Pfizer Highlights Diverse Oncology Portfolio and Combination Approaches at ESMO 2024

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More than 10 oral and mini-oral presentations span Pfizer’s extensive Oncology portfolio of approved and investigational therapiesTwo late-breaking presentations include longer-term results from BRAFTOVI ® + MEKTOVI ® PHAROS study in BRAF V600E-mutant metastatic NSCLC and new Phase 2 ponsegromab data in cancer cachexiaEncouraging early results for PD-L1 vedotin ADC, disitamab vedotin and the novel combination of CDK4 + CDK2 inhibitors highlight rapidly advancing pipeline

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) continues to showcase potential practice-changing research and next-generation candidates across its robust Oncology portfolio at the European Society for Medical Oncology (ESMO) Congress 2024, being held September 13-17 in Barcelona. Data from more than 50 company-sponsored, investigator-sponsored and collaborative research abstracts, including more than 10 oral and mini-oral presentations, will be presented across the company’s tumor areas and core scientific modalities, as well as a potential treatment for a cancer-related condition.

“At this year’s ESMO, we are looking forward to demonstrating our progress toward delivering next-generation biologics and novel combinations that have the potential to be new standards of care for patients,” said Chris Boshoff, Chief Oncology Officer and

Executive Vice President, Pfizer. “Our key data presentations highlight our scientific leadership in developing targeted therapies, including small molecules and antibody-drug conjugates, across our core tumor areas, including breast, bladder and thoracic cancers.”

“At ESMO, Pfizer will share important data highlighting our commitment to transforming outcomes for patients living with lung cancer, including longer-term follow-up results from the BRAFTOVI + MEKTOVI PHAROS study in *BRAF* V600E-mutated metastatic non-small cell lung cancer,” said Karin Tollefson, Chief Oncology Medical Officer, Pfizer. “We are also looking forward to sharing progress on our industry-leading pipeline of new molecules, including encouraging early results for two novel, investigational antibody-drug conjugates and preliminary data on a novel combination of Pfizer’s next-generation CDK inhibitors.”

Key research includes a late-breaking presentation of updated results from the pivotal Phase 2 PHAROS* study of BRAFTOVI (encorafenib) + MEKTOVI (binimetinib) in patients with *BRAF* V600E-mutant metastatic non-small cell lung cancer (mNSCLC). Longer-term efficacy and safety data will be presented, following the initial primary overall response results (ORR) that supported the FDA approval for BRAFTOVI + MEKTOVI in this indication in 2023 and the recent approval by the European Commission in August 2024. Further, Pfizer will share updated data from the safety lead-in of the ongoing Phase 3 BREAKWATER trial, showing antitumor activity of BRAFTOVI + cetuximab + FOLFIRI in patients with untreated *BRAF* V600E-mutant metastatic colorectal cancer (mCRC) in a mini-oral presentation.

Additionally, Pfizer will present a late-breaking Proffered Paper Presentation on the Phase 2 efficacy and safety results for its GDF-15 inhibitor, ponsegromab, in patients with cancer-associated cachexia, highlighting the company’s commitment to improving the treatment journey for people living with cancer. Cancer cachexia is a common, life-threatening wasting condition characterized by severe weight loss. The condition affects patients with advanced cancers and can greatly impact a patient’s ability to tolerate cancer treatment and quality of life. Despite its severity, there are no FDA-approved treatments for cachexia. i,ii

Pfizer will also present early clinical-stage research for a number of priority pipeline areas, including encouraging Phase 1 results of the potential first-in-class antibody-drug conjugate (ADC) candidate SGN-PDL1V (PF-08046054) in NSCLC and head and neck squamous cell carcinoma (HNSCC); initial data for the investigational ADC disitamab vedotin in combination with KEYTRUDA ® (pembrolizumab) in human epidermal growth factor receptor 2 (HER2)-expressing locally advanced or metastatic urothelial cancer

(la/mUC); and the first data combining atirmociclib, our highly-selective cyclin-dependent kinase 4 (CDK4) inhibitor (CDK4i), with a novel CDK2 inhibitor (CDK2i) in hormone receptor-positive (HR+)/HER2-negative metastatic breast cancer (MBC) from a Phase 1 dose-escalation study.

