Tyra Biosciences Reports Initial Phase 2 SURF302 Results Supporting the First Potential Oral Innovation in LG IR NMIBC with Dabogratinib

September 9, 2026

TYRA's mission is to make dabogratinib the clear first-line treatment choice for patients with LG IR NMIBC

Favorable safety and tolerability results support chronic dosing potential

No clinically significant hyperphosphatemia, nail toxicity or ocular toxicity; low frequency of transaminase TEAEs (<10%); Grade 3 treatment-related AEs in fewer than 5% of patients (none at 60 mg QD)

79% ORR and 64% best overall response CR rate with 60 mg QD in combined single and multiple marker lesion patients (n=14), with 100% ORR and 75% best overall response CR rate with 60 mg QD in single marker lesion patients (n=8), supporting planned adjuvant Phase 3 strategy

First patient treated in Phase 2 SURF303 study in LG UTUC achieved a 3-month CR with 60 mg QD

Conference call today, September 9, at 8 am ET to discuss results

CARLSBAD, Calif., Sept. 9, 2026 /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, today announced initial results from SURF302, its Phase 2 study evaluating oral dabogratinib in patients with FGFR3-altered low-grade intermediate-risk non-muscle invasive bladder cancer (LG IR NMIBC). The study provided clinical proof of concept for selective oral FGFR3 inhibition and identified 60 mg once-daily (QD) as the potential dose supporting TYRA's planned registrational adjuvant development strategy.

Approximately 70% of patients with LG IR NMIBC do not receive adjuvant therapy intended to reduce recurrence, despite evidence that intravesical treatment lowers recurrence risk. Instead, many patients choose surveillance, or "watch and wait", because existing therapies involve repeated catheterization and office-based procedures that can make the burden of treatment outweigh its perceived benefit. TYRA believes oral dabogratinib, if approved, has the potential to change that paradigm by offering patients a convenient, once-daily oral therapy.

"We are extremely excited to report initial results from SURF302 today as we work to advance what we believe could become the first once-daily oral therapy for patients with low-grade IR NMIBC," said Todd Harris, Ph.D., Chief Executive Officer of TYRA Biosciences. "These results belong first and foremost to the patients participating in SURF302 and the investigators and study teams who have made this research possible. We're incredibly grateful for their partnership."

"SURF302 has effectively given us two studies in one, informing dual settings in which dabogratinib could potentially be used. Patients with a single marker lesion — whose minimal disease most closely mirrors the adjuvant setting (where no tumor is left behind) and historical marker lesion studies — achieved a 100% overall response rate (ORR) (8/8) with 60 mg QD, including a 75% complete response (CR) rate as best overall response (BOR), demonstrating the activity of this dose for our planned Phase 3 adjuvant study," said Doug Warner, M.D., Chief Medical Officer of TYRA. "Patients with multiple marker lesions carry a higher tumor burden, more representative of an ablative setting, and our preliminary exposure-response analyses suggest that higher drug exposure may be important there. Dabogratinib's favorable safety results to date give us the opportunity to evaluate a higher dose in that setting. Taken together, these data have meaningfully expanded our understanding of dabogratinib as we look to continue to advance development into Phase 3 studies."

"As a community-based urologist, one of the greatest challenges isn't identifying patients who could benefit from therapy—it's that many choose surveillance because the burden of repeated catheterization and intravesical treatments outweighs the perceived benefit," said Mark Silva, M.D., Greater Boston Urology. "Too often, those patients are simply waiting to recur. A well-tolerated once-daily oral therapy could fundamentally change that conversation – giving patients an option they may be more willing to accept, and giving physicians the chance to intervene before the next recurrence rather than react after it occurs."

Initial safety and tolerability results. As of the August 31, 2026 data cutoff, initial safety and tolerability results for oral dabogratinib were favorable across the 60 mg QD (n=22) and 50 mg QD (n=22) dose cohorts. Most treatment-emergent adverse events (TEAEs) were Grade 1 or 2, with Grade 3 TEAEs in 3 participants (14%) at 60 mg and 2 participants (9%) at 50 mg. Grade 3 treatment-related AEs occurred in 2 of 44 participants (4.5%) across both cohorts, both at 50 mg QD, with none at 60 mg QD. There were no Grade 4 or 5 TEAEs. TYRA believes these results are consistent with the potential for chronic once-daily administration.

- At 60 mg QD, there were no dose reductions or treatment-related discontinuations.
- No clinically significant hyperphosphatemia, nail toxicity, or ocular toxicity was observed.
- TEAEs were generally manageable.
    - Transaminase TEAEs were observed at low frequency (< 10%).
    - The most frequently reported TEAEs at 60 mg QD were fatigue, diarrhea and dry eye. Diarrhea was generally Grade 1, transient, and limited.

