Kyntra Bio

Corporate Presentation | March 2026

Forward-Looking Statements

This presentation contains forward-looking statements regarding Kyntra Bio's strategy, future plans and prospects, including statements regarding its commercial products and clinical programs and those of its partners Fortis and UCSF. These forward-looking statements include, but are not limited to, statements regarding the efficacy, safety, and potential clinical or commercial success of Kyntra Bio products and product candidates, statements under the caption "Recent and Near-Term Catalysts", statements about regulatory interactions, the payoff of the Morgan Stanley Tactical Value term loan, statements regarding cash, such as the expectation that cash, cash equivalents and accounts receivable will be sufficient to fund Kyntra Bio's operating plans into 2028, and statements about Kyntra Bio's plans and objectives. These forward-looking statements are typically identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. Kyntra Bio's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of its various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in Kyntra Bio's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, each as filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Kyntra Bio undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

Investment Highlights

Transformed into Kyntra Bio: Creating Outsized Impact for Patients and Shareholders

- Completed sale of FibroGen China to AstraZeneca for approximately $220 million
- Successfully repaid term loan to Morgan Stanley Tactical Value, further simplifying capital structure
- Extended cash runway into 2028

FG-3246 & FG-3180: Attractive Assets in Prostate Cancer, Phase 2 Enrolling

- FG-3246, a potential first-in-class, CD46 targeting ADC, with clinically meaningful responses in pretreated mCRPC and a well-characterized safety profile
- FG-3180, a PET imaging agent, in clinical development as potential novel patient selection biomarker
- Phase 2 monotherapy trial of FG-3246 and FG-3180 in mCRPC, post-ARPI / pre-chemo setting enrolling; interim results expected in 2H 2026

Roxadustat: A Phase-3 Ready Development Opportunity

- Approved in > 40 countries and commercialized by AstraZeneca and Astellas for anemia associated with CKD
- Compelling wholly owned, Phase 3-ready U.S. development opportunity in anemia due to LR-MDS and high red blood cell transfusion burden
- Reached agreement with the FDA on important Phase 3 clinical trial design elements, providing a regulatory pathway forward
- Orphan Drug Designation in MDS granted by FDA in December 2025

Recent and Near-Term Catalysts

- Interim results for the Phase 2 monotherapy trial of FG-3246 expected in 2H 2026
- Submitted final Phase 3 protocol to FDA in December 2025 for roxadustat in anemia of LR-MDS with a potential Phase 3 initiation in 2H 2026*

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ADC=antibody drug conjugate; LR-MDS=low-risk myelodysplastic syndromes; mAb=monoclonal antibody; mCPRC=metastatic castration-resistant prostate cancer; SOC=standard of care.
*Costs of an internally run Phase 3 LR-MDS study are not included in current cash runway projections.

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FG-3246 & FG-3180 Program

Prostate Cancer Has a High Unmet Need for Treatment Options That Extend Survival in Late-Stage Disease

Prostate cancer is the **second most common** cancer type

~ 65,000 drug treatable mCRPC cases in the U.S. annually

13% of men **will be diagnosed with prostate cancer** at some point during their lifetime

30% **5-year survival** in mCRPC is **~30%**

Highest Unmet Needs in mCRPC

- Therapies that extend survival in patients who are ineligible for or progressed on ARPI and/or chemotherapy
- Novel MOAs that can treat patients who progressed on available treatment options (ex. non-PSMA)
- Predictive tools to inform patient selection
- Optimal combination and sequencing of therapies

CD46 as a Novel Tumor Selective Target in Solid Tumors

CD46 negatively regulates the complement system and helps tumors evade complement-dependent cytotoxicity

CD46
is a multi-functional protein, overexpressed in cancer

- Negatively regulates the complement system and helps tumors evade complement-dependent cytotoxicity
- A part of a protein complex mediating cytoskeletal dynamics, invasion, and metastasis
- Overexpressed in mCRPC, colorectal cancer, and other solid tumors with limited expression in normal tissues

CD46
is overexpressed in mCRPC

- CD46 expression is up-regulated as prostate cancer progresses from localized castration-sensitive prostate cancer to mCRPC and is further overexpressed following treatment with androgen signaling inhibitors
- 50%-70% of mCRPC patients are estimated to have high expression of CD46 ($CD46^{high}$)
- CD46 is expressed more homogenously and at higher levels compared to PSMA

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* $p<0.05$.

1. Su Y, et al. *JCI Insight*. 2018; 3(17):e121497.

Targeting a Novel Epitope of CD46 Has Therapeutic and Diagnostic Potential

FG-3246 Therapeutic

Targeting antibody + Payload

MMAE: a potent anti-microtubule agent (validated chemotherapy)

Offers an androgen receptor agnostic and non-PSMA approach

YS5 is a fully-human, full length, IgG1 mAb to tumor-selective epitope of CD46 that is:

Less accessible on most normal cells

Does not interfere with complement system regulation

FG-3180 PET Imaging Agent

Targeting antibody +^{89}Zr tracer

Demonstrated specific uptake in CD46 positive tumors

Potential to inform patient selection

PET-based biomarker currently considered superior to CD46 IHC in prostate cancer

Development strategy aims to achieve **clinically differentiated profile** in competitive yet dissatisfied mCRPC market

Phase 1 Monotherapy Study of FG-3246 in Patients with mCRPC

First-in-human, dose-escalation with dose expansion study

Dose Escalation (n=33)

Main Eligibility Criteria

- Metastatic CRPC by PCWG3 criteria
- Prior treatment with at least one androgen signaling inhibitor (e.g., abiraterone, enzalutamide)
- No prior taxane for the treatment of metastatic CRPC
  - Prior taxane for castration-sensitive disease allowed if > 6 months prior
- CD46 expression by IHC not required for eligibility

Dose Levels

0.1 mg/kg	n=7
0.3 mg/kg	
0.6 mg/kg	
1.2 mg/kg	n=3
1.8 mg/kg	n=7
2.1 mg/kg	n=3
2.4 mg/kg	n=3
2.4 mg/kg*	n=4
2.7 mg/kg*	n=3
3.0 mg/kg*	n=3

Dose Expansion (n=23)

Two Cohorts

Same eligibility as dose escalation

Cohort 1: n = 18

2.7 mg/kg*

mCRPC without small cell/neuroendocrine histology

Cohort 2: n = 5

2.7 mg/kg*

mCRPC with unequivocal small cell/neuroendocrine histology

Study endpoints

- Primary Endpoints: Evaluate the safety and tolerability and determine the MTD and/or recommended Phase 2 dose in mCRPC patients
- Secondary Endpoints: PK and efficacy including rPFS, PSA50, and objective response rate
- Exploratory Endpoint: Evaluate potential relationships between CD46 expression and measures of antitumor activity

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*Adjusted Body Weight Dosing.