Key ESMO Presentations

Genitourinary Cancer

PADCEV + KEYTRUDA:** additional analysis from the pivotal EV-302 trial continues to support the combination as a new standard of care for patients with previously untreated la/mUC. An exploratory analysis shows PADCEV + KEYTRUDA ® showed consistent progression free survival (PFS), overall survival (OS), and ORR versus chemotherapy regardless of Nectin-4 or PD-L1 expression.**Disitamab Vedotin:** preliminary efficacy and safety data for disitamab vedotin in combination with KEYTRUDA highlights Pfizer’s continued commitment to developing novel therapeutics to meet the needs of patients with bladder cancer. Results from the safety run-in of the ongoing Phase 2 trial showed encouraging early efficacy and a safety profile consistent with previously presented data in treatment-naive patients with HER2-expressing la/mUC.

Thoracic Cancer

SGN-PDL1V (PF-08046054): encouraging Phase 1 results will be presented for PDL1V, a novel, investigational vedotin ADC directed to PD-L1-expressing solid tumors. Data from the dose-escalation and dose optimization cohorts of the ongoing Phase 1 study show PDL1V as monotherapy was generally well tolerated with no unexpected adverse events, and encouraging antitumor activity was observed in patients with heavily pretreated NSCLC and HNSCC.

Breast Cancer

Atirmociclib (PF-07220060) + PF-07104091 : initial data from a dose-escalation study evaluating the innovative combination of atirmociclib, a potential first-in-class CDK4-selective inhibitor, with PF-07104091, a novel CDK2-selective inhibitor, showed a manageable safety profile and encouraging efficacy in patients with heavily pretreated HR+/HER2- breast cancer. These early results highlight the potential of Pfizer's strategy to advance atirmociclib as a future CDK inhibitor backbone therapy that may address treatment resistance with first generation CDK4/6i, subject to clinical success and regulatory approval. The CDK4i+2i combination is continuing to be explored in an ongoing Phase 1b/2 dose escalation and dose expansion study (NCT05262400).

Additional information on the Pfizer-sponsored abstracts, including date and time of presentation, follow in the chart below.

Pfizer is continuing its commitment to help non-scientists understand the latest findings with the development of abstract plain language summaries (APLS) for company-sponsored research being presented at ESMO, which are written in non-technical language. Those interested in learning more can visit www.Pfizer.com/apls to access the summaries starting September 16, 2024.

BREAST CANCER

Mini Oral Presentation (Abstract 618MO) Saturday, September 14, 2:45 PM-4:15 PM CEST Phase 1b/2 first-in-class novel combination trial of next generation CDK4-selective inhibitor PF-07220060 and next generation CDK2-selective inhibitor PF-07104091 in HR+ HER2- metastatic breast cancer and advanced solid tumors Yap et al

Poster Presentation (Abstract 413P) Monday, September 16, 9:00 AM-5:00 PM CEST Longitudinal circulating tumor DNA (ctDNA) dynamics in Phase 1/2a study of the first-in-class CDK4-selective inhibitor, PF-07220060, in combination with endocrine therapy in patients with HR+/HER2− metastatic breast cancer (mBC) who progressed on prior CDK4/6 inhibitors Yap et al

Poster Presentation (Abstract 359P) Monday, September 16, 9:00 AM-5:00 PM CEST Overall survival of palbociclib (PAL) + endocrine therapy (ET) in Japanese patients with hormone receptor-positive (HR+)/ human epidermal growth factor receptor 2-negative (HER2-) advanced breast cancer (ABC) in the 1st line (1L) or 2nd line (2L) setting: A multicenter observational study Nakayama et al

Poster Presentation (Abstract 354P) Monday, September 16, 9:00 AM-5:00 PM CEST Synergistic preclinical efficacy through combination of the CDK4 and CDK2 selective inhibitors, PF-07220060 and PF-07104091, respectively, in HR+ HER2- breast cancer Anders et al

