

Urine-Based Testing for Patient Selection and Genomic Characterization of Patients With *FGFR* Alteration-Positive Non-Muscle-Invasive Bladder Cancer Treated With TAR-210

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KEY TAKEAWAY



A novel urine-based test for *FGFRalt* eligibility was successfully implemented into the first-in-human study evaluating TAR-210, a novel intravesical drug delivery system that provides sustained, local release of erdafitinib within the bladder, with 27% (7/26) of patients enrolled based on urine alone due to lack of tissue or no *FGFRalt* found in tissue

FGFRalt, *FGFR* alterations.

Urothelial Cancer



Presented by R Li at the 2024 ASCO Genitourinary Cancers Symposium; January 25-27, 2024; San Francisco, CA, USA

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CONCLUSIONS

- ✔ Implementing a urine-based test expands the molecular testing methods to identify 7 (27%) additional patients that may respond to TAR-210
- ✔ The spectrum of genomic alt detected using the urine test was similar to that described in prior studies using tissue-based testing
- ✔ All patients in Cohort 3 who were enrolled by urine test showed clinical activity
- ✔ Data highlight that the complex genomic landscape in bladder cancer can be assessed from urine
- ✔ Data from this study support further clinical evaluation of the urine test

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INTRODUCTION

- Erdafitinib, an oral selective pan-FGFR tyrosine kinase inhibitor, is approved for locally advanced or metastatic urothelial carcinoma in adults with susceptible *FGFR3/2* alterations (alt) after progression on platinum-containing chemotherapy¹⁻⁵
- TAR-210 is a novel intravesical drug delivery system designed to provide local, sustained release of erdafitinib within the bladder while limiting systemic toxicities⁶
 - TAR-210 shows promising clinical activity and is well tolerated in *FGFR*-altered non-muscle-invasive bladder cancer (NMIBC) in the first-in-human study (NCT05316155)⁶ (Figure 1)
- To overcome tissue-based challenges in identifying *FGFRalt*, including insufficient sample, sample integrity, and sample extraction from a single tumor,⁷ Janssen Research & Development partnered with Predicine to use a urine cell-free DNA diagnostic test (PredicineCARE™) to select patients for treatment with TAR-210
 - Validation of the urine test to detect *FGFRalt* was previously demonstrated using contemporaneous tissue and urine samples⁸
- Reported here are preliminary results of the urine test to detect *FGFRalt* to enable study enrollment, early efficacy data based on urine testing, and the characterization of the urine-defined genomic landscape

FGFR, fibroblast growth factor receptor.

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- First-in-human study enrollment was based on detection of prespecified *FGFRalt* from either tumor tissue obtained from previous biopsies or urine samples obtained prior to enrollment (PredicineCARE™ next-generation sequencing test)

FGFRalt, *FGFR* alterations.

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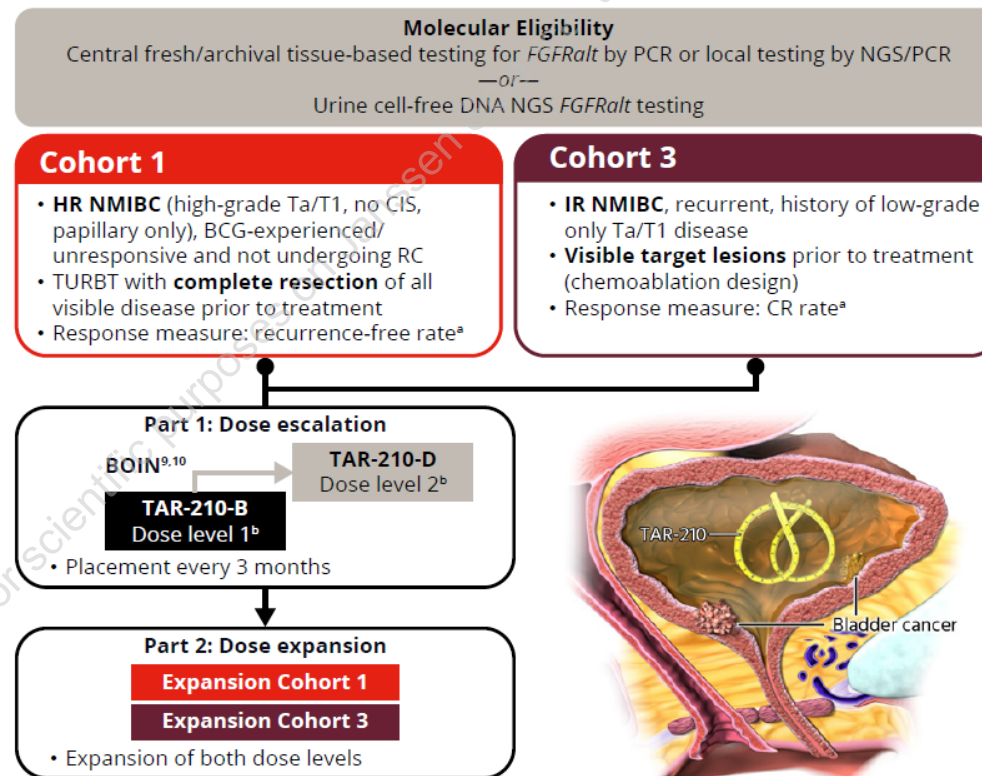
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FIGURE 1: First-in-human TAR-210 study design and depiction of TAR-210 in the bladder