MTD=maximally tolerated dose; ORR=overall response rate; rPFS=radiographic progression free survival; PSA=prostate specific antigen.

Phase 1 Monotherapy Study of FG-3246: Baseline Characteristics

Adenocarcinoma study cohort (N = 51)

Median age, years (range)	69 (42 – 81)
Race, n White/Black/Asian/Native American	43 / 5 / 2 / 1
Median PSA, ng/mL (range)	41 (0.2 – 1627)
Measurable disease (RECIST 1.1), n (%)	31 (60.8)
Type of disease progression at study entry, n (%)	
PSA	36 (70.6)
Node only (no bone disease)	5 (9.8)
Bone (± nodal disease)	26 (51.0)
Visceral ± other sites	13 (25.5)
Symptomatic progression	1 (2.0)
No. of prior therapy lines, median (range)	5 (2 – 14)

Prior Systemic Therapies, n (%)	
Androgen deprivation	
Medical	47 (92.2)
Leuprolide	46 (90.2)
Other LHRH/GnRH	10 (19.6)
Surgical	4 (7.8)
Androgen signaling inhibitor	51 (100)
Bicalutamide	31 (60.8)
Enzalutamide	35 (68.6)
Abiraterone	36 (70.6)
Other	9 (17.6)
Sipuleucel-T	16 (31.4)
Immune checkpoint inhibitors	11 (21.6)
Docetaxel (CSPC setting)	12 (23.5)
Other/Investigational	13 (25.5)

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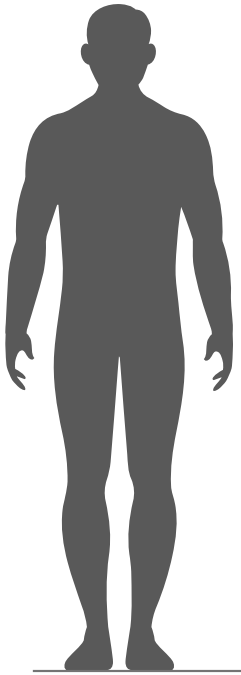
FG-3246 Demonstrated Meaningful Monotherapy Clinical Activity in 5L+ mCRPC Patients

Phase 1 dose escalation and expansion study results in biomarker unselected and heavily pre-treated patient population with median of 5 prior lines of therapy

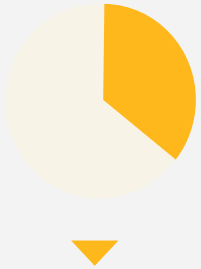


Efficacy analysis included **40 patients** from the dose escalation cohorts-level ≥ 1.2 mg/kg and cohort 1 (adenocarcinoma) of the dose expansion cohort at 2.7 mg/kg AJBW

8.7
months

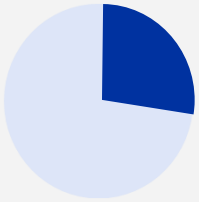
Median rPFS

95% CI:
5.49 - 11.14



~36%

PSA Decline by >50%



~20%
ORR

7.5
months

Median DOR

Range:
4.53 - 9.69

2.7 mg/kg AJBW declared as the MTD in the study

DOR=duration of response; ORR=overall response rate; rPFS=radiographic progression free survival; PSA=prostate specific antigen.

FG-3246 Demonstrated Competitive Survival Benefit in a Phase 1 Study of Heavily Pre-Treated and Biomarker Unselected Patients vs Select Comparable Early-Stage Studies

Sponsor	Therapeutic	Median Treatment Line	rPFS Evaluable Patients	rPFS (months)
Amgen	Xaluritamig (AMG509)	4L	N=106	7.8
Janux	JANX007	5L	N=16	7.5
Daiichi Sankyo	DS-7300	6L	N=54 (DOR only)	4.4 (DOR Only)
ARX517	Ambrx (now J&J)	5L	Not Reported	Not Reported
Fortis	**FOR46 / FG-3246**	**5L+**	**N=40**	**8.7**

Monotherapy Study: Heavily pre-treated patient population with median of 5 prior lines of therapy

While we cannot make direct comparisons to other trials due to differences in study design, analysis methods, population sizes, controls and phases of development, we are encouraged there are opportunities for new treatments.

FG-3246 Phase 1 Monotherapy Safety Profile Consistent with Other MMAE-ADCs

All Grades by Patient (≥ 10%)	All Grades N (%)	≥ Grade 3 N (%)
Fatigue	25 (56.8)	3 (6.8)
Weight decreased	23 (52.3)	1 (2.3)
Infusion related reaction	21 (47.7)	1 (2.3)
Nausea	20 (45.5)	0
Neutropenia	20 (45.5)	**16 (36.4)**
Constipation	19 (43.2)	0
Decreased appetite	16 (36.4)	1 (2.3)
Diarrhoea	16 (36.4)	0
Neutrophil count decreased	16 (36.4)	**13 (29.5)**
White blood cell count decreased	16 (36.4)	**12 (27.3)**
Neuropathy peripheral	15 (34.1)	1 (2.3)
Anaemia	14 (31.8)	3 (6.8)
Arthralgia	14 (31.8)	0
Alopecia	13 (29.5)	0
Hypoalbuminaemia	11 (25.0)	1 (2.3)
Vomiting	11 (25.0)	0
Alanine aminotransferase ↑	10 (22.7)	0
Aspartate aminotransferase ↑	10 (22.7)	0
Back pain	10 (22.7)	1 (2.3)
Lymphocyte count decreased	10 (22.7)	3 (6.8)

