

Final analysis of the phase 1 first-in-human study of erda-iDRS, an erdafitinib intravesical drug-releasing system, in patients with non-muscle-invasive bladder cancer harboring select *FGFR* alterations

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Disclosures

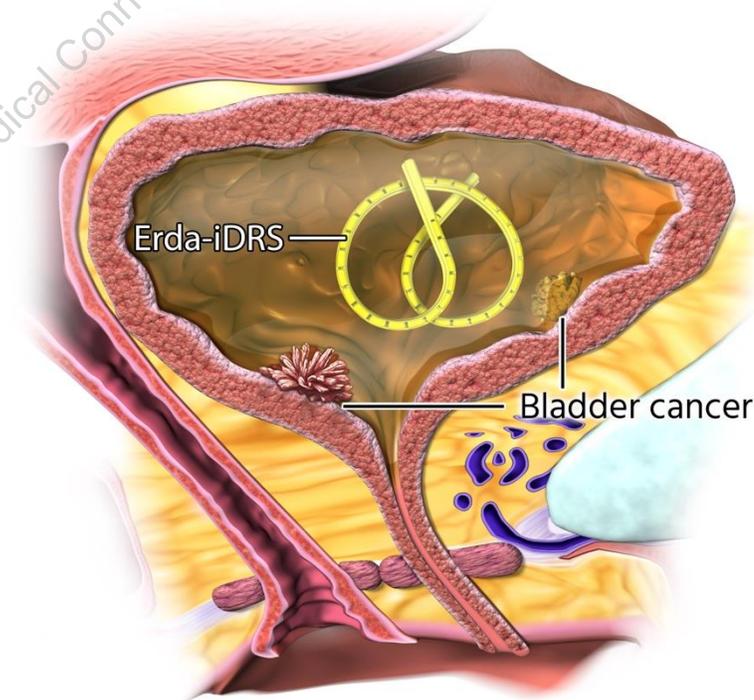
- Dr Vilaseca has received honoraria from Astellas Pharma, Johnson & Johnson/Janssen, Recordati, and Bayer; consulting/advisory fees from Johnson & Johnson/Janssen, Astellas Pharma, Recordati, and Accord Healthcare; and travel expenses from Ipsen and Recordati



Unmet Need in NMIBC and Potential for Local *FGFR*-targeted Therapy

- Despite available treatment options for patients with NMIBC, recurrence rates and progression risk remain high¹⁻⁴
 - This results in multiple resections or eventually radical cystectomy, underscoring the need for more effective bladder-sparing therapies¹⁻³
- *FGFR* alterations occur in ~70% of IR NMIBC and ~40% of HR NMIBC tumors and may function as oncogenic drivers^{5,6}
- Erdafitinib is an oral, selective pan-*FGFR* inhibitor approved to treat *FGFR3*-altered mUC following progression after prior systemic treatment⁷⁻⁹

Erda-iDRS (TAR-210) is an intravesical drug-releasing system designed to provide sustained delivery of erdafitinib to the bladder in 3-month treatment cycles, aiming to limit systemic toxicities



Erda-iDRS is inserted using a urinary placement catheter in a brief in-office procedure

FGFR, fibroblast growth factor receptor; HR, high-risk; intermediate-risk, IR; mUC, locally advanced or metastatic urothelial carcinoma; NMIBC, non-muscle-invasive bladder cancer.

1. Gontero P, et al. *Eur Urol*. 2024;86:531-549. 2. Babjuk M, et al. *Eur Urol* 2022;81:75-94. 3. Holzbeierlein JM, et al. *J Urol*. 2024;211:533-538. 4. Ritch CR, et al. *J Urol*. 2020;203:505-511. 5. Roupret M, et al. *Eur Urol*. 2022;87(S1):A0673. 6. Catto JWF, et al. *Ann Oncol*. 2024;35:98-106. 7. Perera TPS, et al. *Mol Cancer Ther* 2017;16:1010-20. 8. BALVERSA® (erdafitinib) tablets, for oral use [prescribing information]. Janssen Products, LP, Horsham PA, USA; 2024 (initial US approval, 2019). 9. BALVERSA® (erdafitinib) tablets, for oral use [summary of product characteristics]. Janssen-Cilag International NV, Beerse, Belgium; 2024 (initial EMA approval, 2024).