^aResponse is assessed every 3 months with continued treatment for up to 1 year if recurrence-free (Cohort 1) or in CR (Cohort 3). ^b2 different erdafitinib release rates are being evaluated. BCG, bacillus Calmette-Guérin; BOIN, Bayesian optimization interval; CIS, carcinoma in situ; CR, complete response; DNA, deoxyribonucleic acid; HR, high risk; IR, intermediate risk; NGS, next-generation sequencing; PCR, polymerase chain reaction; PK, pharmacokinetics; RC, radical cystectomy; TURBT, transurethral resection of bladder tumor.

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RESULTS (1/6)

Screening

- As of Jun 20, 2023, urine test performance was compared to the tissue test from all screened patients with NMIBC (N=178) (Figure 2)
- The proportions of samples that yielded evaluable results were 58% and 60% from urine and tissue, respectively
- *FGFRalt* detection rates in the subsets that yielded positive results were 42% from urine and 62% from tissue
- *FGFR3* S249C was the most frequent alt detected in both urine (61%) and tissue (48%) (Table 1)
- For 36% of urine samples in which *FGFRalt* were detected, there was no corresponding tissue result
- In all instances, the same *FGFRalt* were detected in both urine and tissue

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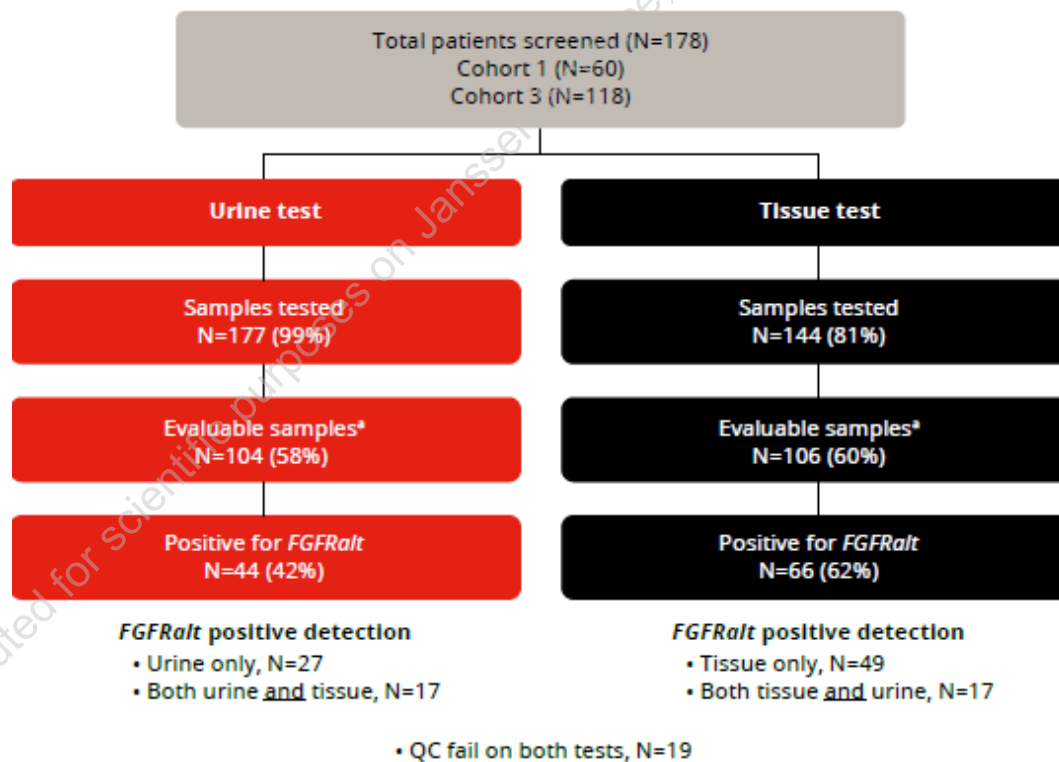