All Grades by Patient (≥ 10%)	All Grades N (%)	≥ Grade 3 N (%)
Blood alkaline phosphatase ↑	9 (20.5)	1 (2.3)
Oedema peripheral	9 (20.5)	0
Abdominal pain	8 (18.2)	0
Blood creatinine increased	8 (18.2)	0
Dyspnoea	8 (18.2)	0
Hypocalcaemia	8 (18.2)	2 (4.5)
Hypokalaemia	8 (18.2)	1 (2.3)
Hypophosphotaemia	8 (18.2)	0
Pain in extremity	8 (18.2)	1 (2.3)
Headache	7 (15.9)	0
Hyponatraemia	7 (15.9)	3 (6.8)
Peripheral sensory neuropathy	7 (15.9)	0
Pyrexia	7 (15.9)	0
Blood lactate dehydrogenase ↑	6 (13.6)	0
Hypomagnesaemia	6 (13.6)	0
Lymphopenia	6 (13.6)	1 (2.3)
Tachycardia	6 (13.6)	0
Fall	5 (11.4)	0
Insomnia	5 (11.4)	0

Selected Cohorts: Dose escalation cohorts-level ≥ 1.2 mg/kg, combined with cohort 1 (adenocarcinoma) of the Expansion cohort (n=44)

Number and severity of AEs were dose-exposure related;
No new safety signals; All AEs were managed by institutional standard of care.
Table 14.3.1.3.7 Summary of Grade ≥ 3 TEAE by Preferred Term Decreasing Frequency
Table 14.3.1.3.9 Summary of All Grade TEAE by Preferred Term Decreasing Frequency

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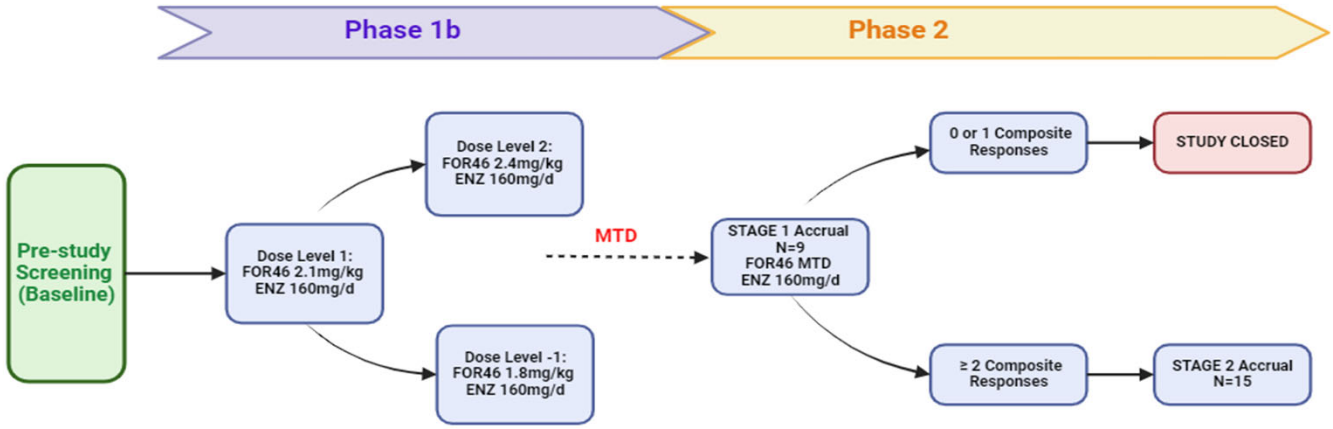
Phase 1b/2 Study of FG-3246 in Combination with Enzalutamide in mCRPC



Key inclusion criteria

- Progressive mCRPC per PCWG3 criteria
- Progressed on at least 1 prior androgen-signaling inhibitor (ASI); no prior taxane for CRPC
- ECOG performance status ≤1

Study endpoints

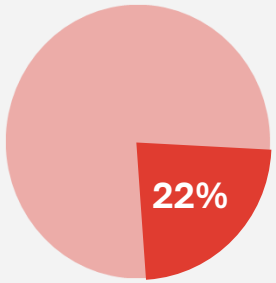
- Primary Endpoint for Phase 1b: Determine maximally tolerated dose (MTD) and recommended Phase 2 dose (RP2D) of FG-3246 in combination with enzalutamide
- Secondary Endpoints: PSA50, ORR by RECIST 1.1 criteria, rPFS, OS and frequency and severity of adverse events by CTCAE version 5.0
- Exploratory Endpoint: Evaluate potential relationships between CD46 expression and measures of antitumor activity

Encouraging Anti-Tumor Activity Observed in the Phase 1b/2 Investigator-Initiated Study of FG-3246 in Combination with Enzalutamide in mCRPC

Phase 1b/2 results in biomarker unselected patients, majority of **who progressed on ≥2 prior ARPIs**

7.0
months

Median rPFS

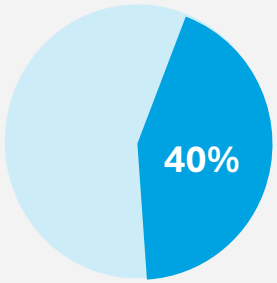


PSA50 Response

Phase 1b/2 results in patients who progressed on **1 prior ARPI***

10.1
months

Median rPFS



PSA50 Response

*Median rPFS similar across different ARPIs (abiraterone, enzalutamide, apalutamide, and darolutamide)

Encouraging FG-3246 anti-tumor activity in patients with mCRPC observed, particularly in patients progressing on only 1 prior ARPI

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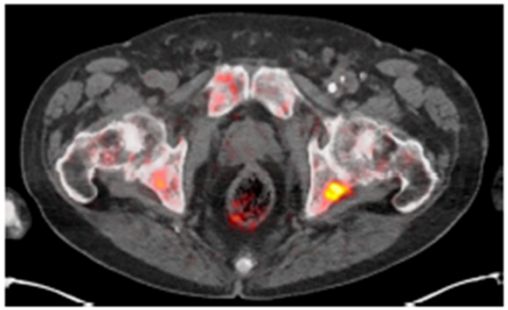
Higher Tumor Uptake of FG-3180 (PET46) was Associated with PSA50 Response

