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# TALZENNA Plus XTANDI Significantly Improves Radiographic Progression-Free Survival in Metastatic Prostate Cancer

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- *Primary endpoint met in Phase 3 TALAPRO-3 study demonstrating a statistically significant and clinically meaningful reduction in risk of disease progression or death in HRR gene-mutated metastatic hormone sensitive prostate cancer*
- *Consistent rPFS efficacy benefit was observed in patients whose tumors harbored BRCA and non-BRCA HRR gene alterations*
- *Interim analysis showed a strong trend toward improvement in overall survival*
- *These results will be discussed with global health authorities to potentially expand TALZENNA indication in this earlier stage disease*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive topline results from the Phase 3 TALAPRO-3 study of TALZENNA® (talazoparib), an oral poly ADP-ribose polymerase (PARP) inhibitor, in combination with XTANDI® (enzalutamide), an androgen receptor pathway inhibitor (ARPI), in people with homologous recombination repair (HRR) gene-mutated metastatic castration-sensitive prostate cancer (mCSPC), also known as metastatic hormone-sensitive prostate cancer (mHSPC).

The study met its primary endpoint, with TALZENNA plus XTANDI demonstrating a statistically significant and clinically meaningful improvement in radiographic progression-free survival (rPFS), compared to placebo plus XTANDI. The results markedly exceeded the pre-specified target hazard ratio of 0.63, with the majority of patients remaining progression-free at the time of analysis. Consistent efficacy benefit was also observed in patients whose tumors harbored BRCA and non-BRCA HRR gene alterations.

“Current treatment approaches leave many patients with HRR gene-mutated metastatic castration-sensitive prostate cancer vulnerable to early disease progression,” said Neeraj Agarwal, M.D., FASCO, Professor and Presidential Endowed Chair of Cancer Research at Huntsman Cancer Institute at the University of Utah, and global lead investigator for TALAPRO-3. “The TALAPRO-3 results demonstrate that treatment with TALZENNA in combination with XTANDI earlier in the disease course significantly extends the time patients can live without their cancer worsening.”

At the time of the interim analysis, results showed a strong trend toward improved overall survival (OS), a key secondary endpoint. Benefits were also observed in other secondary endpoints, including overall response rate, duration of response, and time to Prostate-Specific Antigen (PSA) progression. The safety of TALZENNA plus XTANDI was consistent with the known safety profile of each medicine, and no new safety signals were identified.

Prostate cancer is the second most common cancer in men worldwide, with an estimated 1.4 million new cases diagnosed globally in 2022[1] and 330,000 new cases anticipated in the United States in 2026.[2] mCSPC, is a form of advanced prostate cancer that has spread beyond the prostate but is still sensitive to androgen inhibition.[3] Despite recent treatment advances, 50% to 65% of patients with mCSPC progress to metastatic castration-resistant prostate cancer (mCRPC) within two years, with increased risk in HRR gene-mutated patients.[4-6]

“Alterations in DNA damage repair genes, such as HRR genes, are found in approximately 25% of metastatic prostate cancers and associated with a worse prognosis and are less responsive to current standards of care, representing a group with a high unmet need,” said Jeff Legos, Chief Oncology Officer, Pfizer. “TALZENNA plus XTANDI is already a standard of care in HRR gene-mutated metastatic castration-resistant prostate cancer, and these unprecedented results demonstrate the potential to deliver benefit earlier in the disease course. These findings underscore Pfizer’s leadership in precision medicine and commitment to bringing more personalized treatment options to people living with prostate cancer.”

TALZENNA plus XTANDI in HRR gene-mutated mCSPC is an investigational treatment regimen. The TALAPRO-3 results will be submitted for presentation at an upcoming medical congress and will be discussed with global health authorities for potential regulatory submissions.

TALZENNA plus XTANDI is currently approved in 60 countries, including in the United States for adults with HRR gene-mutated mCRPC and in the European Union for adults with mCRPC in whom chemotherapy is not clinically indicated.