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FIGURE 2: Molecular screening or eligibility by urine and tissue testing



^aEvaluable samples = total samples submitted – sample quality control failures, invalid, pending samples, and no results. *FGFRalt*, *FGFR* alterations.

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TABLE 1: Type and prevalence of *FGFRalt* identified by urine and tissue were similar

| <i>FGFRalt</i> type, n (%) | N=178 | |
|--------------------------------|------------|-------------|
| | Urine test | Tissue test |
| Specific <i>FGFR3</i> mutation | | |
| S249C | 27 (61) | 33 (48) |
| Y373C | 14 (32) | 25 (36) |
| R248C | 2 (5) | 6 (9) |
| G370C | 0 | 2 (3) |
| Specific gene fusions | | |
| <i>FGFR3:TACC3_V1</i> | 1 (2) | 3 (4) |

FGFRalt, *FGFR* alterations.

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Efficacy Based on Urine Testing

- Of the disease-evaluable patients with HR NMIBC (N=11) in Cohort 1 or IR NMIBC (N=15) in Cohort 3, 46% (5/11) and 20% (3/15), respectively, were enrolled based on both urine and tissue testing
- 18% (2/11) of disease-evaluable patients in Cohort 1 and 33% (5/15) in Cohort 3 were enrolled based on urine testing alone due to no sample/insufficient tumor tissue
- In Cohort 1, 82% of patients were recurrence-free at the first disease evaluation, and in Cohort 3, 87% achieved a complete response at the first disease evaluation (Figure 3)
 - All patients (Cohort 1, N=2, and Cohort 3, N=5) enrolled by “urine only” were recurrence free or achieved a complete response
- Urine-based testing reliably captured the spectrum of genomic alt that were similar to those observed in tissue-based genomic landscape assessments of bladder cancer¹¹ (Figure 4)

HR, high risk; IR, intermediate risk; NMIBC, non-muscle-invasive bladder cancer.



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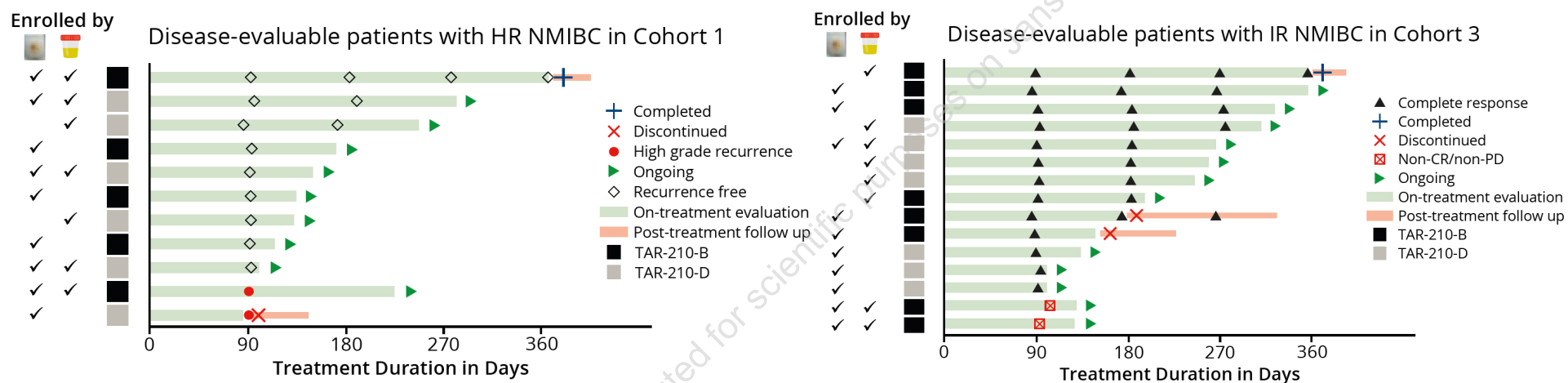
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FIGURE 3: Urine- and tissue-based testing identifies patients that experience clinical benefit from TAR-210



CR, complete response; PD, progressive disease.