	PSA50 Response		P-value
	Yes (n=7)	**No (n=16)**	
$SUV_{max\text{-}ave}$	11.68 [9.91-13.88]	9.24 [7.98-10.64]	0.109
$SUV_{max\text{-}ave}$/ $SUV_{mean\ blood\ pool}$	**9.57 [9.24-11.93]**	**7.58 [6.66-9.80]**	**0.053**



Results demonstrate FG-3180's potential as PET imaging biomarker for patient selection; further evaluation ongoing in the Phase 2 monotherapy trial

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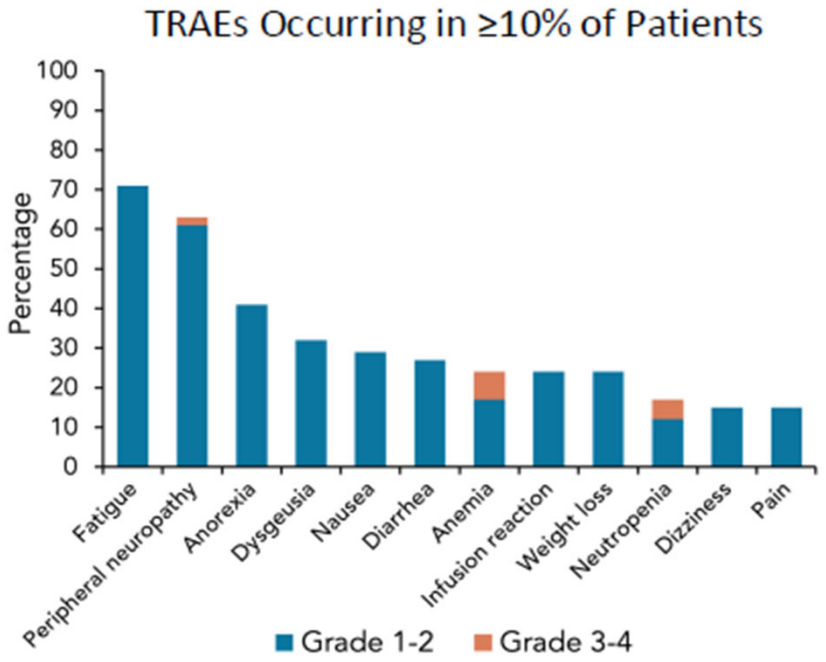
FG-3246 + Enzalutamide Combination Safety Profile Consistent with FG-3246 Monotherapy

TRAEs Summary

	Evaluable patients (n=41) n (%)
Any grade	41 (100)
Grade ≥ 3	9 (22.)
Serious TRAEs	3 (7.3)
Leading to death	0 (0)
Leading to FG-3246 discontinuation	15 (36.6)



- **Neutropenia risk was successfully mitigated with use of G-CSF prophylaxis**
- **Cumulative toxicities, especially peripheral neuropathy, led to treatment discontinuation for some patients**

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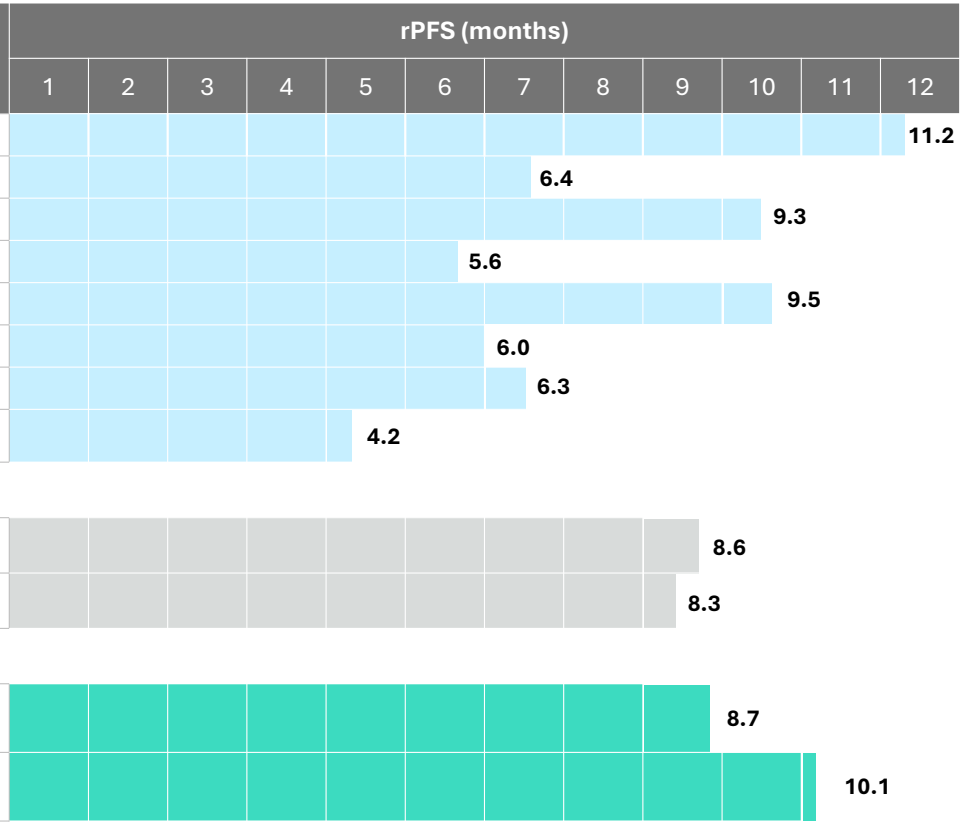
FG-3246 5L+ Monotherapy and 2L+ Combination Therapy Demonstrated Compelling Survival Benefit in Biomarker Unselected Patient Population vs 2L Therapies in Late-Stage Trials

Phase 3 Trial	Sponsor	Patient Selection	Therapeutic | Comparator	rPFS (months)
TRITON3[1,*]	pharmaand	BRCA mutant	Rucaparib	11.2
			Enza/abi/docetaxel	6.4
PSMAfore[2]	Novartis	PSMA positive	^{177}Lu-PSMA-617	9.3
			Enza/abi	5.6
Splash[3]	POINT Biopharma	PSMA positive	^{177}Lu- PNT2002	9.5
			Enza/abi	6.0
CONTACT-02[5]	Exelixis	Visceral disease or extrapelvic adenopathy	Cabozantinib/ Atezolizumab	6.3
			Enza/abi/prednisone	4.2
Contemporary Chemotherapy Data				
KEYNOTE-921	Merck	All Comers	pembro + docetaxel	8.6
			Docetaxel	8.3
Results in unselected patients:				
Ph1 FG-3246 Monotherapy	**Fortis**	**All Comers**	**FG-3246**	8.7
Ph1b/2 FG-3246 Combination	**UCSF**	**1 prior ARPI****	**FG-3246 + Enzalutamide**	10.1



While we cannot make direct comparisons to other trials due to differences in study design, analysis methods, population sizes, controls and phases of development, we are encouraged there are opportunities for new treatments

*in patients with BRCA mutation. **In the Phase 1b/2 combination trial of FG-3246 with enzalutamide, the median rPFS was 7.0 months in the overall cohort (majority of whom progressed on ≥2 prior ARPIs).