First-in-human, Open-label, Multicenter Phase 1 Study of erda-iDRS in *FGFR*-altered IR NMIBC and HR NMIBC

Study Design

NCT05316155

Molecular Eligibility

Flexible molecular eligibility strategy used to detect *FGFR* alterations:

- Local or central fresh/archival **tissue-based** testing by NGS or PCR
- or—
- Central **urine cell-free DNA** NGS testing

Clinical cutoff: Nov 3, 2025

Cohort 1 (HR NMIBC)

- Recurrent, high-grade Ta/T1, papillary only, no CIS
- BCG-experienced^a and not undergoing radical cystectomy
- TURBT with complete resection of all visible disease prior to treatment

Cohort 3 (IR NMIBC)

- Recurrent, history of low-grade only Ta/T1 disease
- **Visible target lesions** prior to treatment (ablation design)

Part 1: Dose Escalation

BOIN^{1,2} → TAR-210-D
~4 mg/day

TAR-210-B
~2 mg/day

- Erda-iDRS placement every 3 months

Parts 2 and 3: Dose Expansion

TAR-210-D
~4 mg/day

RP2D TAR-210-C
~3 mg/day

TAR-210-B
~2 mg/day

- Expansion of all 3 dose levels

Primary End Point

- Safety

Secondary End Points

- PK: plasma and urine concentrations of erdafitinib
- RFS (Cohort 1)
- **CR rate and duration (Cohort 3)^b**
- Treatment for up to 12 months
- Response was assessed every 3 months^c

BCG, bacillus Calmette-Guérin; BOIN, Bayesian optimization interval; CIS, carcinoma in situ; HR, high risk; IR, intermediate risk; NGS, next-generation sequencing; PCR, polymerase chain reaction; PK, pharmacokinetics; RP2D, recommended phase 2 dose; TURBT, transurethral resection of bladder tumor.

^aBCG experienced is defined as 5 of 6 induction doses with or without maintenance or intolerant of BCG.

^bCR was defined as absence of malignant tumors by cystoscopy with negative urine cytology.

^cResponse assessments were every 3 months in year 1 and year 2, then every 6 months in year 3.

1. Liu S, Yuan Y. *J R Stat Soc Ser C Appl Stat.* 2015;64:507-523. 2. Yuan Y, et al. *Clin Cancer Res.* 2016;22:4291-4301.



Patient Characteristics and Treatment Exposure

| Characteristic | Cohort 1 (HR NMIBC) (N=26) | Cohort 3 (IR NMIBC) (N=62) |
|--------------------------------------|----------------------------------|----------------------------------|
| Median age, years (range) | 72.5 (37-90) | 68.5 (41-89) |
| Male, n (%) | 19 (73.1) | 48 (77.4) |
| Race, n (%) | | |
| White | 21 (80.8) | 38 (61.3) |
| Asian | 5 (19.2) | 24 (38.7) |
| Tumor stage, n (%) | | |
| Ta | 21 (80.8) | 60 (96.8) |
| T1 | 5 (19.2) | 2 (3.2) |
| Tumor grade, n (%) | | |
| Low grade | 0 | 62 (100) |
| High grade | 26 (100) | 0 |
| Number of tumors, n (%) ^a | | |
| 1 | 13 (50.0) | 31 (50.8) |
| 2 | 2 (7.7) | 12 (19.7) |
| 3 | 4 (15.4) | 5 (8.2) |
| 4 | 4 (15.4) | 5 (8.2) |
| ≥5 | 3 (11.5) | 8 (13.1) |

| Characteristic | Cohort 1 (HR NMIBC) (N=26) | Cohort 3 (IR NMIBC) (N=62) |
|---|----------------------------------|----------------------------------|
| ECOG performance status, n (%) | | |
| 0 | 17 (65.4) | 52 (83.9) |
| 1 | 6 (23.1) | 7 (11.3) |
| 2 | 3 (11.5) | 3 (4.8) |
| Prior cancer treatment, n (%) | | |
| Surgery or procedure | 26 (100) | 62 (100) |
| Intravesical BCG | 26 (100) | 14 (22.6) |
| Intravesical chemotherapy | 6 (23.1) | 33 (53.2) |
| Systemic therapy | 1 (3.8) | 0 |
| Prior TURBT or other ablative procedure, n (%) ^b | | |
| 1 | 0 | 14 (22.6) |
| 2 | 1 (3.8) | 18 (29.0) |
| 3 | 10 (38.5) | 9 (14.5) |
| 4 | 6 (23.1) | 10 (16.1) |
| ≥5 | 9 (34.6) | 11 (17.7) |

- Median treatment duration was 11.9 months (range, 3-15) in Cohort 1 and 11.8 months (range, 0.1-15) in Cohort 3

^aIn Cohort 1, number of tumors prior to required TURBT (n=26). In Cohort 3, number of tumors at time of screening cystoscopy (n=61 patients with available data).

