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Pfizer’s Sasanlimab in Combination with BCG Improves Event-Free Survival in Patients with BCG-Naïve, High-Risk Non-Muscle Invasive Bladder Cancer

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- *C linically meaningful and statistically significant results are the first pivotal Phase 3 data for sasanlimab, a subcutaneously administered PD-1 inhibitor*
- *If approved, sasanlimab would be the first PD-1 inhibitor, in combination with BCG, to significantly prolong event-free survival in this patient population*
- *Treatment na ï ve high-risk NMIBC is an area of significant unmet need, where therapeutic options have largely remained unchanged for over three decades*

NEW YORK--(BUSINESS WIRE)-- Pfizer Inc. (NYSE: PFE) today announced positive topline results from its pivotal Phase 3 CREST trial evaluating sasanlimab, an investigational anti-PD-1 monoclonal antibody (mAb), in combination with Bacillus Calmette-Guérin (BCG) as induction therapy with or without maintenance in patients with BCG-naïve, high-risk non-muscle invasive bladder cancer (NMIBC). The study met its primary endpoint of event-free survival (EFS) by investigator assessment, demonstrating a clinically meaningful and statistically significant improvement with sasanlimab in combination with BCG (induction and maintenance) as compared to BCG alone (induction and maintenance).

“Patients with BCG-naïve high-risk non-muscle invasive bladder cancer have high rates of recurrence and progression,” said Neal Shore, M.D., FACS, Medical Director for the Carolina Urologic Research Center, and lead investigator for the CREST trial. “These study results demonstrate the potential for sasanlimab in combination with BCG to redefine the treatment paradigm for patients living with BCG-naïve, high-risk non-muscle invasive bladder cancer, including patients with carcinoma in-situ (CIS), providing prolonged event-free survival which may delay or reduce the need for more aggressive treatment options. Administered subcutaneously every four weeks, sasanlimab, if approved, could also help lower the treatment burden on both patients and healthcare systems.”

Each year, approximately 100,000 people globally are diagnosed with high-risk NMIBC.[3] Induction therapy with BCG followed by maintenance has been the standard of care for patients with high-risk NMIBC for decades.[4] 40-50% of patients experience recurrent disease, often requiring radical cystectomy,[5,6,7] which is associated with significant risks[8,9,10] and bladder-sparing treatment options are still limited.[11,12]

“The initial therapy of high-risk, non-muscle invasive bladder cancer with BCG has not advanced in decades. Today’s pivotal Phase 3 CREST results are potentially practice-changing, representing the first advance in therapy for BCG-naïve, high-risk, non-muscle invasive cancer in over 30 years,” said Roger Dansey, M.D., Chief Oncology Officer, Pfizer. “These results reinforce Pfizer’s leadership in genitourinary cancer research and development, demonstrating our ongoing commitment to deliver new treatment options for patients with bladder cancer.”

The overall safety profile of sasanlimab in combination with BCG was generally consistent with the known profile of BCG and data reported from clinical trials with sasanlimab. The profile of sasanlimab was also generally consistent with the reported safety profile of PD-1 inhibitors.

Results will be submitted for presentation at an upcoming medical congress. Pfizer plans to discuss these data with global health authorities to support potential regulatory filings. Sasanlimab also continues to be investigated in combination with Pfizer's antibody drug conjugate (ADC) portfolio in advanced solid tumors.

About CREST

The CREST trial is a Phase 3, multinational, randomized, open-label, three parallel-arm study of sasanlimab, an anti-PD-1 mAb, in combination with BCG (BCG induction with or without BCG maintenance) versus BCG (induction and maintenance) in participants with BCG-naïve, high-risk NMIBC. Patients were randomized to receive sasanlimab 300 mg by subcutaneous (SC) injection every four weeks up to cycle 25 (cycle = four weeks), in combination with BCG once weekly for six consecutive weeks (induction period) followed (Arm A) or not (Arm B) by maintenance with BCG, or BCG induction and maintenance up to cycle 25 (Arm C). The primary endpoint is EFS as assessed by the investigator, between Arm A and C, defined as the time from randomization to the earliest of recurrence of high-grade disease, progression of disease, persistence of CIS, or death. Key secondary endpoints include EFS as assessed by the investigator between Arm B and Arm C.

About Sasanlimab

Sasanlimab is a humanized immunoglobulin G4 mAb that binds to human programmed death-1 (PD-1) to block its interaction with PD-1 and PD-L1/PD-L2. PD-1 is a protein expressed on T cells, dendritic cells, natural killer cells, macrophages, and B cells, that functions as an immune checkpoint that negatively regulates T-cell activation and effector function when activated by its ligands and may play an important role in tumor evasion from host immunity. It can be administered through a once every four weeks subcutaneous injection by prefilled syringe (2mL).

In early-stage clinical studies, sasanlimab administered at 300 mg SC every four weeks showed clinical efficacy in advanced solid tumors and advanced urothelial cancer. In addition to NMIBC, sasanlimab is being evaluated in several ongoing clinical trials with other novel combinations.

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 bispecific 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, genitourinary cancer, 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.

Disclosure Notice

The information contained in this release is as of January 10, 2025. 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, sasanlimab, an investigational anti-PD-1 monoclonal antibody, in combination with Bacillus Calmette-Gurin (BCG), as induction therapy with or without maintenance in patients with BCG-naïve, high-risk non-muscle invasive bladder cancer, including their potential benefits, the CREST results and plans to share the results with global health authorities to support potential regulatory filings, 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, 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; 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 sasanlimab in combination with BCG may be filed in any jurisdictions for any potential indications; whether and when any such applications for sasanlimab in combination with BCG that may be 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 sasanlimab in combination with BCG 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 sasanlimab in combination with BCG; 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 .

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