1. Fizazi K, et al. NEJM. 2023;388(8):719-732. 2. Pluvicto Prescribing Information. 3.POINT Biopharma PR. December 18, 2023. 4. de Bono J, et al. NEJM. 2020;382(22):2091-2102. 5. Agarwal N, et al. ASCO 2024.

FG-3246 and FG-3180 Phase 2 Monotherapy Trial Initiated

Interim results expected in 2H 2026

Phase 2 - FG-3246 Dose Optimization in Post-ARPI, Pre-Chemo mCRPC, All Comers (US only)

Primary Endpoint: Optimal dose for Phase 3 based on efficacy, safety, and PK

Secondary Endpoints: rPFS, PSA50, PSA90

Exploratory Endpoint: FG-3180 (PET imaging agent) as a diagnostic radiopharmaceutical

1:1:1 Randomization

- **Arm A: Dose Level 1 (N=25) 1.8 mg/kg AJBW**
- **Arm B: Dose Level 2 (N=25): 2.4 mg/kg AJBW**
- **Arm C: Dose Level 3 (N=25): 2.7 mg/kg AJBW**

All arms will use primary prophylaxis with G-CSF

Expected 2H 2026

Safety Review Committee

- Planned review when 10 patients in each arm complete cycle 1
- Planned review when 25 patients in each arm complete cycle 1
- Ad hoc as needed

Interim Analysis

- Planned for 12 weeks after 12 patients in each arm are enrolled
- DMC recommendation based on futility analysis and review of other available efficacy, safety, PK and E-R data
- Futility evaluated by Composite Response Rate (PSA50/ORR)

Final Analysis

- Planned for 12 months post N=25 enrolled in each cohort
- Benefit/Risk assessment (Recommended Phase 3 Dose)
- Decision on FG-3180 for patient pre-selection in Phase 3

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FG-3246 Phase 2 Monotherapy Trial: Three Main Design Elements Driving the Potential for Increasing rPFS versus the Phase 1 Study (>8.7 months)

Further validated by Phase 1b/2 Combination IST

Use of three of the highest doses (1.8mg/kg; 2.4mg/kg; 2.7mg/kg), given the exposure response established during the Phase 1 dose escalation and expansion trial

Use of primary prophylaxis G-CSF to help mitigate MMAE-associated adverse events like neutropenia, and maintain patients on their drug regimen longer

Moving upline to patients who have progressed on one prior ARPI – 1L or 2L mCRPC treatment as opposed to 5L+ in the Phase 1 monotherapy trial

FG-3246 and FG-3180 Near-Term Development Highlights

Development strategy provides significant optionality in prostate cancer alone

Robust Phase 2 monotherapy trial in pre-chemo mCRPC…

- Designed to select dose for optimal benefit/risk profile
- 3 factors expected to drive rPFS in all-comers: Preliminary evidence of exposure-response relationship, primary prophylaxis with G-CSF, and enrolling patients in earlier lines of therapy
- Validation of FG-3180 as predictive patient selection biomarker

…unlocks multiple registrational pathways sequentially or in parallel

- Multiple lines of therapy in prostate cancer
- Monotherapy and/or combination therapy approaches
- All comers or CD46^{high} selected patient populations

FG-3246 Program Recent & Upcoming Catalysts

2Q 2025

FG-3180 IND Clearance

3Q 2025

Initiated Phase 2 FG-3246 monotherapy trial, including FG-3180

1Q 2026

Topline results from the investigator sponsored study of FG-3246 + enzalutamide

- 10.1 months of median rPFS in patients who progressed on only one prior ARPI
- Validates key Phase 2 monotherapy design elements

2H 2026

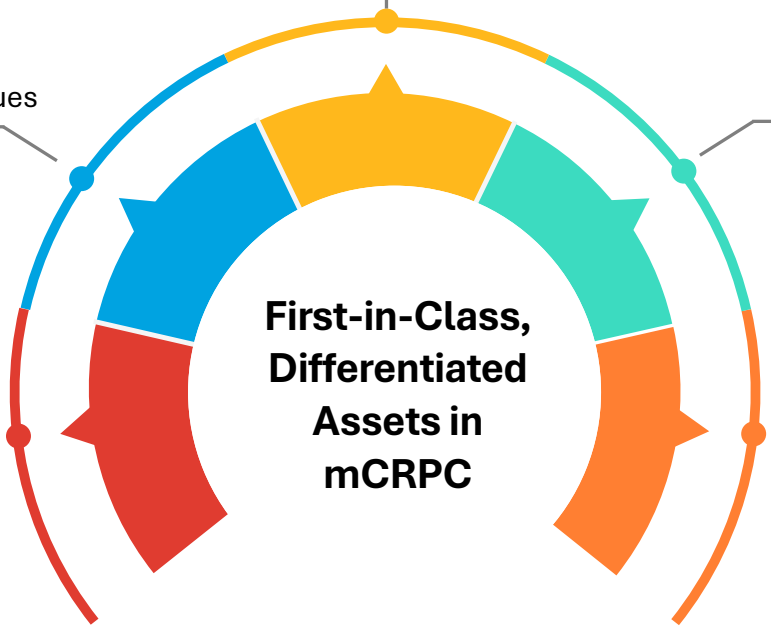
Interim analysis from Phase 2 FG-3246 monotherapy trial

FG-3246 and FG-3180 Present Unique Opportunity in mCRPC

Compelling Results in Two Phase 1 Studies
FG-3246 was clinically active as monotherapy and in combination with enzalutamide