^bSurgeries/procedures were counted only once on a given date and included the following: TURBT, fulguration, cauterization, or laser photoablation.



Erda-iDRS Was Well Tolerated With Mostly Low-grade Urinary Toxicities

| Patients With ≥ 1 Event, n (%) | Cohort 1 (HR NMIBC) (N=26) | Cohort 3 (IR NMIBC) (N=62) | All Patients (N=88) |
|--|----------------------------|----------------------------|----------------------|
| Any TRAE | 20 (76.9) | 39 (62.9) | 59 (67.0) |
| TRAEs in $\geq 10\%$ of patients by preferred term | | | |
| Hematuria | 10 (38.5) | 18 (29.0) | 28 (31.8) |
| Dysuria | 7 (26.9) | 12 (19.4) | 19 (21.6) |
| Pollakiuria | 2 (7.7) | 11 (17.7) | 13 (14.8) |
| Micturition urgency | 4 (15.4) | 9 (14.5) | 13 (14.8) |
| Urinary tract infection | 3 (11.5) | 9 (14.5) | 12 (13.6) |
| Bladder spasm | 2 (7.7) | 7 (11.3) | 9 (10.2) |
| Grade ≥ 3 TRAEs | 1 (3.8) | 3 (4.8) | 4 (4.5) ^a |
| TRAE leading discontinuation | 2 (7.7) | 6 (9.7) | 8 (9.1) ^b |
| TRAE leading to treatment interruption | 1 (3.8) | 3 (4.8) | 4 (4.5) |
| TRAE leading to death | 0 | 0 | 0 |

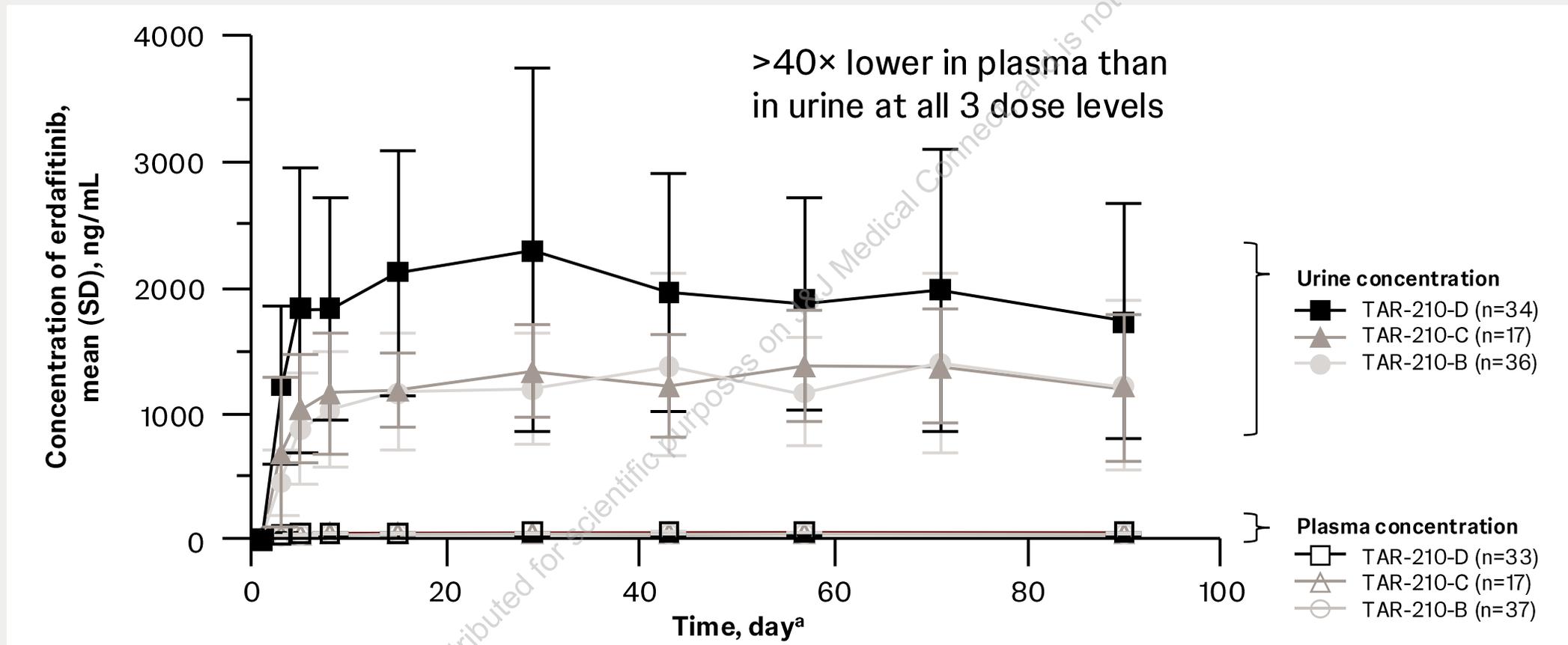
- The most frequent TRAEs were hematuria (32%) and dysuria (22%), mostly grade 1/2
- 4 patients (5%) had grade ≥ 3 TRAEs
- 8 patients (9%) had TRAEs leading to discontinuation
- 2 patients (2%) had serious TRAEs (1 with pyelonephritis and sepsis; 1 with hematuria)
- No hyperphosphatemia or retinal toxicities (systemic side effects associated with oral erdafitinib) were observed

