News Release

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Janssen Reports First Results from Phase 2 SunRISe-1 Study of TAR-200 and Anti-PD-1 Antibody Cetrelimab in Patients with Bacillus Calmette-Guérin-Unresponsive Non-Muscle-Invasive Bladder Cancer

Study results of novel drug-eluting technology highlight potential durability of TAR-200 in patient population with high unmet need

CHICAGO, April 30, 2023 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today the first results from the open-label Phase 2 SunRISe-1 study evaluating the efficacy and safety of TAR-200 monotherapy (a novel investigational intravesical drug delivery system) and cetrelimab monotherapy (an investigational anti-PD-1 monoclonal antibody administered intravenously) in patients with Bacillus Calmette-Guérin (BCG)-unresponsive high-risk non-muscle-invasive bladder cancer (HR-NMIBC), who are ineligible for, or decline, radical cystectomy. The study demonstrated that 72.7 percent of patients treated with TAR-200 alone (95 percent confidence interval [CI] 49.8-89.3) and 38.1 percent of patients treated with cetrelimab alone (CI 18.1-61.6) achieved the primary endpoint of a complete response (CR). These data were featured today in a Late Breaker Podium Presentation Session (Abstract #LBA02-03) at the American Urological Association Annual Meeting (AUA).

"We continue to see significant unmet need among high-risk patients with non-muscle-invasive bladder cancer, who often experience negative outcomes and poor quality of life with existing standard of care treatments, such as radical cystectomy," said Siamak Daneshmand*, M.D., Professor of Urology, Director of Urologic Oncology at the Norris Comprehensive Cancer Center, Keck School of Medicine of University of Southern California and SunRISe-1 study principal investigator. "As a clinician, my ultimate treatment goal is to achieve deep and durable responses in these patients. It is encouraging to see an improvement among those treated with TAR-200 alone, as well as cetrelimab alone, and we look forward to reporting on results from the study cohort that is evaluating these two treatments in combination in the future."

HR-NMIBC includes lesions confined to the bladder mucosa and has a higher likelihood of local recurrence and distant progression to other parts of the body.[1] HR-NMIBC is typically treated with BCG – a type of intravesical immunotherapy – as the standard of care. BCG involves injecting a weakened form of tuberculosis bacteria into the bladder, stimulating the immune system to attack the cancer cells; however, approximately one-third of HR-NMIBC patients will not respond to the treatment. For BCG-unresponsive patients, there is an anti-PD-1 monoclonal antibody as an alternate, approved treatment option.[2,3,4] NMIBC represents some 70 percent of newly diagnosed bladder cancer cases, of which 10 percent are carcinoma in situ (CIS), early cancer cells confined within the innermost layer of the bladder lining; 50 percent of all cases of CIS will progress to muscle-invasive bladder cancer (MIBC) within 5 years if left untreated.[5,**Error! Bookmark not defined.**]

TAR-200 is a novel investigational intravesical drug delivery system designed to provide sustained local release of gemcitabine into the bladder urine. Cetrelimab is an investigational anti-PD-1 monoclonal antibody administered intravenously. The SunRISe-1 study evaluated patients with histologically confirmed CIS, with or without concomitant high-grade Ta (CIS) or T1 (CIS cases with higher risk of progressing to MIBC) papillary disease, a type of NMIBC. Patients were randomized to one of three cohorts: treatment with TAR-200 in combination with cetrelimab (Cohort 1 [C1]), TAR-200 alone (Cohort 2 [C2]) or cetrelimab alone (Cohort 3 [C3]). C2 and C3 results were reported at AUA with C1 results to be reported at a future date. The primary endpoint of CR at any time was determined by cystoscopy, central cytology, and central pathology (Weeks 24 and 48). Secondary endpoints included duration of response (DOR), overall survival (OS), pharmacokinetics, quality of life, safety, and tolerability.

Preliminary results of the SunRISe-1 study included 23 evaluable patients in C2 and 24 evaluable patients in C3. After median follow-up of 10.6 months, 15 of 16 responses in C2 are still ongoing; median DOR was not reached. Additionally, six of the patients in C2 maintained their response beyond 12 months and none of the complete responders had documented recurrence or progression.