Novel Mechanism of Action and Potential First-in-Class Opportunity
Binds a unique epitope on CD46 present on cancer cells but absent in most normal tissues

Consistent Safety Profile
Adverse events consistent with those observed with other MMAE-based ADC therapies



Investigating PET Biomarker Imaging Agent
CD46 biomarker diagnostic, FG-3180 (PET46), in development for screening, patient selection and enrichment

Significant Potential Opportunity
FG-3246 has potential in multiple lines of mCRPC as well as in other solid tumors such as colorectal cancer

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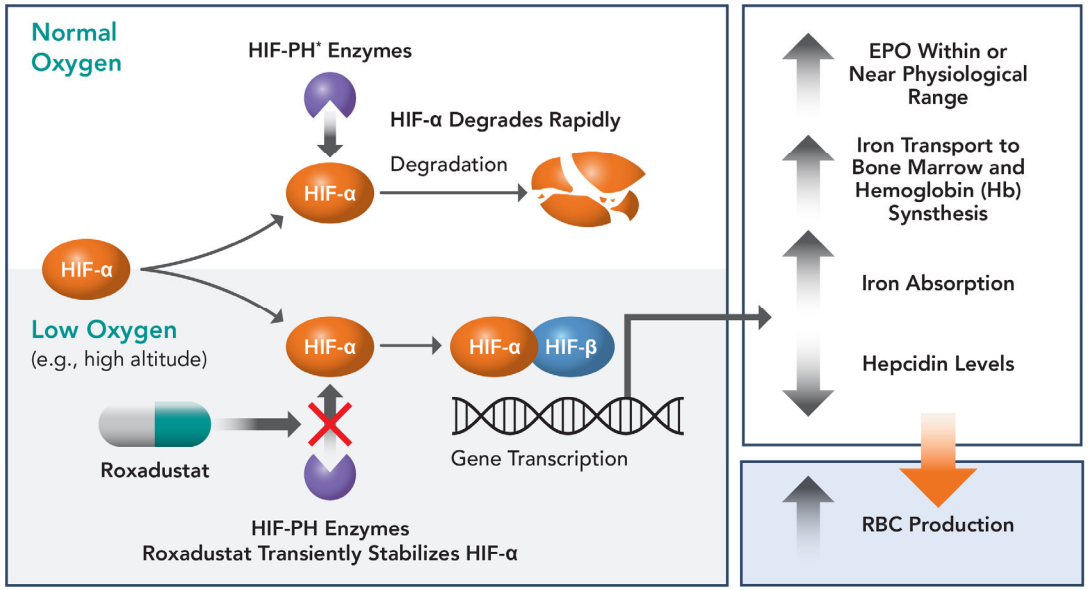
Roxadustat Program

Roxadustat is a Global First-in-Class, Oral HIF-PH Inhibitor



*Hypoxia-inducible factor prolyl hydroxylase (HIF-PH)

Increases hemoglobin (Hb) by mimicking the body's natural response to low oxygen

Approved for treatment of anemia in CKD patients, both on (DD) and not on (NDD) dialysis

2019 Nobel Prize In Physiology or Medicine

"for their discoveries of how cells sense and adapt to oxygen availability."

Awarded jointly to:

William G. Kaelin Jr. Harvard University

Peter J. Ratcliffe
Francis Crick Institute London

Gregg L. Semenza
Johns Hopkins University

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Anemia Associated with Lower-Risk MDS Represents a Significant Opportunity

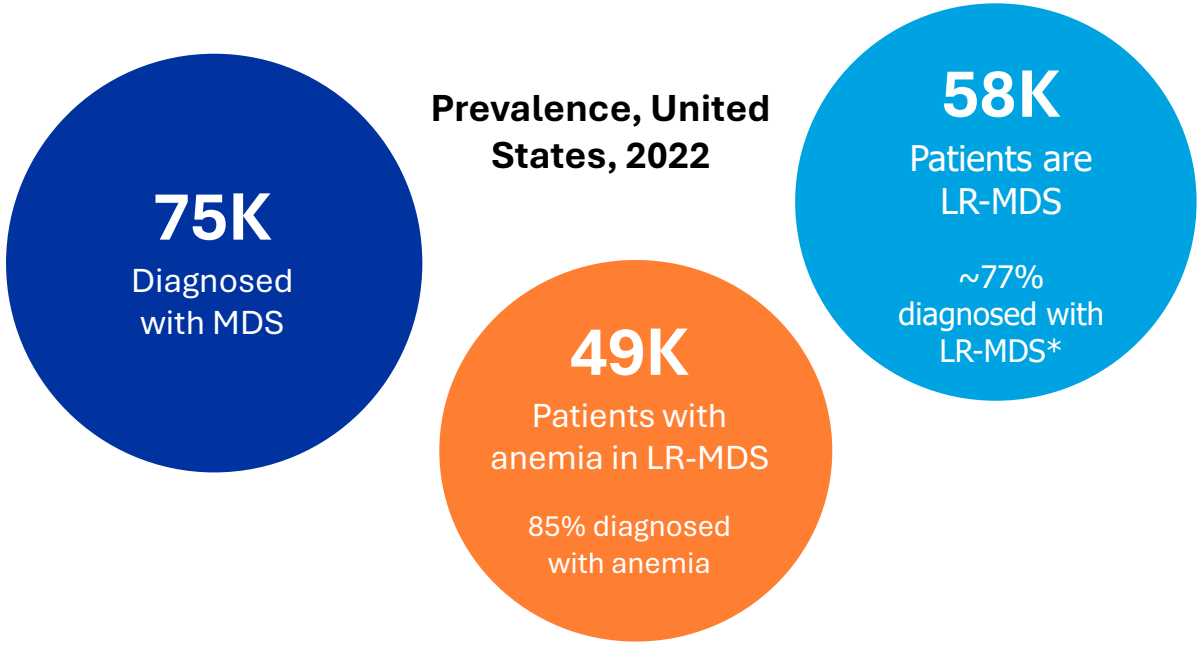
Anemia is the hallmark symptom of MDS that gives rise to significant morbidity

~75K
patients live with MDS in the U.S.