^aTwo patients with grade 3 hematuria (1 serious TRAE); one patient with pyelonephritis and sepsis (serious TRAEs); one patient with aseptic cystitis.

^bMost frequent TRAEs leading to discontinuation were hematuria (n=3) and micturition urgency (n=2); other TRAEs leading to discontinuation were proctalgia, constipation, urinary tract pain, urinary incontinence, bladder spasm, bladder pain, and urethral pain (n=1 each); patients could have had ≥ 1 TRAE leading to discontinuation.



Erda-iDRS Provided Sustained Erdafitinib Concentrations in Urine With Very Low Plasma Concentrations



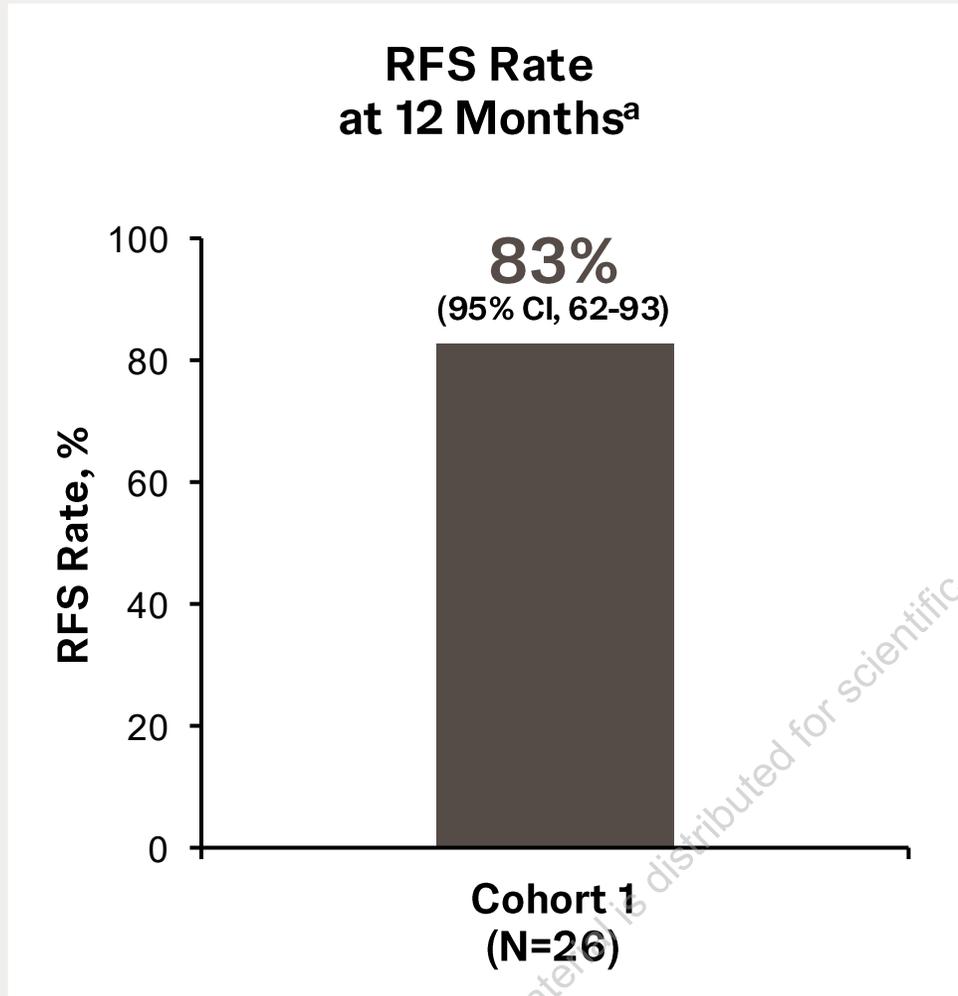
- Plasma concentrations of erdafitinib delivered via erda-iDRS were >40x times lower than those observed with oral erdafitinib at 9 mg daily¹

^aUrine samples were taken on Day 1, 3, 5, 8, 15, 29, 43, 57, 71, and 90. Plasma samples were taken on Day 1, 3, 5, 8, 15, 29, 43, 57, and 90.

