Tyra Biosciences Receives IND Clearance from FDA to Proceed with Phase 2 Study of TYRA-300 in Non-Muscle Invasive Bladder Cancer (SURF302)

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-TYRA appoints urologic oncologist, Erik Goluboff, M.D., as SVP, Clinical Development to lead NMIBC-

-First patient expected to be dosed in SURF302 in Q2 2025-

CARLSBAD, Calif., Jan. 10, 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 U.S. Food and Drug Administration (FDA) cleared its Investigational New Drug (IND) application for TYRA-300 allowing the company to proceed with a Phase 2 clinical trial of TYRA-300 in low-grade, intermediate risk non-muscle invasive bladder cancer (IR NMIBC). This program will be led by newly appointed Dr. Erik Goluboff, SVP, Clinical Development of TYRA, who brings more than thirty years of experience as an academic urologic oncologist, principal investigator, practicing urologist and most recently Principal Medical Lead for GU/GI cancers at Genentech/Roche.

TYRA-300 is a potential first-in-class, investigational, oral, FGFR3-selective inhibitor designed to avoid the toxicities associated with inhibition of FGFR1, FGFR2 and FGFR4, while being agnostic for the FGFR3 gatekeeper mutations. FGFR3 is the most frequently altered gene in NMIBC, with 60-80% of IR NMIBC showing alterations. TYRA-300 is expected to be evaluated in three Phase 2 studies: SURF302 for IR NMIBC, BEACH301 for pediatric achondroplasia (ACH) and SURF301 for metastatic urothelial carcinoma (mUC).

SURF302 will be 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.

"Receiving FDA IND clearance is an important milestone in the advancement of TYRA-300 and for patients with NMIBC who urgently need better tolerated therapeutic options," commented Doug Warner, Chief Medical Officer of TYRA. "We look forward to leveraging Erik's impressive background to guide our development plans in NMIBC. We expect to initiate patient dosing in the second quarter of this year, with initial three-month CR data to follow."

Dr. Goluboff joins TYRA from Genentech/Roche, where he was Principal Medical Lead for GU/GI cancers and was responsible for driving business and pipeline opportunities in those indications. Prior to Genentech/Roche, Dr. Goluboff held positions of increasing responsibility at AstraZeneca, including most recently as Global Clinical Head for IMFINZI® (durvalumab) and tremelimumab for GU, GYN and tumor agnostic. Before joining industry, he held urology professorships at Columbia and Mount Sinai and managed thousands of patients from diagnosis to late line disease, medically and surgically, with bladder, prostate, and kidney cancers. He was a principal investigator for multiple clinical trials and has published over 100 peer-reviewed papers. He received his B.A. from Columbia University, an M.D. from Johns Hopkins, and an M.B.A. from NYU's Stern School of Business. Dr. Goluboff completed his surgical internship at Johns Hopkins Hospital and his urology residency and urologic oncology fellowship at Columbia-Presbyterian Medical Center.

"For the last thirty years, I have dedicated my career to helping patients with bladder cancer as a urologic oncologist, a principal investigator running clinical trials, and as a drug developer seeking new and more effective therapies for patients with urologic cancers," added Dr. Goluboff. "I believe that TYRA-300 is the most compelling agent in development for the treatment of IR NMIBC, with a proven mechanism of action and more attractive tolerability profile than pan-FGFR inhibitors, which made joining TYRA a very exciting opportunity. I look forward to advancing TYRA-300 through the Phase 2 SURF302 study and delivering benefit to patients in need."

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 SNAP platform. TYRA-300 is an investigational, oral, FGFR3-selective inhibitor currently in development for the treatment of cancer and skeletal dysplasia, including achondroplasia and hypochondroplasia. In oncology, TYRA-300 is being evaluated in metastatic urothelial cancer (mUC) and intermediate risk non-muscle invasive bladder cancer (IR NMIBC). In mUC, TYRA-300 is being evaluated in a multi-center, open label Phase 1/2 clinical study, SURF301 (**S**tudy in **U**ntreated and **R**esistant **F**GFR3+ Advanced Solid Tumors) (NCT05544552). The study is designed to determine the optimal and the recommended Phase 2 dose (RP2D) of TYRA-300, as well as to evaluate the preliminary antitumor activity of TYRA-300. In October 2024, TYRA reported interim clinical proof-of-concept data in mUC from SURF301. TYRA has received IND clearance from the U.S. FDA to proceed with its SURF302 clinical trial in patients with IR NMIBC. In skeletal dysplasia, TYRA-300 has demonstrated positive preclinical results in achondroplasia and hypochondroplasia, and TYRA has received IND clearance from the U.S FDA to proceed with its BEACH301 clinical trial in children with achondroplasia.

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 the FGFR3 gatekeeper mutations. TYRA-300 is expected to be evaluated in 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 initiation of, and first patient dosing in, 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 first-in-class, and the potential safety and therapeutic benefits of TYRA-300; the expected timing and phase of development of TYRA-300, including the expected Phase 2 study in IR NMIBC; and the potential for SNÅP to develop therapies in targeted oncology and genetically defined conditions. 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: later developments with the FDA may be inconsistent with prior feedback from the FDA, including with respect to the proposed initiation and design of our planned Phase 2 study of TYRA-300 in IR NMIBC; we are early in our development efforts, have only recently begun testing TYRA-300 and TYRA-200 for oncology in clinical trials 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; potential delays in the commencement, enrollment, data readouts and completion of preclinical studies and clinical trials; 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 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; 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 TYRA-300; 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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