Initial efficacy results. As of the August 31, 2026 data cutoff, 26 participants were evaluable for efficacy across the 60 mg QD (n=14) and 50 mg QD (n=12) cohorts (participants who received study treatment and had undergone at least the month 3 disease assessment). All responses below are subject to change with continued treatment and follow-up.

Combined Single and Multiple Marker Lesion Response

	60 mg QD Cohort (n=14)		50 mg QD Cohort (n=12)
	3-Month Assessment	BOR	3-Month Assessment and BOR
ORR	79% (11/14)	79% (11/14)	67% (8/12)
CR	57% (8/14)	64% (9/14)#	33% (4/12)
Partial Response (PR)	21% (3/14)	14% (2/14)	33% (4/12)

#Best overall response CR includes the initial 60 mg participant with a 3-month PR who converted to CR at the 6-month assessment. No other 60 mg participant with a 3-month PR had reached the 6-month assessment at data cutoff.

Single Marker Lesion Response

	60 mg QD Cohort (n=8)		All Doses, 50 mg and 60 mg Pooled (n=16)	
	3-Month Assessment	BOR	3-Month Assessment	BOR
ORR	100% (8/8)	100% (8/8)	94% (15/16)	94% (15/16)
CR	63% (5/8)	75% (6/8)#	50% (8/16)	56% (9/16)#
PR	38% (3/8)	25% (2/8)	44% (7/16)	38% (6/16)

#Best overall response CR includes the initial 60 mg participant with a 3-month PR who converted to CR at the 6-month assessment. No other 60 mg participant with a 3-month PR had reached the 6-month assessment at data cutoff.

- All 3-month CRs with 6-month assessments remained in response at 6 months (n=5).
- The first participant in the study remained in CR at 12 months and continued on study drug at 14 months.

Dose-optimization and registrational strategy.

- Preliminary exposure-response analyses across the 50 mg QD and 60 mg QD cohorts showed an ORR of 86% (12/14) among participants with a target steady-state exposure above the AUC threshold of 2500 ng·hr/mL, compared with 58% (7/12) among participants below the threshold. The exposure-response relationship was most apparent among participants with multiple marker lesions, while responses in participants with a single marker lesion occurred across the observed exposure range — supporting 60 mg QD in the planned adjuvant setting, where disease burden is minimal, and the evaluation of a higher dose in the ablative setting.
- TYRA plans to complete enrollment in the 60 mg QD cohort and initiate a 70 mg QD cohort to explore dabogratinib in the ablative setting. TYRA also plans to engage health authorities on Phase 3 study design and dose selection and, subject to that feedback, to continue preparations for a planned registrational adjuvant study.

Initial observation from SURF303 in LG UTUC. In SURF303, TYRA's Phase 2 study evaluating oral dabogratinib in patients with low-grade upper tract urothelial cancer (LG UTUC), the first patient treated achieved a complete response at the 3-month assessment with 60 mg QD, with no observed TEAEs and remained on study drug as of the August 31, 2026 data cutoff.

Conference Call and Webcast

TYRA is hosting a conference call and webcast today, September 9, 2026, at 8:00 am ET to discuss the initial SURF302 study results with oral dabogratinib. Participants may access a live webcast of the call and the associated slide presentation following the conclusion of the call on the "For Investors" page of the TYRA website at https://ir.tyra.bio. To participate via telephone, please register in advance at this link. Upon registration, all telephone participants will receive a confirmation email detailing how to join the conference call, including the dial-in number along with a unique passcode and registrant ID that can be used to access the call. A replay of the conference call and webcast will be archived on the Company's website for at least 90 days.

About SURF302

SURF302 (NCT06995677) is a Phase 2, multicenter, open-label clinical study evaluating the efficacy and safety of oral dabogratinib in adults with FGFR3-altered low-grade IR NMIBC. The study includes dose-optimization cohorts and is designed to support the potential development of dabogratinib as an adjuvant therapy. Key endpoints include best overall response, complete response at three months, time to recurrence, duration of response, recurrence-free survival, progression-free survival, safety and tolerability. For more information, please visit the Patients page of the Company's website at https://tyra.bio/patients/ or https://clinicaltrials.gov/study/NCT06995677.

