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A Phase 2 Multicenter, Open-Label
Study Evaluating the Efficacy and
Safety of Dabogratinib (TYRA-300) in
Participants with FGFR3-Altered Low-
Grade, Intermediate Risk Non-Muscle
Invasive Bladder Cancer (SURF302)

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Disclosures

- Stock and Other Ownership Interests - Aura Biosciences
- Honoraria - Grand Rounds in Urology; UroToday
- Consulting or Advisory Role – Aura Biosciences, Bristol-Myers Squibb Foundation/Janssen, Ferring, ImmunityBio, Merck, Protara Therapeutics, Tyra Biosciences, UroGen, Verity Pharmaceuticals
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- Patents, Royalties, Other Intellectual Property - TCGA expression subtype single patient classifier

FGFR3 Drives a Large Unmet Need in IR NMIBC

Early-stage urothelial carcinoma (UC) is a major source of morbidity worldwide

NMIBC

~75% of patients with UC present with NMIBC¹

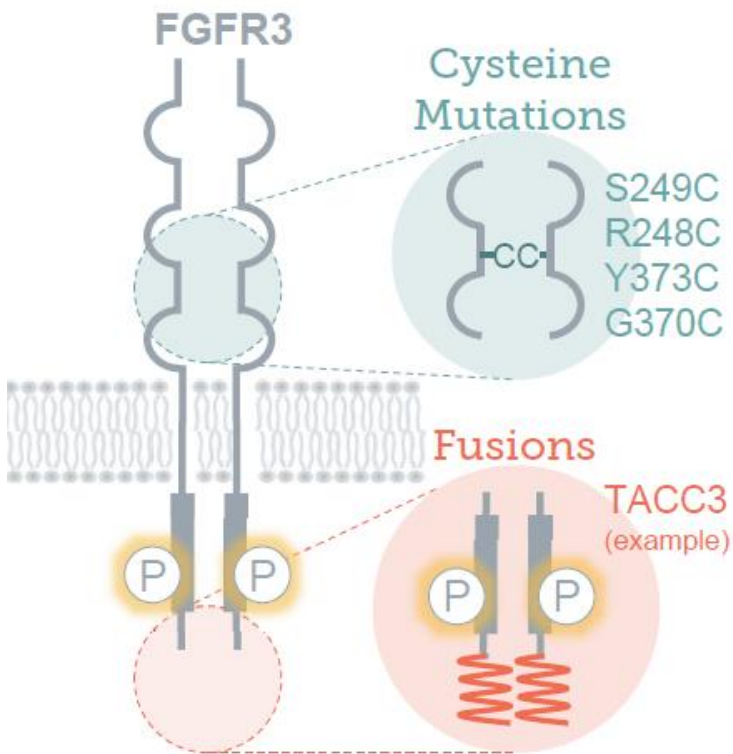
Up to 30% of IR NMIBC recurs within 1 year and up to 40% of disease recurs within 2 years¹

Unmet Need

Low rate of progression, but physical and emotional QoL burden of repeated TURBTs and intravesical chemotherapy²

Need for innovative, patient-friendly therapies

FGFR3 Biology



Mechanism

FGFRs are key regulators of cellular growth, differentiation, and homeostasis¹

FGFR3 alterations are present in:

