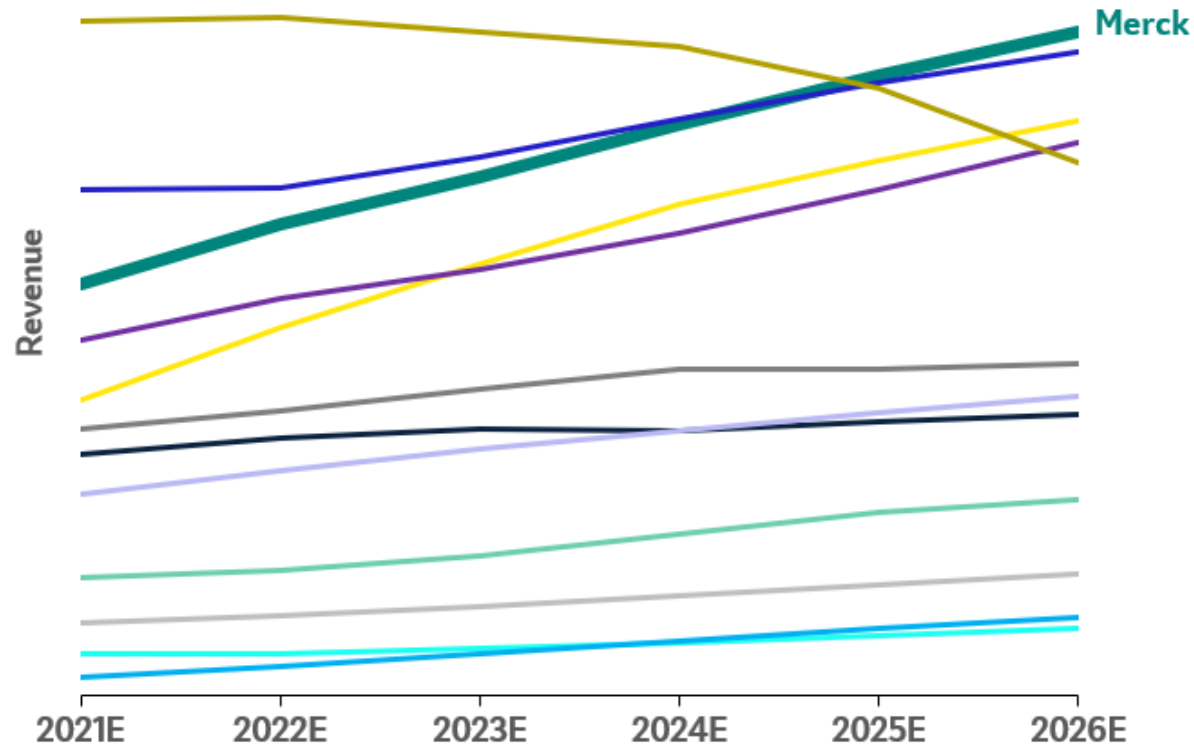


Expect to be the oncology market leader driven by additional indications, earlier lines of therapy and new assets and technologies

>90 potential approvals expected by 2028
with more than 50 expected by 2025 ...



...enables **Merck** to become the **leading** oncology company by 2025



Source: Evaluate Pharma (as of 9/14/2021)