**About TALAPRO-3**

The Phase 3 TALAPRO-3 trial is a multicenter, randomized, double-blind, placebo-controlled study that enrolled 599 patients with mCSPC [with ?3 months of ADT (chemical or surgical) with or without an approved ARPI in the mCSPC setting] at sites in the U.S., Canada, Europe, South America, and the Asia-Pacific region. Patients with histologically/cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, small cell, or signet cell features and with alterations in one or more HRR genes (as per HRR12 gene panel) in the trial were randomized to receive TALZENNA 0.5 mg/day plus XTANDI 160mg/day, or placebo plus XTANDI 160mg/day.

The primary endpoint of the trial is investigator-assessed radiographic progression-free survival (rPFS), defined as the time from the date of randomization to radiographic progression in soft tissue per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1), or in bone per Prostate Cancer Working Group 3 (PCWG3) criteria by investigator assessment, or death, whichever occurs first. Secondary endpoints include overall survival (OS), objective response rate (ORR), duration of response (DOR), prostate-specific antigen (PSA) response, and patient-reported outcomes.

For more information on the TALAPRO-3 trial (NCT04821622), go to www.clinicaltrials.gov.

**About TALZENNA® (talazoparib)**

TALZENNA is an oral inhibitor of poly ADP-ribose polymerase (PARP), which plays a role in DNA damage repair. Preclinical studies have demonstrated that TALZENNA blocks PARP enzyme activity and traps PARP at the site of DNA damage, leading to decreased cancer cell growth and cancer cell death.

TALZENNA was initially approved in the U.S., EU, and multiple other regions as a single agent for the treatment of adult patients with deleterious or suspected deleterious gBRCAm HER2-negative locally advanced or metastatic breast cancer.

TALZENNA in combination with XTANDI was approved by the U.S. Food and Drug Administration (FDA) for the treatment of adult patients with HRR gene-mutated mCRPC in June 2023. The combination was also approved by the European Commission in January 2024 for the treatment of adult patients with mCRPC in whom chemotherapy is not clinically indicated. TALZENNA in combination with XTANDI is approved in 60 countries, indications vary by country.

**TALZENNA® (talazoparib) Indication in the U.S.**

TALZENNA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for:

HRR gene-mutated mCRPC:

- In combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

Breast Cancer:

- As a single agent, for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for TALZENNA.

**TALZENNA® (talazoparib) Important Safety Information**

**WARNINGS and PRECAUTIONS**

**Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML)**, including cases with a fatal outcome, has been reported in patients who received TALZENNA. Overall, MDS/AML has been reported in 0.4% (3 out of 788) of solid tumor patients treated with TALZENNA as a single agent in clinical studies. In TALAPRO-2, MDS/AML occurred in 2 out of 511 (0.4%) patients treated with TALZENNA and enzalutamide and in 0 out of 517 (0%) patients treated with placebo and enzalutamide. The durations of TALZENNA treatment in these 5 patients prior to developing MDS/AML were 0.3, 1, 2, 3, and 5 years. Most of these patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

Do not start TALZENNA until patients have adequately recovered from hematological toxicity caused by previous chemotherapy. Monitor blood counts monthly during treatment with TALZENNA. For prolonged hematological toxicities, interrupt TALZENNA and monitor blood counts weekly until recovery. If counts do not recover within 4 weeks, refer the patient to a hematologist for further investigations including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue TALZENNA.

**Myelosuppression** consisting of anemia, neutropenia, and/or thrombocytopenia, have been reported in patients treated with TALZENNA. In TALAPRO-2, Grade ?3 anemia, neutropenia, and thrombocytopenia were reported, respectively, in 48%, 19%, and 9% of patients receiving TALZENNA and enzalutamide. Forty-two percent of patients (216/511) required a red blood cell transfusion, including 25% (127/511) who required more than one transfusion. Discontinuation due to anemia, neutropenia, and thrombocytopenia occurred, respectively, in 8%, 3%, and 0.4% of patients.