- Up to 80% of NMIBC^{2,3}
- Up to 96% of LG UTUC⁴⁻⁶

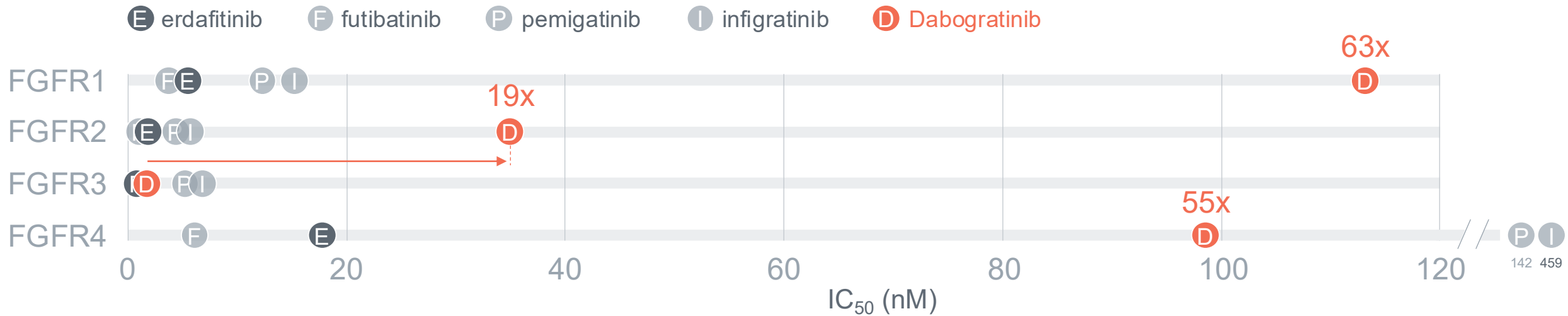
Need for selectivity

Available FGFR inhibitors inhibit FGFR1, 2, 3, and 4 and lack selectivity for FGFR3

FGFR1/2/4-associated toxicities are observed and include hyperphosphatemia, nail disorders, stomatitis, central serous retinopathy, and others^{7,8}

Dabogratinib is a Highly Selective Oral FGFR3 Inhibitor

Selectivity observed for dabogratinib vs. approved/late-stage clinical compounds: *in vitro* Ba/F3 Cellular IC₅₀ (nM)²⁻⁵



All experiments conducted under identical conditions, tested in duplicate. Note: Dabogratinib FGFR3 selectivity is defined by its activity against FGFR3 relative to its activity against the other individual FGFR isoforms. Erdafitinib and futibatinib are FGFR1, 2, 3, 4 or Pan-FGFR inhibitors and infigratinib and pemigatinib are selective FGFR1, 2, 3 inhibitors.

1. National Library of Medicine. NCT06995677. March 10, 2025. <https://clinicaltrials.gov/study/NCT06995677>. 2. Loriot Y, et al. *New Engl J Med*. 2023;389:1961-1971. 3. Goyal L, et al. *New Engl J Med*. 2023;388:228-239. 4. Savarirayan R, et al. *New Engl J Med*. 2025;392:865-874. 5. Vogel A, et al. *ESMO Open*. 2024;9:103488.

SURF301 (Phase 1) Oral Dabogratinib Showed Activity and Was Well-Tolerated at 90mg QD in mUC

FGFR3+ mUC Efficacy Data

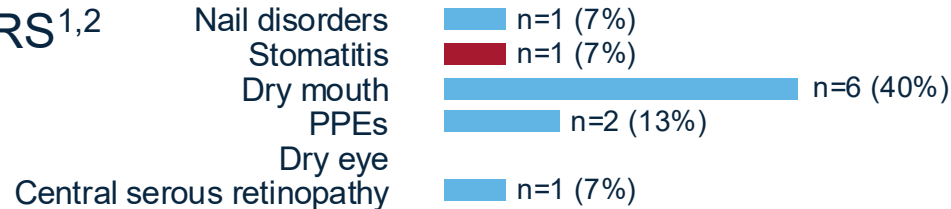
Dabogratinib
50% ORR (n=10)

Erdafitinib
35% ORR (n=136⁴)