About Intermediate-Risk Non-Muscle Invasive Bladder Cancer (IR NMIBC)

Bladder cancer is one of the most common cancers in the United States, with more than 760,000 people living with the disease. Many patients are diagnosed with intermediate-risk non-muscle invasive bladder cancer (IR NMIBC), a disease characterized by frequent tumor recurrence that often requires repeated surveillance and surgical intervention over many years. Current treatment typically includes transurethral resection of bladder tumor (TURBT) followed by intravesical chemotherapy administered through repeated bladder catheterization. Despite evidence that adjuvant intravesical therapy can reduce recurrence, approximately 70% of patients with LG IR NMIBC do not receive treatment intended to prevent recurrence, highlighting a significant unmet medical need for more accessible and better-tolerated treatment options. Dabogratinib is the only investigational oral FGFR3-selective therapy currently in clinical development for patients with FGFR3-altered IR NMIBC.

About Dabogratinib

Dabogratinib is TYRA's lead precision medicine candidate stemming from its in-house SNÅP platform. Dabogratinib is an investigational, oral, FGFR3-selective inhibitor currently in Phase 2 development for the treatment of urologic cancers and skeletal dysplasias, specifically low-grade upper tract urothelial carcinoma (LG UTUC), IR NMIBC and achondroplasia (ACH). TYRA believes dabogratinib was the first orally available, FGFR3-selective inhibitor to enter clinical development, and it has been studied in more than 200 individuals to date across multiple clinical and healthy volunteer studies. Oral dabogratinib is currently advancing in three Phase 2 clinical trials: SURF303 in LG UTUC, SURF302 in IR NMIBC and BEACH301 in ACH. The FDA has granted Orphan Drug Designation and Rare Pediatric Disease Designation to oral dabogratinib for the treatment of 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. TYRA's in-house precision medicine platform, SNÅP, enables rapid and precise drug design through iterative molecular SNÅPshots that help TYRA design and predict which candidates may demonstrate the highest potency, selectivity and tolerability in the clinic. TYRA's expertise in FGFR biology has created a differentiated pipeline with clinical-stage programs in targeted oncology and genetically defined conditions. TYRA's lead precision medicine stemming from SNÅP, oral dabogratinib, is a potential first-in-class selective FGFR3 inhibitor in development for LG UTUC, IR NMIBC and ACH. TYRA is also developing TYRA-430, an oral, investigational FGFR4/3-biased inhibitor for FGF19+/FGFR4-driven cancers, in the SURF431 study for advanced hepatocellular carcinoma, and TYRA-200, an oral, investigational FGFR1/2/3 inhibitor, in the SURF201 study for metastatic intrahepatic cholangiocarcinoma. TYRA is based in Carlsbad, California. For more information, please visit www.tyra.bio and engage with TYRA on LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements contained in this press release that are not historical facts are forward-looking statements, including, but not limited to, statements regarding: the potential safety, efficacy, tolerability and therapeutic benefits of dabogratinib; the potential for dabogratinib to change the treatment paradigm for patients with FGFR3-altered LG IR NMIBC, to reduce recurrence, or to become a first-in-class once-daily oral therapy for FGFR3-altered LG IR NMIBC; the interpretation, significance and clinical implications of the initial SURF302 results, including observations regarding overall response rate, complete response, durability of response, dose-response relationships, exposure-response analyses and safety; the clinical significance of the initial response observed in the SURF303 study; the continued clinical development of dabogratinib, including continued enrollment at 60 mg, evaluation of the 70 mg dose cohort, and discussions with the U.S. Food and Drug Administration and other global health authorities regarding dose selection and Phase 3 study design; the timing, design and initiation of future clinical trials, including a potential registrational adjuvant study; and the potential commercial opportunity for dabogratinib.

These forward-looking statements are based on TYRA's current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation: initial or 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; preliminary pharmacokinetic, pharmacodynamic and exposure-response analyses may not be predictive of future clinical outcomes or later-stage studies; early clinical observations from SURF303, including those from an individual participant, may not be predictive of future results; the safety and efficacy observed to date may not continue in ongoing or future studies; TYRA's ability to successfully enroll, conduct and complete its clinical trials; the timing and outcome of interactions with the FDA and other regulatory authorities on TYRA's plans to advance to a registrational adjuvant study, which may differ from TYRA's expectations; the ability to obtain regulatory approval for dabogratinib; and the other risks and uncertainties described under the heading "Risk Factors" in TYRA's Annual Report on Form 10-K and in subsequent filings with the Securities and Exchange Commission.

You should not place undue reliance on these forward-looking statements, which speak only as of the date they are made. TYRA undertakes no obligation to update or revise any forward-looking statements to reflect new information, future events or otherwise, except as required by applicable law.

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