Q&A

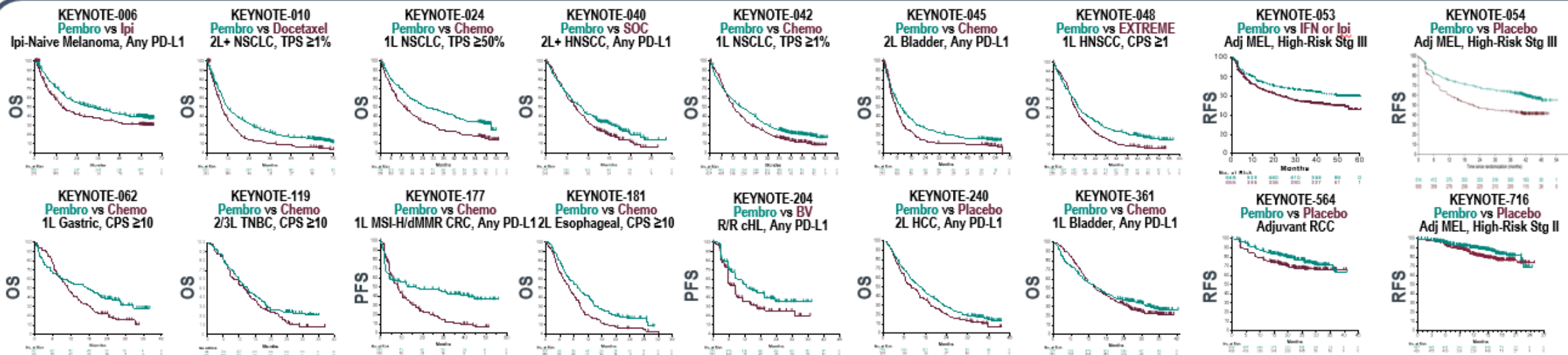
To ask a question on the operator-assisted audio line, press *1.

Note: be sure to mute your computer speakers if you are listening to the audio webcast.

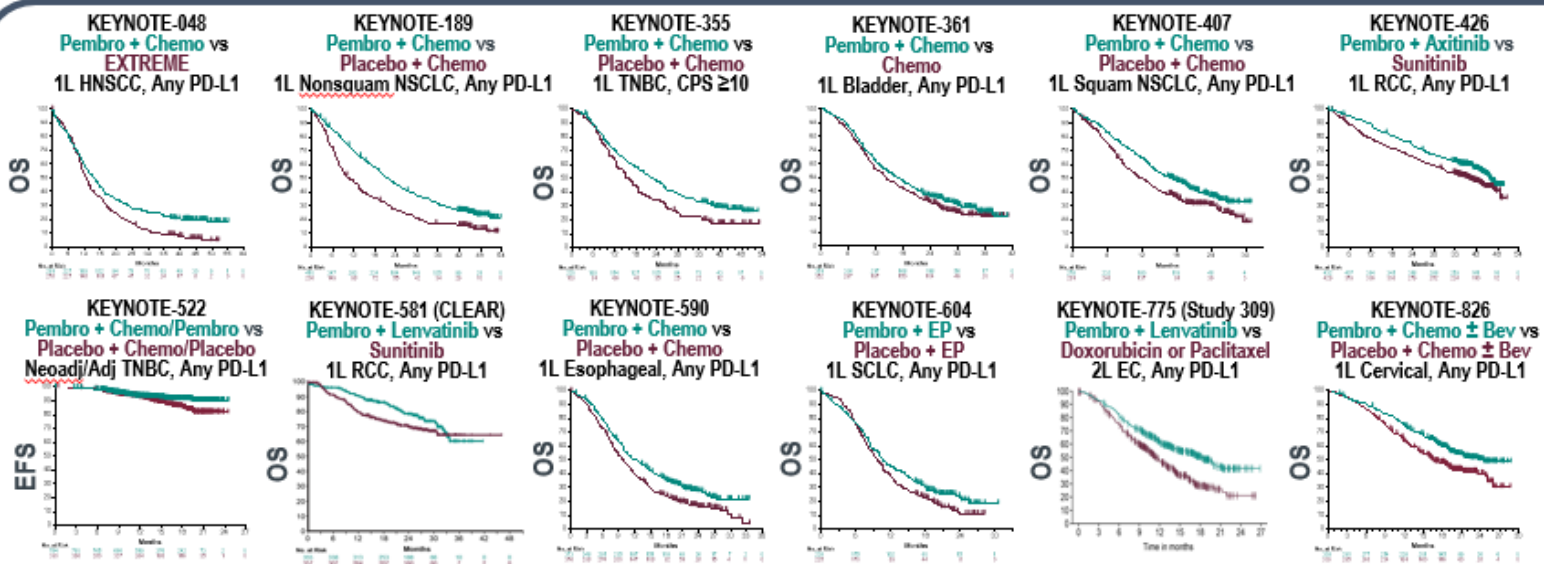
Appendix

KEYTRUDA monotherapy and in combination improved cancer outcomes in phase 3 studies across a broad range of malignancies

