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For Immediate Release

TAR-200 monotherapy shows greater than 80 percent complete response rate in patients with high-risk non-muscle-invasive bladder cancer

New data from Phase 2b SunRISe-1 study show rapid achievement of complete response (CR) with 98 percent achieving a CR within 12 weeks[1]

TAR-200 provides durable CRs in patients with Bacillus Calmette-Guérin (BCG)-unresponsive high-risk non-muscle invasive bladder cancer (HR-NMIBC) with carcinoma in situ – a disease area with limited treatment options for patients[1]

BEERSE, BELGIUM (3 May 2024) – Janssen-Cilag International NV, a Johnson & Johnson company, announced today updated results from Cohort 2 of the Phase 2b SunRISe-1 study evaluating the efficacy and safety of investigational TAR-200 monotherapy in patients with BCG - HR-NMIBC with carcinoma in situ (CIS), who are ineligible for, or decline, radical cystectomy. These data were featured today in a plenary session (Abstract #P2-01) at the 2024 American Urological Association Annual Meeting (AUA) taking place 3-6 May 2024, in San Antonio, Texas.[1]

“The high complete response rate and durability of these responses observed in patients treated with TAR-200 underscores the potential of this treatment approach for patients with BCG-unresponsive HR-NMIBC,” said Joseph Jacob*, M.D., M.S., Department of Urology, Upstate Medical University, presenting author. “These results address an area of high unmet need for bladder sparing therapies in this patient population.”

Results included an evaluation of 85 patients (median age of 71 years old: range 40-88; 32.9 percent with concurrent papillary disease) who received TAR-200 monotherapy.[1] The centrally confirmed complete response (CR) rate was 82.8 percent by urine cytology and/or biopsy (95 percent confidence interval (CI), 70.6-91.4).[1] The study protocol did not allow retreatment for nonresponders, consistent with U.S. Food and Drug Administration (FDA) guidance.[1] The estimated one-year duration of response (DOR) rate is 74.6 percent (95 percent CI, 49.8-88.4), with median follow-up in responders of 29.9 weeks (range, 14-140); 41 of 48 responders (85 percent) remain in CR at data cutoff as of 2 January, 2024, and none of the responders progressed to muscle-invasive bladder cancer or metastasis.[1] 98 percent (47 of 48) of CRs were achieved at first disease assessment at week 12, and four of five patients who have completed two years of treatment remain in CR.[1] The investigator-assessed confirmed CR rate correlated strongly with central results.[1]

“The SunRISe-1 study results reinforce our dedication to improving the lives of patients with bladder cancer,” said Henar Hevia, Senior Director, EMEA Therapeutic Area Lead, Oncology, Johnson & Johnson Innovative Medicine. “By focusing on bladder preservation through targeted, sustained release, these data underscore the potential of TAR-200 to offer a differentiated approach that not only improves clinical outcomes, but also the quality of life for patients with this otherwise difficult-to-treat form of bladder cancer.”

Interim results from the SunRISe-1 study were featured at the European Society for Medical Oncology 2023 Congress[2] and shared at AUA 2023.[3] These results were also presented at the European Association of Urology 2024 Congress.[4]

Treatment-related adverse events (TRAEs) occurred in 61 patients (71.8 percent).[1] The most common (≥10 percent) were pollakiuria (35.3 percent), dysuria (29.4 percent), micturition urgency (15.3 percent), and urinary tract infections (15.3 percent).[1] Seven patients (8.2 percent) had Grade 3 or higher TRAEs and four patients (4.7 percent) had one or more serious TRAEs.[1] Four patients (4.7 percent) had TRAEs leading to discontinuation and no deaths were reported.[1]

“These study results mark a significant step in our mission to bring new treatment options to patients that focus on bladder preservation and long-term survival,” said Christopher Cutie, M.D., Vice President, Disease Area Leader, Bladder Cancer, Johnson & Johnson Innovative Medicine. “These results reinforce the potential of TAR-200 to transform the treatment landscape and our ongoing dedication to address unmet needs for patients facing this challenging disease.”

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Europe has one of the highest rates of bladder cancer in the world[5] with nearly 225,000 patients diagnosed in 2022,[6] a 10 percent increase from 2020.[7] NMIBC accounts for approximately 75 percent of all newly diagnosed bladder cancers.[8] Although BCG immunotherapy has been accepted as the standard of care for nearly five decades, 30 to 40 percent of patients do not respond to BCG, and experience disease recurrence or progression.[9] In such scenarios for patients with HR-NMIBC, radical cystectomy (removal of the bladder and neighbouring structures and organs) emerges as the primary treatment option.[9] This major abdominal procedure requires a urinary diversion to be created to collect and store urine.[10]

#ENDS#

About SunRISe-1
SunRISe-1 (NCT04640623) is a randomised, parallel-assignment, open-label Phase 2 clinical study evaluating the safety and efficacy of TAR-200 in combination with cetrelimab, TAR-200 alone, or cetrelimab alone for patients with BCG-unresponsive HR-NMIBC CIS with or without papillary disease who are ineligible for, or elected not to undergo, radical cystectomy.[11] Participants are randomised to one of four cohorts: treatment with TAR-200 in combination with cetrelimab (Cohort 1), TAR-200 alone (Cohort 2), cetrelimab alone (Cohort 3), or TAR-200 alone with papillary disease only (Cohort 4).[11] The primary endpoint is CR rate at any time point.[11] Secondary endpoints include DOR, overall survival, pharmacokinetics, quality of life, safety, and tolerability.[11] Cohorts 1 and 3 were closed to further enrollment effective 1 June, 2023.[11]

About TAR-200
TAR-200 is an investigational targeted releasing system, enabling controlled release of gemcitabine into the bladder, increasing the amount of time the drug delivery system spends in the bladder and sustaining local drug exposure.[12,13] 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 (NCT04658862)[14] and SunRISe-4 (NCT04919512),[15] NMIBC in SunRISe-1 (NCT04640623)[11] , SunRISe-3 (NCT05714202)[16] and SunRISe-5 (NCT06211764).[17]

About Cetrelimab
Administered intravenously, cetrelimab is an investigational programmed cell death receptor-1 (PD-1) monoclonal antibody being studied for the treatment of bladder cancer,[18,19] prostate cancer, melanoma, and multiple myeloma as part of a combination treatment. Cetrelimab is also being evaluated in multiple other combination regimens across the Johnson & Johnson 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.[20] HR-NMIBC is characterised by a high-grade, large tumour size, presence of multiple tumours, and CIS.[20] Radical cystectomy is currently recommended for HR-NMIBC patients who fail BCG therapy, with over 90 percent cancer-specific survival if performed before muscle-invasive progression.[20] Given that NMIBC typically affects older patients, many may be unwilling or unfit to undergo radical cystectomy.[20] The high rates of recurrence and progression can pose significant morbidity and distress for these patients.[20]

About Johnson & Johnson
At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

Learn more at https://www.jnj.com/emea. Follow us at https://twitter.com/JNJInnovMedEMEA and https://www.linkedin.com/company/jnj-innovative-medicine-emea/ for our latest news. Janssen-Cilag International NV, Janssen Pharmaceutica NV, and Janssen Research & Development, LLC are Johnson & Johnson companies.

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-Cilag International NV, Janssen Pharmaceutica NV, and Janssen Research & Development, LLC and 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 December 31, 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-Cilag International NV, Janssen Pharmaceutica NV, and Janssen Research & Development, LLC nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

**Dr. Jacob has not been paid for any media work.*

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