SAFETY DATA

%, n=15 ■ Grade 1-2 ■ ≥Grade 3

FGFR2 DRIVERS^{1,2}



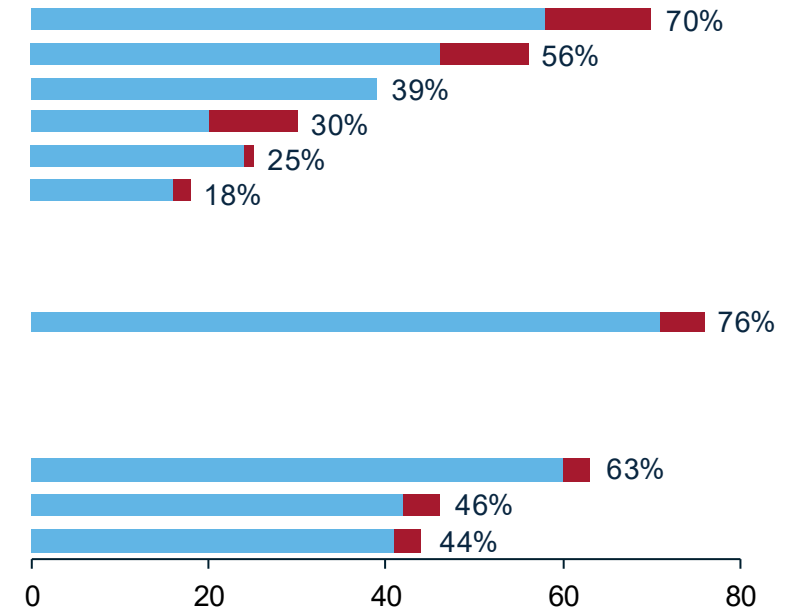
FGFR1 DRIVER^{2,3}



UNKNOWN DRIVERS



%, n=136^{4,#}



ALT, alanine aminotransferase; AST aspartate aminotransferase; ORR, overall response rate; TRAE, treatment-related adverse event.

As of August 15, 2024 data cutoff. Dabogratinib 90 mg QD: Dose reduction, n = 4; Discontinuation, n = 1. Results are preliminary based on the emerging data from the ongoing Phase 1 portion of the SURF301 study. Information provided in the table above is for illustrative purposes only and is not a head-to-head comparison. Differences exist between study or trial designs and subject characteristics, and caution should be exercised when comparing data across studies.

1. Lacouture ME et al. *Oncologist*. 2021; 26 (2):e31626. 2. Subbiah V, Verstovsek S. *Cell Rep Med*. 2023; 4:101204. 3. Kommalapati A et al. *Cancers*. 2021;13, 2968. 4. BALVERSA® (erdafitinib) Prescribing information. Janssen Products, Ltd. 01/2024.

#BLC3001 Cohort 1 data on file, Adverse reactions leading to dosage interruptions or reductions of erdafitinib in >4% of patients.

SURF301 (Phase 1) Safety Read Through at Lower Doses: FGFR-related Toxicities Were Infrequent in mUC

No hyperphosphatemia at ≤ 60 mg

No discontinuations or reductions at ≤ 60 mg

TRAEs in >10% of all participants, n (%)

≤ 60 mg
(n=22)

90 mg
(n=15)

120 mg
(n=4)

All
(n=41)

	Gr. 1-2	\geq Gr. 3
ALT increase	1 (5)	—
Diarrhea	4 (18)	—
Dry mouth	3 (14)	—
AST increase	—	—
Dry skin	2 (9)	—
Fatigue	2 (9)	—

	Gr. 1-2	\geq Gr. 3
ALT increase	5 (33)	2 (13)
Diarrhea	2 (13)	1 (7)
Dry mouth	6 (40)	—
AST increase	6 (40)	1 (7)
Dry skin	2 (13)	—
Fatigue	2 (13)	—

	Gr. 1-2	\geq Gr. 3
ALT increase	2 (50)	—
Diarrhea	2 (50)	—
Dry mouth	—	—
AST increase	1 (25)	—
Dry skin	2 (50)	—
Fatigue	1 (25)	—

	Gr. 1-2	\geq Gr. 3
ALT increase	8 (20)	2 (5)
Diarrhea	8 (20)	1 (2)
Dry mouth	9 (22)	—
AST increase	7 (17)	1 (2)
Dry skin	6 (15)	—
Fatigue	5 (12)	—

SURF302 | Study Design

SURF302 (NCT06995677) is a phase 2, multicenter, open-label, randomized marker lesion study evaluating the safety and efficacy of oral dabogratinib (QD) in adults with FGFR3-altered, low grade IR NMIBC