Poster Presentation (Abstract 356P) Monday, September 16, 9:00 AM-5:00 PM CEST Real-world effectiveness in subgroups of palbociclib + endocrine therapy in HR+/HER2- ABC patients: Interim Results of the PERFORM study Pfeiler et al

EARLY PIPELINE

Oral Presentation, Proffered Paper (Abstract 607O) Friday, September 13, 4:00 PM-5:30 PM CEST Interim results of a Phase 1 study of SGN-PDL1V (PF-08046054) in patients with

PDL1-expressing solid tumors Oliva Bernal et al

GASTROINTESTINAL CANCER

Mini Oral Presentation (Abstract 515MO) Saturday, September 14, 2:45 PM-4:15 PM CEST Encorafenib + cetuximab (EC) + FOLFIRI for *BRAF* V600E-mutant metastatic colorectal cancer (mCRC): updated results from the BREAKWATER safety lead-in (SLI) Tabernero et al

GENITOURINARY CANCER

Mini Oral Presentation (Abstract 1966MO) Sunday, September 15, 8:30 AM-10:00 AM CEST EV-302: Exploratory analysis of nectin-4 expression and response to 1L enfortumab vedotin (EV) + pembrolizumab (P) in previously untreated locally advanced or metastatic urothelial cancer (la/mUC) Powles et al

Poster Presentation (Abstract 1968P) Sunday, September 15, 9:00 AM-5:00 PM CEST Study EV-103 dose escalation/cohort A (DE/A): 5y follow-up of first-line (1L) enfortumab vedotin (EV) + pembrolizumab (P) in cisplatin (cis)-ineligible locally advanced or metastatic urothelial carcinoma (la/mUC) Rosenberg et al

Poster Presentation (Abstract 2001P) Sunday, September 15, 9:00 AM-5:00 PM CEST Epidemiology and treatment patterns of patients with locally advanced or metastatic urothelial cancer in France: a non-interventional database study Joly et al

Poster Presentation (Abstract 1638P) Sunday, September 15, 9:00 AM-5:00 PM CEST Enzalutamide (ENZA) with or without leuprolide in patients (pts) with high-risk biochemically recurrent (hrBCR) prostate cancer (PC): EMBARK post hoc analysis by age Shore et al

Poster Presentation (Abstract 1626P) Sunday, September 15, 9:00 AM-5:00 PM CEST Incidence of hematologic toxicities in the homologous recombination repair (HRR)-deficient population of the TALAPRO-2 trial and their potential association with germline vs somatic origin of HRR gene alterations Azad et al

Poster Presentation (Abstract 1637P) Sunday, September 15, 9:00 AM-5:00 PM CEST Efficacy of talazoparib and enzalutamide in metastatic castration-resistant prostate cancer (mCRPC) patients previously treated with androgen receptor pathway inhibitors (ARPI) or docetaxel – post hoc analysis from both cohorts in TALAPRO-2 study Agarwal et al

Poster Presentation (Abstract 1633P) Sunday, September 15, 9:00 AM-5:00 PM CEST Phase 3 study of talazoparib (TALA) + enzalutamide (ENZA) vs placebo (PBO) + ENZA as first-line (1L) treatment in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC): TALAPRO-2 (TP-2) China cohort Zeng et al

Mini Oral Presentation (Abstract 1967MO) Sunday, September 15, 8:30 AM-10:00 AM CEST Preliminary efficacy and safety of disitamab vedotin (DV) with pembrolizumab (P) in treatment (Tx)-naive HER2-expressing, locally advanced or metastatic urothelial carcinoma (la/mUC): RC48G001 Cohort C Galsky et al

MELANOMA

Poster Presentation (Abstract 1071TiP) Saturday, September 14, 9:00 AM-5:00 PM CEST Phase 1 study of the investigational CD228 x 4-1BB costimulatory antibody Anticalin bispecific SGN-BB228 (PF-08046049) in advanced melanoma and other solid tumors Dummer et al

SUPPORTIVE AND PALLIATIVE CARE

Oral Presentation, Proffered Paper (Abstract LBA82) Saturday, September 14, 2:45 PM-4:25 PM CEST Efficacy and safety of ponsegromab, a first-in-class, monoclonal antibody inhibitor of growth differentiation factor-15, in patients with cancer cachexia: A randomized, placebo-controlled, Phase 2 study Crawford et al