Withhold TALZENNA until patients have adequately recovered from hematological toxicity caused by previous therapy. Monitor blood counts monthly during treatment with TALZENNA. If hematological toxicities do not resolve within 28 days, discontinue TALZENNA and refer the patient to a hematologist for further investigations including bone marrow analysis and blood sample for cytogenetics.

**Embryo-Fetal Toxicity** TALZENNA can cause fetal harm when administered to pregnant women. Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 4 months following the last dose of TALZENNA.

**ADVERSE REACTIONS**

Serious adverse reactions reported in >2% of patients included anemia (9%) and fracture (3%). Fatal adverse reactions occurred in 1.5% of patients, including pneumonia, COVID infection, and sepsis (1 patient each).

The most common adverse reactions (? 10%, all Grades), including laboratory abnormalities, for patients in the TALAPRO-2 study who received TALZENNA with enzalutamide vs patients receiving placebo with enzalutamide were hemoglobin decreased (79% vs 34%), neutrophils decreased (60% vs 18%), lymphocytes decreased (58% vs 36%), fatigue (49% vs 40%), platelets decreased (45% vs 8%), calcium decreased (25% vs 11%), nausea (21% vs 17%), decreased appetite (20% vs 14%), sodium decreased (22% vs 20%), phosphate decreased (17% vs 13%), fractures (14% vs 10%), magnesium decreased (14% vs 12%), dizziness (13% vs 9%), bilirubin increased (11% vs 7%), potassium decreased (11% vs 7%), and dysgeusia (10% vs 4.5%).

Clinically relevant adverse reactions in <10% of patients who received TALZENNA with enzalutamide included abdominal pain (9%), vomiting (9%), alopecia (7%), dyspepsia (4%), venous thromboembolism (3%) and stomatitis (2%).

**DRUG INTERACTIONS**

**Coadministration with P-gp inhibitors** The effect of coadministration of P-gp inhibitors on talazoparib exposure when TALZENNA is taken with enzalutamide has not been studied. Monitor patients for increased adverse reactions and modify the dosage as recommended for adverse reactions when TALZENNA is coadministered with a P-gp inhibitor.

**Coadministration with BCRP inhibitors** Monitor patients for increased adverse reactions and modify the dosage as recommended for adverse reactions when TALZENNA is coadministered with a BCRP inhibitor. Coadministration of TALZENNA with BCRP inhibitors may increase talazoparib exposure, which may increase the risk of adverse reactions.

**USE IN SPECIFIC POPULATIONS**

**Males of Reproductive Potential** Based on animal studies, TALZENNA may impair fertility.

**Renal Impairment** The recommended dosage of TALZENNA for patients with moderate renal impairment (CLcr 30 - 59 mL/min) is 0.35 mg taken orally once daily with enzalutamide. The recommended dosage of TALZENNA for patients with severe renal impairment (CLcr 15 - 29 mL/min) is 0.25 mg taken orally once daily with enzalutamide. No dose adjustment is required for patients with mild renal impairment. TALZENNA has not been studied in patients requiring hemodialysis.

Please see full U.S. Prescribing Information and Patient Information for TALZENNA® (talazoparib) at www.TALZENNA.com.

**About XTANDI® (enzalutamide)**

XTANDI (enzalutamide) is an androgen receptor pathway inhibitor. XTANDI is a standard of care and has received regulatory approvals in one or more countries around the world for use in people with metastatic hormone-sensitive prostate cancer (mHSPC), metastatic castration-resistant prostate cancer (mCRPC), non-

metastatic castration-resistant prostate cancer (nmCRPC) and non-metastatic hormone-sensitive prostate cancer (nmHSPC) with high-risk biochemical recurrence (BCR). XTANDI is currently approved for one or more of these indications in more than 80 countries, including in the United States, European Union and Japan. Over 1.5 million patients have been treated with XTANDI globally.[7]

**About XTANDI® (enzalutamide) and Important Safety Information**

XTANDI (enzalutamide) is indicated for the treatment of patients with:

- castration-resistant prostate cancer (CRPC)
- metastatic castration-sensitive prostate cancer (mCSPC)
- nonmetastatic castration sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (high-risk BCR)

**Important Safety Information**

**Warnings and Precautions**

**Seizure** occurred in 0.6% of patients receiving XTANDI in eight randomized clinical trials. In a study of patients with predisposing factors for seizure, 2.2% of XTANDI-treated patients experienced a seizure. It is unknown whether anti-epileptic medications will prevent seizures with XTANDI. Patients in the study had one or more of the following predisposing factors: use of medications that may lower the seizure threshold, history of traumatic brain or head injury, history of cerebrovascular accident or transient ischemic attack, and Alzheimer's disease, meningioma, or leptomeningeal disease from prostate cancer, unexplained loss of consciousness within the last 12 months, history of seizure, presence of a space occupying lesion of the brain, history of arteriovenous malformation, or history of brain infection. Advise patients of the risk of developing a seizure while taking XTANDI and of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

**Posterior Reversible Encephalopathy Syndrome (PRES)** There have been reports of PRES in patients receiving XTANDI. PRES is a neurological disorder that can present with rapidly evolving symptoms including seizure, headache, lethargy, confusion, blindness, and other visual and neurological disturbances, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably MRI. Discontinue XTANDI in patients who develop PRES.

**Hypersensitivity** reactions, including edema of the face (0.5%), tongue (0.1%), or lip (0.1%) have been observed with XTANDI in eight randomized clinical trials. Pharyngeal edema has been reported in post-marketing cases. Advise patients who experience any symptoms of hypersensitivity to temporarily discontinue XTANDI and promptly seek medical care. Permanently discontinue XTANDI for serious hypersensitivity reactions.

**Ischemic Heart Disease** In the combined data of five randomized, placebo-controlled clinical studies, ischemic heart disease occurred more commonly in patients on the XTANDI arm compared to patients on the placebo arm (3.5% vs 2%). Grade 3-4 ischemic events occurred in 1.8% of patients on XTANDI versus 1.1% on placebo. Ischemic events led to death in 0.4% of patients on XTANDI compared to 0.1% on placebo. Monitor for signs and symptoms of ischemic heart disease. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Discontinue XTANDI for Grade 3-4 ischemic heart disease.

**Falls and Fractures** occurred in patients receiving XTANDI. Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use

of bone-targeted agents. In the combined data of five randomized, placebo-controlled clinical studies, falls occurred in 12% of patients treated with XTANDI compared to 6% of patients treated with placebo. Fractures occurred in 13% of patients treated with XTANDI and in 6% of patients treated with placebo.

**Embryo-Fetal Toxicity** The safety and efficacy of XTANDI have not been established in females. XTANDI can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment with XTANDI and for 3 months after the last dose of XTANDI.

**Dysphagia or Choking** Severe dysphagia or choking, including events that could be life-threatening requiring medical intervention or fatal, can occur due to XTANDI product size. Advise patients to take each capsule or tablet whole with a sufficient amount of water to ensure that all medication is successfully swallowed. Consider use of a smaller tablet size of XTANDI in patients who have difficulty swallowing. Discontinue XTANDI for patients who cannot swallow capsules or tablets.

**Interference with Immunoassay Measurement of Digoxin** XTANDI can interfere with certain digoxin immunoassays (e.g., Chemiluminescent Microparticle Immunoassays), resulting in falsely elevated digoxin plasma concentration results. Notify the laboratory conducting the digoxin plasma concentration assay to use an appropriate method in patients receiving XTANDI and digoxin.

**Adverse Reactions (ARs)**

In the data from the five randomized placebo-controlled trials, the most common ARs (? 10%) that occurred more frequently (? 2% over placebo) in XTANDI-treated patients were musculoskeletal pain, fatigue, hot flush, constipation, decreased appetite, diarrhea, hypertension, hemorrhage, fall, fracture, and headache. In the bicalutamide-controlled study, the most common ARs (? 10%) reported in XTANDI-treated patients were asthenia/fatigue, back pain, musculoskeletal pain, hot flush, hypertension, nausea, constipation, diarrhea, upper respiratory tract infection, and weight loss.