Key Eligibility Criteria

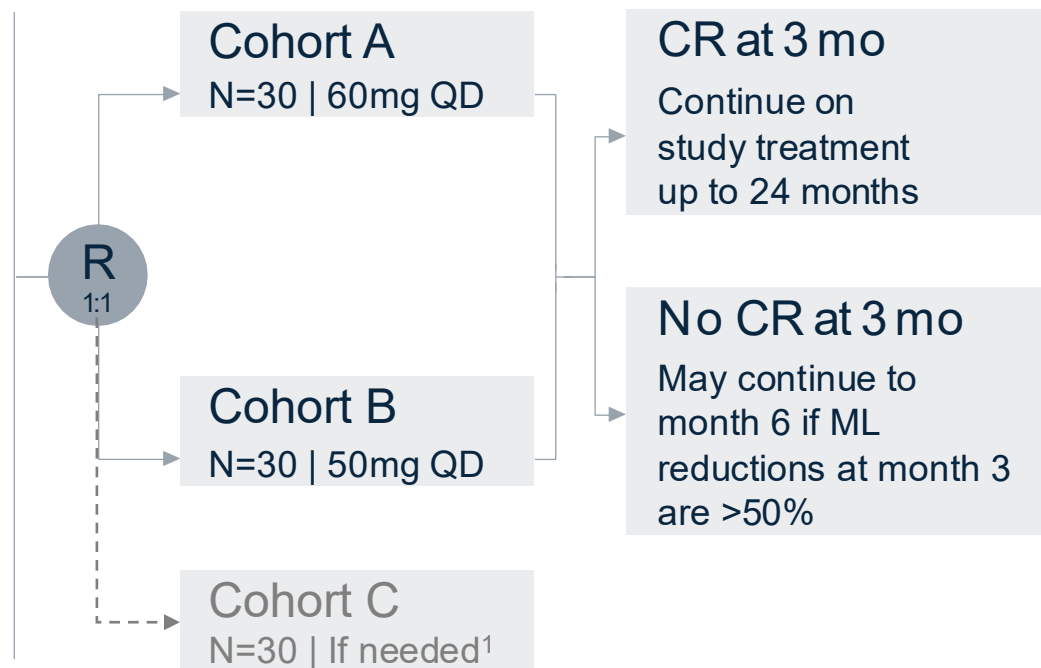
Adults (≥ 18 years)

FGFR3 activating gene alterations confirmed by urine or tissue test

IR NMIBC based on AUA Guidelines, 2024

- Recurrence within 1 year, LG Ta
- Solitary LG Ta >3cm
- LG Ta, multifocal
- LG T1

At least 1 marker lesion;
total aggregate ≥ 3 mm ≤ 12 mm



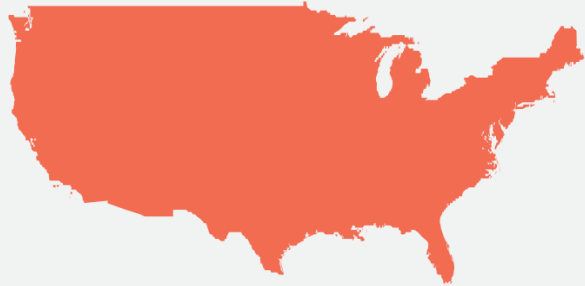
Primary Endpoint

CR at 3 months

Secondary Endpoints

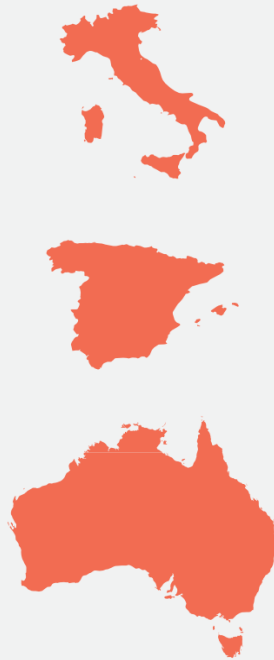
- Time to recurrence
- Median duration of response
- Recurrence free survival
- Progression free survival
- Safety and tolerability

SURF³⁰² SITE LIST



UNITED STATES

- Homewood, AL
- Little Rock, AR
- Murrieta, CA
- San Diego, CA
- Chicago Ridge, IL
- Lisle, IL
- Jeffersonville, IN
- Kansas City, KS
- Baltimore, MD
- Morristown, NJ
- New York, NY
- Durham, NC
- Raleigh, NC
- Springfield, OH
- Bala Cynwyd, PA
- Lancaster, PA
- North Charleston, SC
- Myrtle Beach, SC
- Nashville, TN
- Houston, TX
- San Antonio, TX



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- Pisa
- Rome
- Pozzuoli

SPAIN

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- Madrid
- Santander

AUSTRALIA

- Melbourne, VIC



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