The initial findings from SunRISe-1 showed low rates of grade three or higher adverse events (AEs) and a limited number of treatment discontinuations due to adverse events were observed with TAR-200. The most common AEs were pollakiuria (34.8 percent), micturition urgency (34.8 percent), dysuria (26.1 percent), and noninfective cystitis (21.7 percent) in C2; pruritus (20.8 percent) and diarrhea (20.8 percent) occurred in patients in C3. Seven patients in C2 (30.4 percent) and two patients in C3 (8.3 percent) had AEs that were grade three or higher.

"Our ambition is to improve the lives of patients living with non-muscle and muscle-invasive bladder cancers and redefine the treatment of this disease in the future," said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Janssen Research & Development, LLC. "With the innovative TAR-200 intravesical drug delivery system, we are committed to advancing bladder cancer treatment across the spectrum of this disease, and we look forward to providing further updates from our robust SunRISe clinical program."

Bladder cancer is the sixth most common cancer in the United States, with more than 80,000 patients diagnosed annually, and is the tenth most common cancer worldwide, with more than 600,000 patients diagnosed each year.[6,7] Bladder cancer occurs when cells in the bladder tissue grow uncontrollably, often forming a tumor that can then spread to other parts of the body if left untreated. Non-muscle-invasive bladder cancers are limited to the urothelium, the innermost layer of the bladder, and may be less aggressive than muscle-invasive bladder cancer, a type of cancer that arises from the muscular layer of the bladder or has grown beyond the urothelium and is more likely to spread to other parts of the body.[8]

About SunRISe-1

SunRISe-1 (NCT04640623) is a Phase 2 randomized, parallel-assignment, open-label clinical study evaluating the safety and efficacy of TAR-200 in combination with cetrelimab,

TAR-200

alone, or cetrelimab alone for BCG-unresponsive HR-NMIBC CIS patients who are ineligible for, or decline, radical cystectomy. Participants are randomized to one of three cohorts: treatment with TAR-200 in combination with cetrelimab (C1), TAR-200 alone (C2), or cetrelimab alone (C3). The primary endpoint is CR rate at any time point. Secondary endpoints include DOR, OS, pharmacokinetics, quality of life, safety, and tolerability.

About TAR-200

TAR-200 is an investigational drug delivery system, enabling controlled release of gemcitabine into the bladder, increasing dwell time and local drug exposure. The safety and efficacy of TAR-200 are being evaluated in Phase 2 and Phase 3 studies in patients with muscle-invasive bladder cancer in SunRISe-2 and SunRISe-4 and NMIBC in SunRISe-1 and SunRISe-3.

About Cetrelimab

Administered intravenously, cetrelimab is an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied to treat bladder cancer, prostate cancer, melanoma, and multiple myeloma as part of a combination treatment. Cetrelimab is also being evaluated in multiple other combination regimens across the Janssen Oncology portfolio.

About High-risk Non-Muscle-Invasive Bladder Cancer

High-risk non-muscle-invasive bladder cancer (HR-NMIBC) is a type of non-invasive bladder cancer that is more likely to recur or spread beyond the lining of the bladder, called the urothelium, and progress to invasive bladder cancer compared to low-risk NMIBC. HR-NMIBC makes up 15-44 percent of patients with NMIBC and is characterized by a high-grade, large tumor size, presence of multiple tumors, and CIS. Radical cystectomy is currently recommended for NMIBC patients who fail BCG therapy, with over 90 percent cancer-specific survival if performed before muscle-invasive progression. Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy. The high rates of recurrence and progression can pose significant morbidity and distress for these patients.[9]

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with

ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us at @JanssenGlobal and @JanssenUS. Janssen Research & Development, LLC and Janssen Biotech, Inc. belong to the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of TAR-200 or cetrelimab. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC; Janssen Biotech, Inc., and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 1, 2023, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of Janssen Research & Development, Janssen Biotech, Inc., the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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[*] Dr. Daneshmand has not been paid for any media work.

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