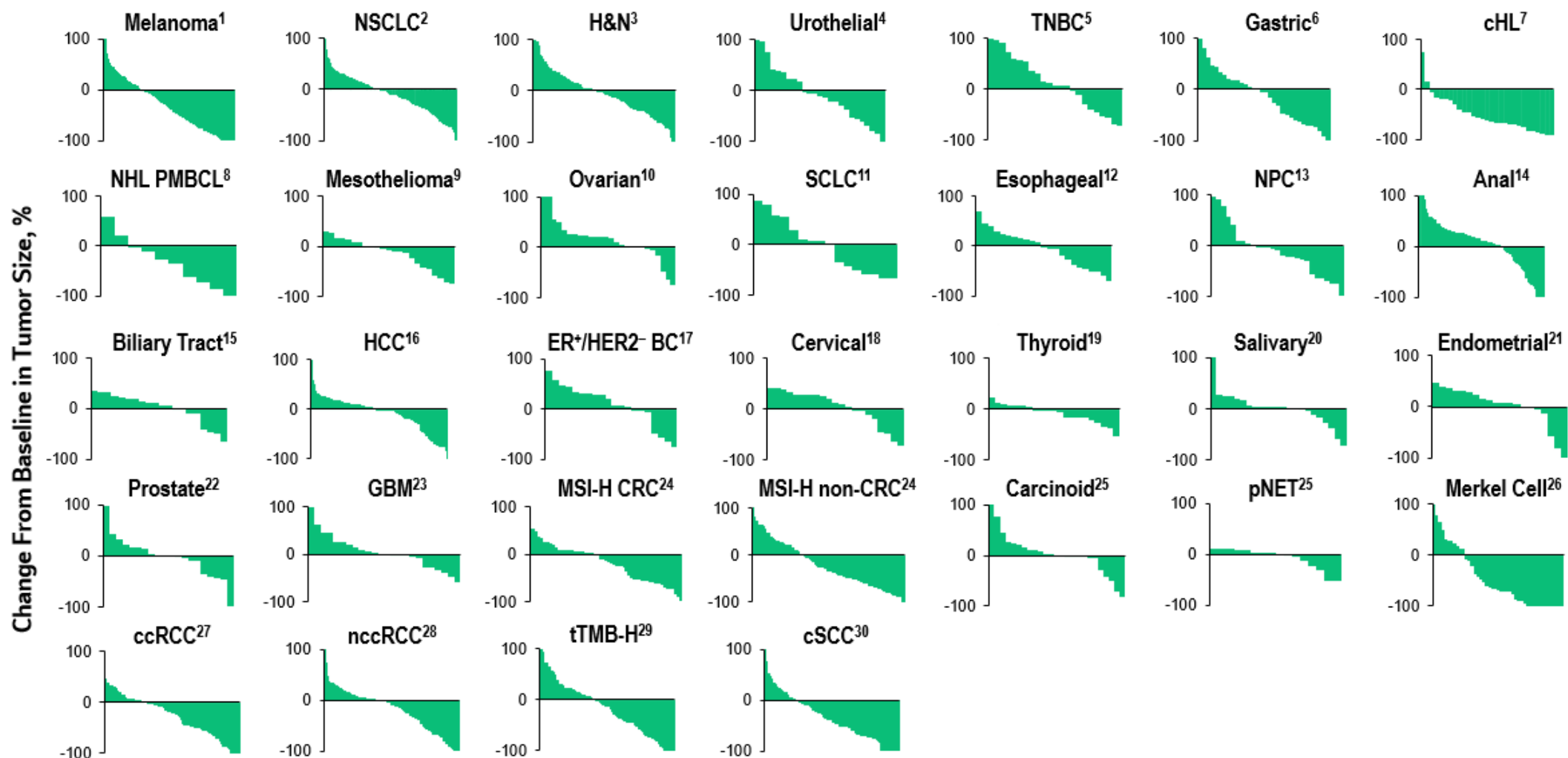
Monotherapy



Combinations



KEYTRUDA anti-tumor activity demonstrated in more than 25 cancer 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. ASCO 2015; 12. Doi T et al. ASCO 2015; 13. Hsu C et al. ECC 2015; 14. Marabelle A et al. ASCO 2020; 15. Bang Y-J et al. ECC 2015; 16. Zhu A et al. ASCO 2018; 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; 21. Ott PA et al. ASCO 2016; 22. Hansen AR et al. ESMO 2016; 23. Reardon D et al. SNO 2016; 24. Diaz L et al. ESMO 2017; 25. Mehnert J et al. ESMO 2017; 26. Nghiem P et al. ASCO 2018; 27. McDermott DF et al. ASCO 2018; 28. McDermott DF et al. ASCO-GU 2019; 29. Marabelle A et al. ESMO 2019; 30. Grob JJ et al. ESMO 2019.

We have an opportunity to shape the future by leveraging our robust portfolio and pipeline...

Expanding the IO-IO strategy by leveraging internal assets and expanding combination possibilities with targeted small molecules

CTLA-4
(MK-1308/
quavonlimab)

TIGIT
(MK-7684/
vibostolimab)

LAG-3
(MK-4280/
favezelimab)

ILT4
(MK-4830)

Diversifying through acquisitions with BTK, HIF-2 α , ROR-1 ADC

 **ARQULE**
BTK
(MK-1026)

 **WELIREG**
(belzutifan)
HIF-2 α
(MK-6482)

 **VELOS BIO**
ROR-1 ADC
(MK-2140/ zilovetamab
vedotin)

Diversifying through partnerships with PARPi, VEGF TKI, HER2 TKI, LIV1 ADC

 **Lynparza**
olaparib
capsules 50 mg

 **Koselugo**
(selumetinib)
10 mg & 25 mg capsules