~90% suffering from anemia and its **negative impact** on quality of life

Current 1L agents are **effective in <50% patients** and relief is often temporary with **limited treatment options in 2L+**

SOCs are challenging to dose-calibrate and can only be administered through in-practice IV infusion or subQ injection

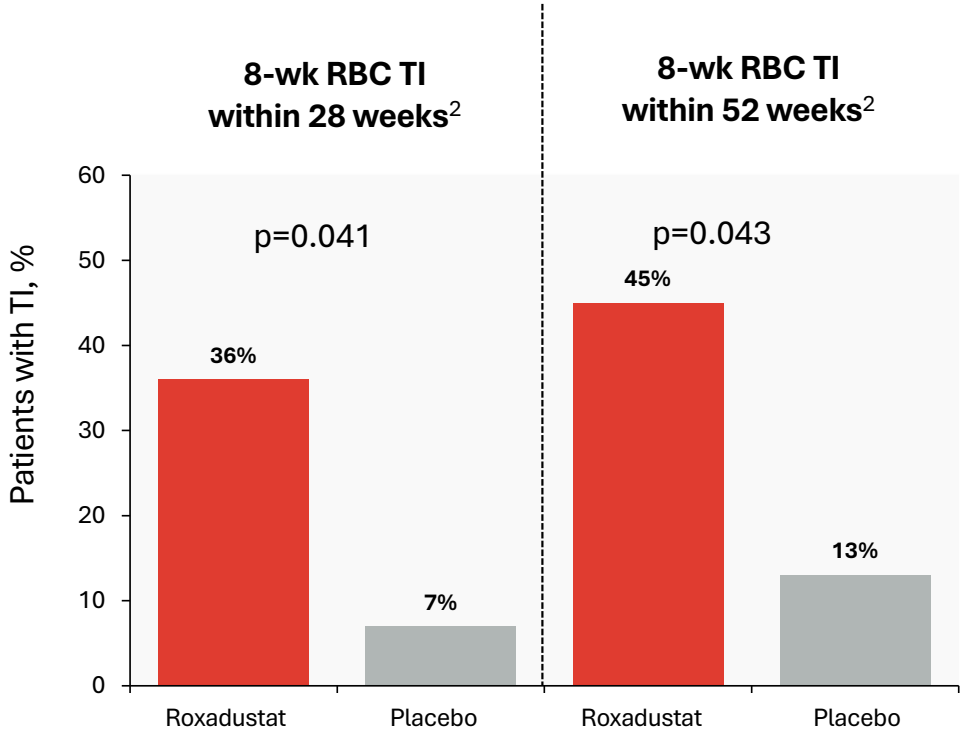


Despite recent approvals, there remains a significant unmet need in the refractory population for additional treatments that provide durable response and the convenience of oral administration

SEER, 2025 ; DRG 2023, Fenaux et al, Leukemia (2018); Platzbecker et al, Leukemia (2017).

Anemia of LR-MDS: Phase 3 Development Opportunity Based on Post Hoc Subgroup Results from MATTERHORN Phase 3 Trial

In patients with high transfusion burden[1], roxadustat showed promising TI benefits compared to placebo



No. of patients with response (% [95% CI])	Roxadustat (n=22)	Placebo (n=15)
8-wk RBC TI within 28 weeks[2]	8 (36% [17-59])	1 (7% [0-32])
8-wk RBC TI within 52 weeks[2]	10 (45% [24-68])	2 (13% (2-40])

Final analysis data cut-off date: Aug 2, 2023

Full analysis population (all randomized patients who received ≥1 dose of study drug and had ≥1 corresponding on-treatment Hb assessment)

[1]High transfusion burden at baseline defined by IWG2018: ≥4 pRBC units in two consecutive 8-week periods prior to randomization

[2]Post-hoc analysis with nominal p-values

CI, confidence interval; pRBC, packed red blood cells; TI, transfusion independence

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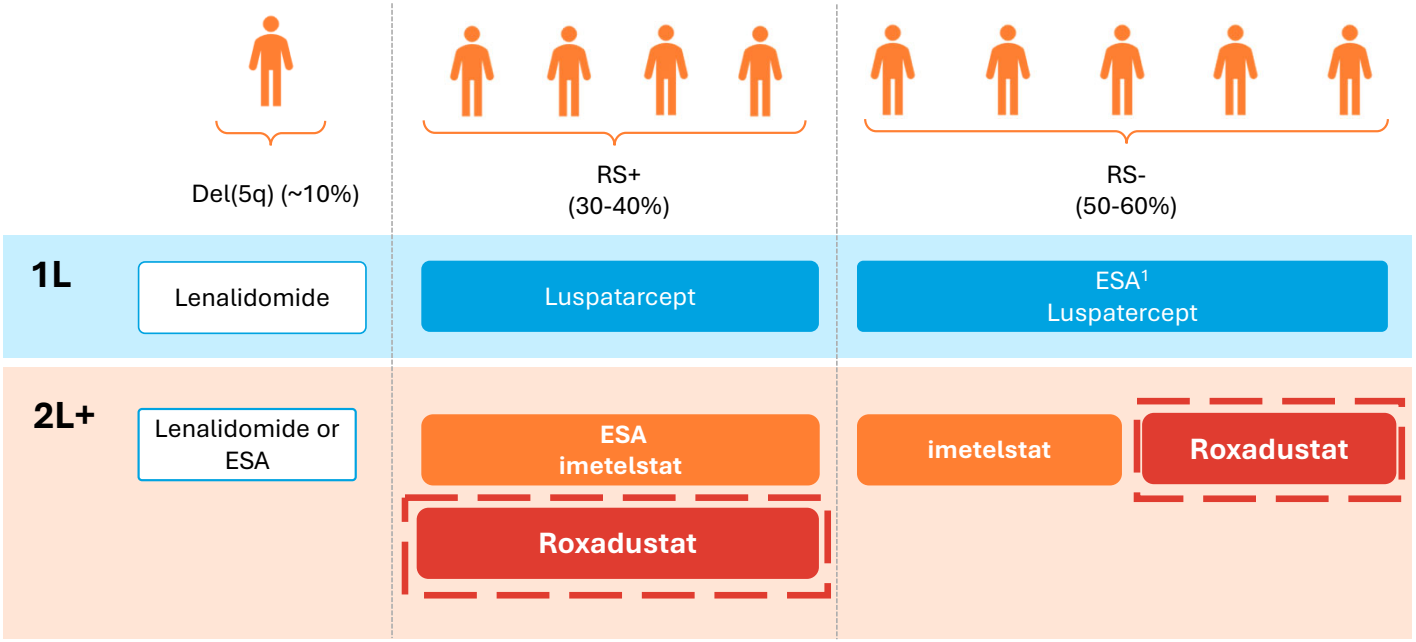
Roxadustat May Elevate the Standard of Care in 2L+ LR-MDS-Anemia

Target indication:

Treatment of anemia in patients with LR-MDS and HTB who are refractory to, intolerant to, or ineligible for, prior ESA treatment



RS = ring sideroblasts.
1. NCCN preferred is ESA, luspatercept approved in this setting. 2. Luspatercept not approved in 2L+ RS- MDS anemia.