THORACIC CANCER

Mini Oral Presentation (Abstract LBA56) Saturday, September 14, 10:15 AM-11:45 AM CEST Updated efficacy and safety from the Phase 2 PHAROS study of encorafenib plus binimetinib in patients with *BRAF* V600E-mutant metastatic NSCLC (mNSCLC) Riely et al

Poster Presentation (Abstract 1398TiP) Saturday, September 14, 9:00 AM-5:00 PM CEST Be6A Lung-01, a Phase 3 study of sigvotatug vedotin (SV), an investigational antibody-drug conjugate (ADC) versus docetaxel in patients (pts) with previously treated non-small cell lung cancer (NSCLC) Peters et al

Poster Presentation (Abstract 1279P) Saturday, September 14, 9:00 AM-5:00 PM CEST First-line lorlatinib vs crizotinib in Asian patients with ALK+ non-small cell lung cancer (NSCLC): 5-year outcomes from the CROWN study Wu et al

**The PHAROS trial is conducted with support from Pierre Fabre.*

**Pfizer and Astellas have a clinical collaboration agreement with Merck to evaluate the combination of PADCEV ® and KEYTRUDA ® in patients with previously untreated metastatic urothelial cancer.*

Prescribing Information for Pfizer Medicines

Please see full Prescribing Information for PADCEV.

Please see full Prescribing Information for BRAFTOVI and full Prescribing Information for MEKTOVI.

About Pfizer Oncology

At Pfizer Oncology, we are at the forefront of a new era in cancer care. Our industry-leading portfolio and extensive pipeline includes three core mechanisms of action to attack cancer from multiple angles, including antibody-drug conjugates (ADCs), small molecules, bispecific antibodies and other immunotherapy biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, genitourinary cancer, hematology-oncology, and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs that help people with cancer globally live better and longer lives.

About Pfizer: Breakthroughs That Change Patients' Lives

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For 175 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com . In addition, to learn more, please visit us on www.Pfizer.com and follow us on X at @Pfizer and @Pfizer News , LinkedIn , YouTube and like us on Facebook at Facebook.com/Pfizer .

DISCLOSURE NOTICE:

The information contained in this release is as of September 11, 2024. The Company assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer Oncology, Pfizer's Oncology portfolio of marketed and investigational therapies, including combinations, and an investigational therapy for a cancer-related condition; expectations for our product pipeline, in-line products and product candidates, including their potential benefits, clinical trial results and other developing data; potential breakthrough, best- or first-in-class or blockbuster status or expected market entry of our medicines; and other statements about our business, operations and financial results that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risk and uncertainties include, among other things, uncertainties regarding the commercial success of Pfizer's oncology portfolio; the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; risks associated with interim and preliminary data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when any drug applications, biologics license applications and/or emergency use authorization applications may be filed in any jurisdictions for any potential indication for Pfizer's product candidates; whether and when any such applications that may be pending or filed for any of Pfizer's product candidates may be approved by regulatory authorities, which will depend on myriad factors, including making a determination as to whether the product's benefits outweigh its known risks and determination of the product's efficacy and, if approved, whether any such product candidates will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of Pfizer's products or product candidates, including development of products or therapies by other companies; manufacturing capabilities or capacity; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-

Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com .

i Cleveland Clinic. Cachexia (Wasting Syndrome). Cachexia (Wasting Syndrome): Symptoms & Treatment (clevelandclinic.org) . Accessed September 3, 2024. ii Lisa Martin, Michael B. Sawyer, Cancer Cachexia: Emerging Preclinical Evidence and the Pathway Forward to Clinical Trials, *JNCI: Journal of the National Cancer Institute* , Volume 107, Issue 12, December 2015, djv322, https://doi.org/10.1093/jnci/djv322

Category: Pipeline

Media Contact: +1 (212) 733-1226 **PfizerMediaRelations@Pfizer.com** Investor Contact: +1 (212) 733-4848 **IR@Pfizer.com**

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