Tyra Biosciences Doses First Patient in Phase 2 Study of TYRA-300 in Low-Grade Intermediate Risk Non-Muscle Invasive Bladder Cancer (SURF302)

-TYRA-300 is the only orally administered investigational agent in clinical development for IR NMIBC-

-Initial 3-month complete response (CR) data expected to be reported in 1H 2026-

CARLSBAD, Calif., June 30, 2025 /PRNewswire/ -- Tyra Biosciences, Inc. (Nasdaq: TYRA), a clinical-stage biotechnology company focused on developing next-generation precision medicines that target large opportunities in Fibroblast Growth Factor Receptor (FGFR) biology, announced today that the first patient has been dosed in the Phase 2 SURF302 clinical trial of TYRA-300 in low-grade, intermediate risk non-muscle invasive bladder cancer (IR NMIBC).

TYRA-300 is a potential first-in-class, investigational, oral, FGFR3-selective inhibitor designed to minimize the toxicities associated with inhibition of FGFR1, FGFR2 and FGFR4, while being agnostic for FGFR3 gatekeeper mutations. FGFR3 is a frequently altered gene in IR NMIBC, with ~70% of low-grade IR NMIBC showing activating mutations.

"Our goal is to develop TYRA-300 as the first once-daily oral treatment designed to reduce disease recurrence, as well as surgical procedural intervention and intravesical therapy, for people living with IR NMIBC," said Dr. Erik Goluboff, SVP of Clinical Development at TYRA. "We believe we are well-positioned to contribute meaningful advancements to the field of bladder cancer with SURF302, and we anticipate that the clinical data will offer valuable insights with the potential to enhance patient outcomes."

SURF302 (NCT06995677) is an open-label Phase 2 clinical study evaluating the efficacy and safety of TYRA-300 in participants with FGFR3-altered low-grade, IR NMIBC. The study will enroll up to 90 participants at multiple sites primarily in the United States. Participants will be randomized initially to treatment with TYRA-300 at 50 mg once daily (QD) (Cohort 1) or treatment with TYRA-300 at 60 mg QD (Cohort 2). Following a review of efficacy and safety, an additional dosing cohort may be evaluated. The primary endpoint is complete response (CR) rate at three months. Secondary endpoints include time to recurrence, the median duration of response, recurrence free survival (RFS), progression free survival (PFS), safety and tolerability.

"I am excited that the Phase 2 trial evaluating oral TYRA-300 in IR NMIBC is now underway," said Dr.Tom Jayram, Director of the Advanced Therapeutics Center at Urology Associates in Nashville, TN. "IR NMIBC is a challenging disease for urologists and patients alike, with the potential for recurrence, progression, and the morbidity of multiple procedures for disease surveillance. Selective FGFR inhibitors are an exciting new option in this disease space that can allow a personalized approach to bladder cancer. TYRA-300 is an investigational, daily oral tablet that has shown encouraging preliminary safety and efficacy in an early phase trial and has the potential to be a paradigm shift in how urologists can treat bladder cancer."

TYRA-300 will also be evaluated in pediatric achondroplasia in the BEACH301 Phase 2 study, which is open for enrollment and for which the Company now expects first child dosing in the second half of the year.

About Non-Muscle Invasive Bladder Cancer

In the United States, it is estimated that there are more than 730,000 people living with bladder cancer. Many of these patients have intermediate risk non-muscle invasive bladder cancer (IR NMIBC) and experience recurrence episodes throughout the course of their disease. Treatment for IR NMIBC and disease recurrence is a surgical procedure called transurethral resection of bladder tumor (TURBT) combined with intravesical-administered chemotherapy. Repeat TURBT procedures and intravesical-administered chemotherapy can impact patients' quality of life and overall health, leading to a significant unmet medical need for better tolerated therapeutic options. TYRA-300 is the only orally administered investigational agent in clinical development for IR NMIBC.

About TYRA-300

TYRA-300 is the Company's lead precision medicine program stemming from its in-house SNÅP platform. TYRA-300 is an investigational, oral, FGFR3-selective inhibitor currently in development for the treatment of cancer and skeletal dysplasia that has demonstrated interim clinical proof-of-concept results in metastatic urothelial cancer (mUC). TYRA-300's planned clinical development includes three Phase 2 clinical trials: SURF302 for IR NMIBC, BEACH301 for pediatric achondroplasia and SURF301 for mUC.

Please visit the Patients page of our website for more information on our clinical trials.

About Tyra Biosciences

Tyra Biosciences, Inc. (Nasdaq: TYRA) is a clinical-stage biotechnology company focused on developing next-generation precision medicines that target large opportunities in FGFR biology. The Company's in-house precision medicine platform, SNÅP, enables rapid and precise drug design through iterative molecular SNÅPshots that help predict genetic alterations most likely to cause acquired resistance to existing therapies. TYRA's expertise in FGFR biology has created a differentiated pipeline with three clinical-stage programs in targeted oncology and genetically defined conditions. The Company's lead precision medicine stemming from SNÅP, TYRA-300, is a potential first-in-class selective FGFR3 inhibitor that is designed to avoid the toxicities associated with inhibition of FGFR1, FGFR2 and FGFR4, while being agnostic for FGFR3 gatekeeper mutations. TYRA-300's planned clinical development includes three Phase 2 studies: SURF302 for IR NMIBC, BEACH301 for pediatric achondroplasia and SURF301 for metastatic urothelial cancer. TYRA is also developing TYRA-200, an oral, investigational, FGFR1/2/3 inhibitor, in the SURF201 study for metastatic intrahepatic cholangiocarcinoma, and TYRA-430, an oral, investigational FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers. TYRA is based in Carlsbad, CA.

For more information about our science, pipeline and people, please visit www.tyra.bio and engage with us on LinkedIn.

Forward-Looking Statements
TYRA cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: expected reporting of data from the SURF302 study and the timing thereof; the design and goals of the SURF302 study; the potential to develop next-generation precision medicines and for TYRA-300 to be a first-in-class, once-daily oral treatment, and the potential safety and therapeutic benefits of TYRA-300; the expected timing and phase of development of TYRA-300, including the expected timing of dosing for the BEACH301 study in pediatric achondroplasia; and the potential for SNÅP to develop therapies. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: potential delays in the commencement, recruitment, enrollment, data readouts and completion of clinical trials and preclinical studies; results from preclinical studies or early clinical trials not necessarily being predictive of future results; interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data, as follow-up on the outcome of any particular patient continues and as more patient or final data becomes available, including the risk that unconfirmed responses may not ultimately result in confirmed responses to treatment after follow-up evaluations; the potential for proof-of-concept results to fail to result in successful subsequent development of TYRA-300; later developments with the FDA may be inconsistent with prior feedback from the FDA; we are early in our development efforts, and the approach we are taking to discover and develop drugs based on our SNÅP platform is novel and unproven and it may never lead to product candidates that are successful in clinical development or approved products of commercial value; our dependence on third parties in connection with manufacturing, research and preclinical testing; acceptance by the FDA of INDs or of similar regulatory submissions by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates; an accelerated development or approval pathway may not be available for TYRA-300 or other product candidates and any such pathway may not lead to a faster development process; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval, and/or commercialization; the potential for our programs and prospects to be negatively impacted by developments relating to our competitors, including the results of studies or regulatory determinations relating to our competitors; unfavorable results from preclinical studies; regulatory developments in the United States and foreign countries; our ability to obtain and maintain intellectual property protection for our product candidates and proprietary technologies; and other risks described in our prior filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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