Potential Pivotal Phase 3 Trial Overview

Currently exploring the opportunity to develop internally or with a strategic partner

Patient Population

- High transfusion burden: Patients requiring ≥ 4 pRBC units in two consecutive 8-week periods prior to randomization
- Refractory to, intolerant to, or ineligible for prior ESAs

Safety

Management of potential thrombotic risk through:

- Eligibility criteria
- Dose modification criteria
- Discontinuation criteria

Efficacy

- Primary endpoint: either ≥8-week or ≥16-week RBC-TI response rate
- Final analysis will be performed when all participants have completed ~12 months of treatment or discontinued

Dose Regimen

- Oral route of administration, three times per week
- Starting dose of 2.5 mg/kg with potential for stepwise dose titration to a maximum of 3.5 mg/kg

Submitted final protocol in December 2025

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Significant Opportunity for Roxadustat in Anemia Associated with LR-MDS

Substantial unmet need in LR-MDS anemia	• Significant unmet need despite recent approvals • No other oral treatments for anemia of LR-MDS commercially available or in late-stage development
Highly differentiated profile	• Differentiated profile with potentially superior tolerability and convenient dosing and administration • Targeted Phase 3 program could enable an approval in anemia associated with LR-MDS • Granted FDA Orphan designation, which provides 7 years of regulatory exclusivity in the U.S.
Large market opportunity	• Worldwide LR-MDS market is expected to exceed $4B in 5 years • Attractive pricing opportunity combined with efficient commercial model • Potential for >$500M in peak U.S. sales

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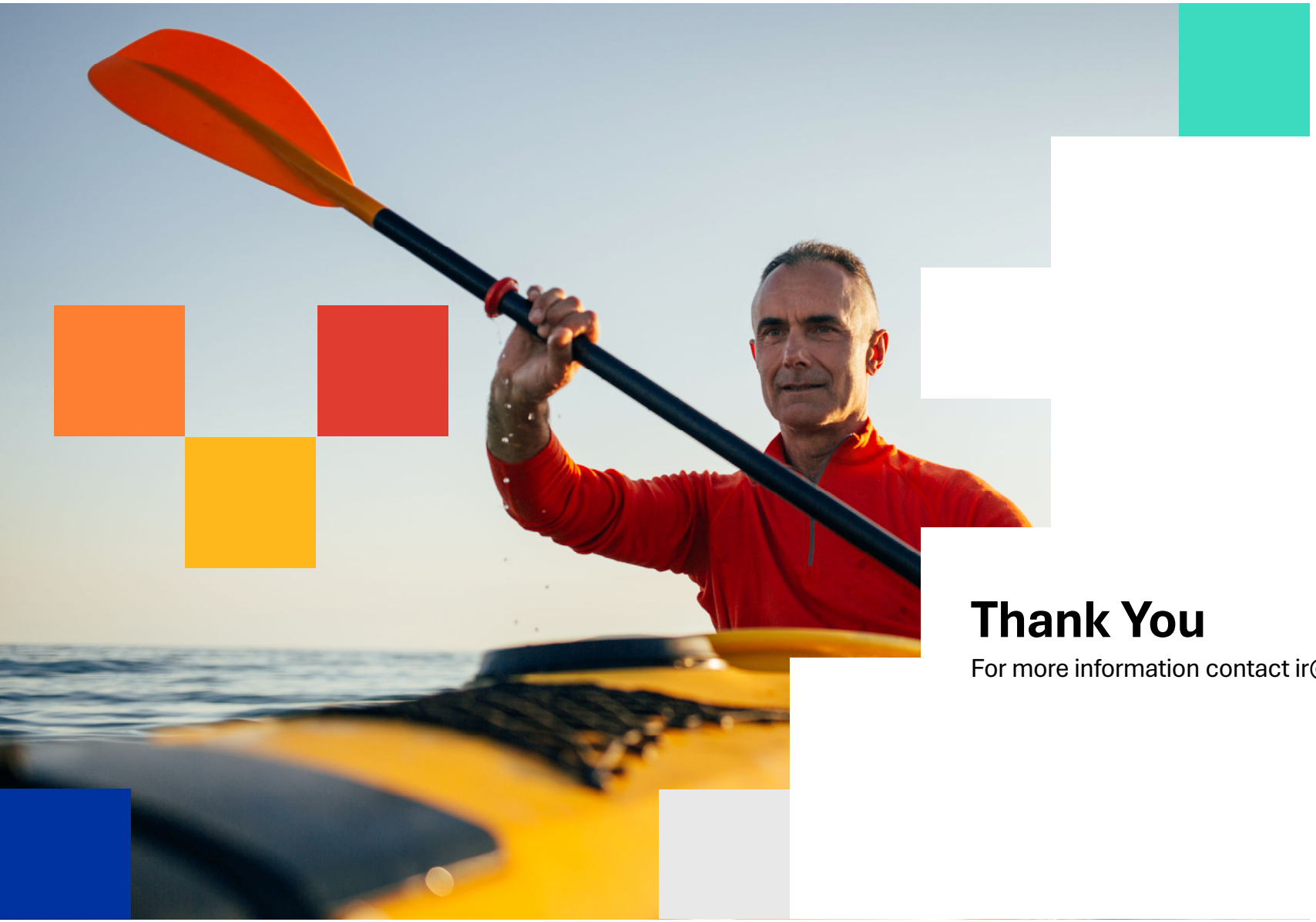

Thank You

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