 **LENVIMA**
(lenvatinib) capsules 10 mg and 4 mg
RESULTS THAT MATTER

 **Eisai**

 **TUKYSA**
tucatinib
50 mg | 150 mg tablets

**Ladiratuzumab
Vedotin (LV)**

 **Seagen**

Further establishing KEYTRUDA[®] as a foundational anti-PD-1 cancer treatment in monotherapy and in combination regimens

 **KEYTRUDA**
(pembrolizumab) Injection 100 mg

Early-stage disease trials

Trial Name:	Tumor:	Mono/Combo:	PCD:
KEYNOTE-091	NSCLC	Mono/standard therapy	2021 - Interim
KEYNOTE-412	Head & Neck	Chemoradiation	2022
KEYNOTE-564	RCC	Mono	2022 - OS
KEYNOTE-676	Non-muscle invasive bladder	BCG	2022
KEYLYNK-001	Ovarian BRCAwt	Chemo followed by Lynparza	2023
KEYNOTE-585	Gastric	Chemo	2024
KEYNOTE-671	NSCLC	Chemo	2024
KEYNOTE-A18	Cervical	Chemoradiation	2024
KEYNOTE-937	HCC	Mono	2025
KEYNOTE-866	Muscle-invasive bladder	Chemo	2025
KEYNOTE-867	NSCLC Stage I/IIA	Stereostatic body radiotherapy	2025
KEYNOTE-689	Head & Neck	Mono/Chemoradiation	2025
KEYNOTE-630	Cutaneous squamous cell	Mono	2025
KEYNOTE-B21	Endometrial	Chemo +/- KEYTRUDA	2025
LEAP-012	HCC	Combo/ Chemoradiation	2025
KEYNOTE-905	Bladder	Cystectomy/EV	2026
KEYNOTE-242	TNBC	Mono	2026
KEYNOTE-992	Muscle-invasive bladder	Chemoradiation	2026
KEYNOTE-975	Esophageal	Chemoradiation	2026
KEYNOTE-B15	Muscle-invasive bladder	Enfortumab Vedotin (EV)	2026
KEYLINK-012	NSCLC	Combo/ Chemoradiation	2026
KEYNOTE-756	ER+/HER2- Breast	Chemo	2031

Includes trials that have not yet read out