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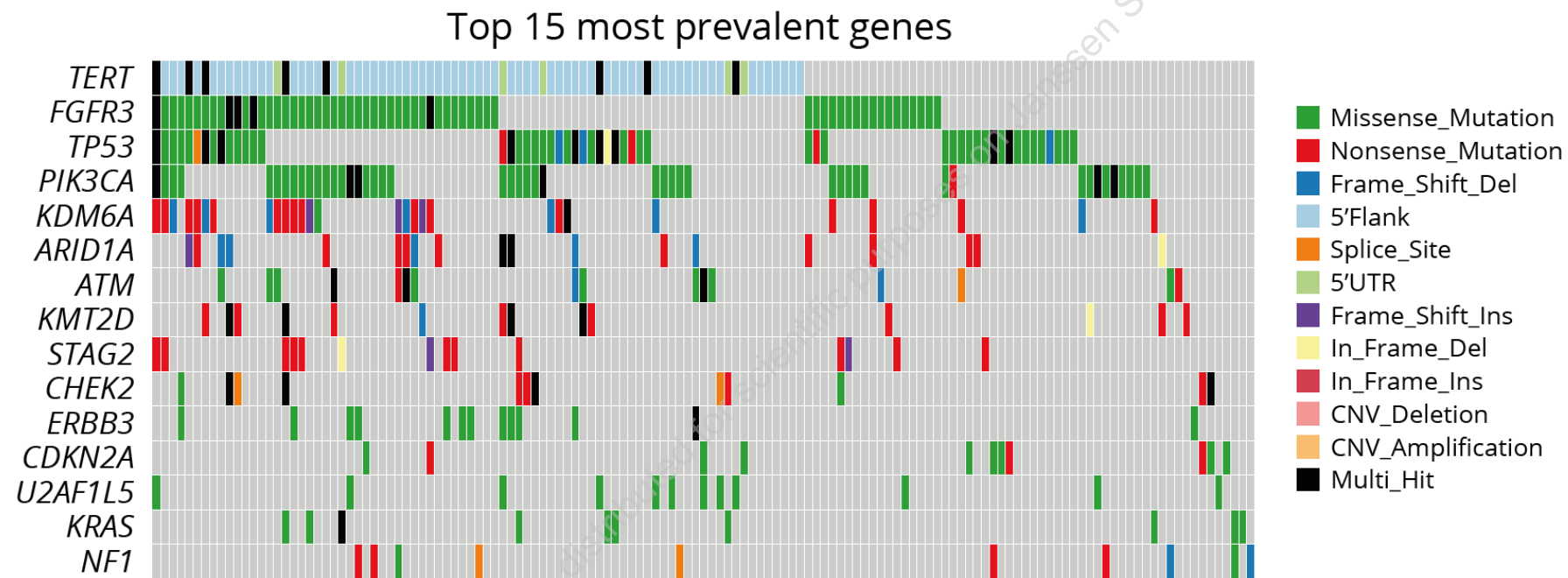
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DISCLOSURES:

Roger Li has served as a scientific advisor/consultant for BMS, Merck, Ferring, Fergene, Arquer Diagnostics, Urogen Pharma, and Lucenc; has served on the clinical trial protocol committee for CG Oncology; has received research support from Predicine, Veracyte, CG Oncology, and Valar Labs; and has received honoraria from SAI MedPartners and Solstice Health Communications.

ACKNOWLEDGMENTS:

This study was funded by Janssen Research & Development. Erdafi tinib (JNJ-42756493) was discovered in collaboration with Astex Pharmaceuticals. The authors thank Shidong Jia, Il-Jin Kim, and Pan Du of Predicine, Inc. Medical writing assistance was provided by Nicolisha Narainpersad, PhD, of Parexel, and was funded by Janssen Global Services, LLC.



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