In EMBARK, the placebo-controlled study of nonmetastatic CSPC (nmCSPC) with high-risk biochemical recurrence (BCR) patients, Grade 3 or higher adverse reactions during the total duration of treatment were reported in 46% of patients treated with XTANDI plus leuprolide, 50% of patients receiving XTANDI as a single agent, and 43% of patients receiving placebo plus leuprolide. Permanent treatment discontinuation due to adverse reactions during the total duration of treatment as the primary reason was reported in 21% of patients treated with XTANDI plus leuprolide, 18% of patients receiving XTANDI as a single agent, and 10% of patients receiving placebo plus leuprolide.

**Lab Abnormalities:** Lab abnormalities that occurred in ? 5% of patients, and more frequently (> 2%) in the XTANDI arm compared to placebo in the pooled, randomized, placebo-controlled studies are hemoglobin decrease, neutrophil count decreased, white blood cell decreased, hyperglycemia, hypermagnesemia, hyponatremia, hypophosphatemia, and hypercalcemia.

**Hypertension:** In the combined data from five randomized placebo-controlled clinical trials, hypertension was reported in 14.2% of XTANDI patients and 7.4% of placebo patients. Hypertension led to study discontinuation in < 1% of patients in each arm.

**Drug Interactions**

**Effect of Other Drugs on XTANDI** Avoid coadministration with strong CYP2C8 inhibitors. If coadministration cannot be avoided, reduce the dosage of XTANDI. Avoid coadministration with strong

CYP3A4 inducers. If coadministration cannot be avoided, increase the dosage of XTANDI.

**Effect of XTANDI on Other Drugs** Avoid coadministration with certain CYP3A4, CYP2C9, and CYP2C19 substrates for which minimal decrease in concentration may lead to therapeutic failure of the substrate. If coadministration cannot be avoided, increase the dosage of these substrates in accordance with their Prescribing Information. In cases where active metabolites are formed, there may be increased exposure to the active metabolites.

Please access this link for XTANDI'S US Full Prescribing Information for additional safety information.

**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 small molecules, antibody-drug conjugates (ADCs), and multispecific antibodies, including other immune-oncology biologics. We are focused on delivering transformative therapies in some of the world's most common cancers, including breast cancer, gastrointestinal cancers, genitourinary cancers, hematology-oncology, and thoracic cancers, which includes lung cancer. Driven by science, we are committed to accelerating breakthroughs to help people with cancer 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.

**About the Pfizer/Astellas Collaboration**

In October 2009, Medivation, Inc., which is now part of Pfizer (NYSE: PFE), and Astellas (TSE: 4503) entered into a global agreement to jointly develop and commercialize XTANDI® (enzalutamide). The companies jointly commercialize XTANDI in the United States, and Astellas has responsibility for manufacturing and all additional regulatory filings globally, as well as commercializing XTANDI outside the United States.

**Disclosure Notice**

The information contained in this release is as of March 19, 2026. Pfizer 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, TALZENNA and XTANDI, including their potential benefits, the TALAPRO-3 results, and plans to discuss the results with global health authorities to potentially expand the TALZENNA indication, that involves substantial risks and uncertainties that

could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, uncertainties regarding the commercial success of TALZENNA in combination with XTANDI; 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; whether the TALAPRO-3 trial will meet the key secondary endpoint for overall survival; risks associated with initial, preliminary or interim 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 applications for TALZENNA, XTANDI or a combination may be filed in any jurisdictions for any potential indications; whether and when any such applications for TALZENNA, XTANDI or a combination that may be pending or filed 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 TALZENNA, XTANDI or a combination 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 TALZENNA, XTANDI or a combination; risks and uncertainties related to issued or future executive orders or other new, or changes in, laws or regulations; 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, 2025, 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.

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