1. Tabernero J, et al. *Ann Oncol*. 2016;27(Suppl 6):VI273.



Erda-iDRS Showed a High 12-month RFS Rate as Adjuvant Therapy in Patients With BCG-treated HR NMIBC



| | Cohort 1 (N=26) |
|---|-------------------|
| Median RFS (95% CI) ^a | 20 months (15-30) |
| Median RFS follow-up (range) ^a | 24 months (15-30) |

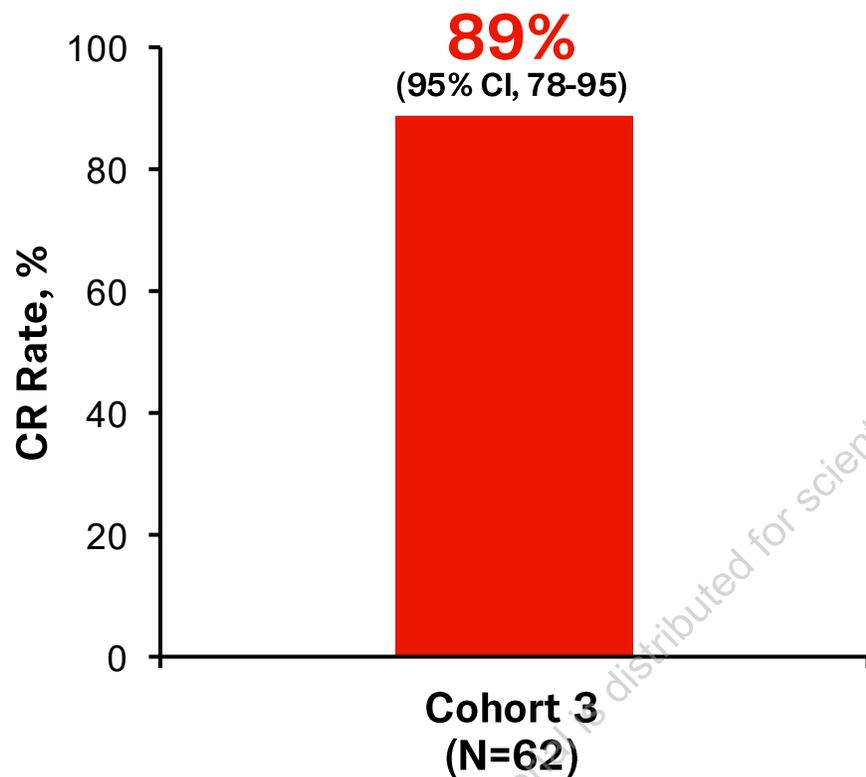
- 31% of patients in Cohort 1 were in ongoing follow-up and recurrence free at the clinical data cutoff

^aKaplan-Meier estimate.



Erda-iDRS Showed a High CR Rate as Ablative Therapy in Patients With IR NMIBC

CR Rate by the 6-month Disease Evaluation^a



| | Cohort 3 (n=55) |
|---|-------------------|
| Median CR duration (95% CI) ^a | 18 months (14-25) |
| Median follow-up in responders (range) ^a | 18 months (15-21) |

- 81% of patients had achieved CR at the 3-month disease evaluation
- 49% of responders were in ongoing follow-up and remained in CR at the clinical data cutoff

^aKaplan-Meier estimate.



Conclusions

- Erda-iDRS achieved proof of concept for sustained local delivery of erdafitinib and demonstrated preliminary clinical activity in patients with *FGFR*-altered NMIBC
 - Erda-iDRS was tolerable with mostly grade 1-2 lower urinary tract symptoms
 - The estimated **12-month RFS rate** was **83%** adjuvant to TURBT in **BCG-treated HR NMIBC**
 - The estimated **overall CR rate** was **89%** with a **median CR duration** of **18 months** as ablative therapy in **IR NMIBC**
- Phase 2 and 3 trials of erda-iDRS are ongoing in patients with *FGFR*-altered NMIBC
 - Phase 3, adjuvant vs intravesical chemotherapy in IR NMIBC (MoonRISe-1; NCT06319820)
 - Phase 2, ablative in IR NMIBC (MoonRISe-2; NCT05316155)
 - Phase 3, adjuvant vs intravesical chemotherapy in papillary-only HR NMIBC (MoonRISe-3; NCT06919965)



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