



REGENERON[®]
ROUNDTABLE

Factor XI

NOVEMBER 10, 2025

This non-promotional presentation contains investigational data as well as forward-looking statements; actual results may vary materially.

Speakers

Regeneron Roundtable – Factor XI



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REGENERON ROUNDTABLE – Factor XI

Regeneron's Hematology Pipeline

Overview of Factor XI Program

Clinical Data: AHA 2025 ROXI-VTE-I and ROXI-VTE-II Results

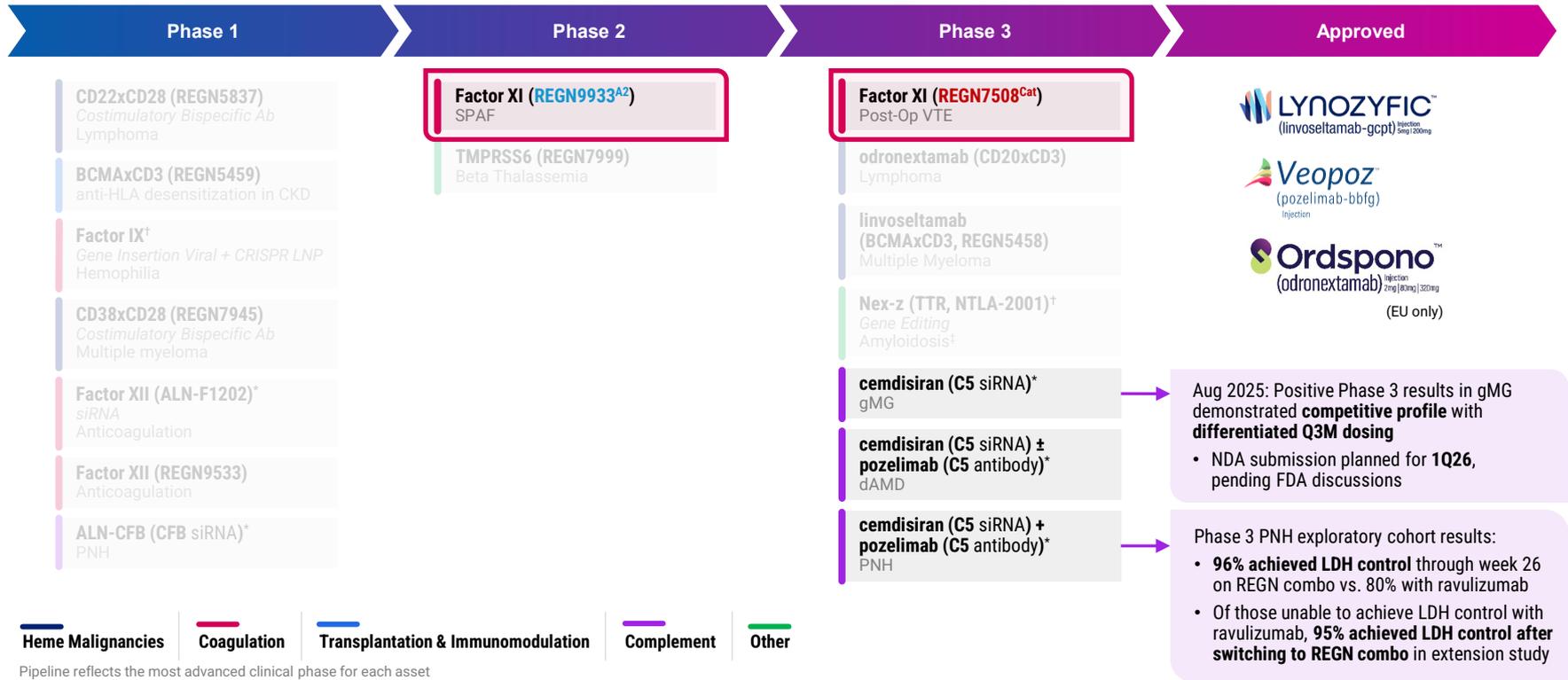
Clinical Data: ROXI-CATH & GI Bleed Preliminary Results

Factor XI Development Plan

Commercial Opportunity

Closing Remarks and Q&A

Hematology and Heme-Onc Development Pipeline



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Why target Factor XI for anticoagulation therapy?

Anticoagulants available today are effective, but use is limited by bleeding concerns

What is the unmet need in anticoagulation treatment?

- The current \$20Bn global market, driven primarily by stroke prevention in atrial fibrillation, remains underrealized due to bleeding risk, with standard-of-care DOAC utilization at ~50%
- In other settings (venous thromboembolism, contact-mediated thrombosis, arterial thrombosis, etc.) anticoagulant use is even lower due to bleeding risk

Why may Factor XI be a better target for anticoagulation?

- Blocking Factor XI (FXI) may prevent amplification and propagation of pathologic clot, while preserving pathways critical for hemostasis
 - FXI inhibition may be an effective antithrombotic strategy with substantially less bleeding risk
- Support from genetics:
 - FXI deficiency: reduced risk of venous thromboembolism and cardioembolic stroke with minimal increased bleeding risk¹
 - FXII deficiency: reduced risk of venous thromboembolism, and no increased bleeding risk²

How is Regeneron's approach differentiated from competing Factor XI-targeting agents?

Preclinical validation:

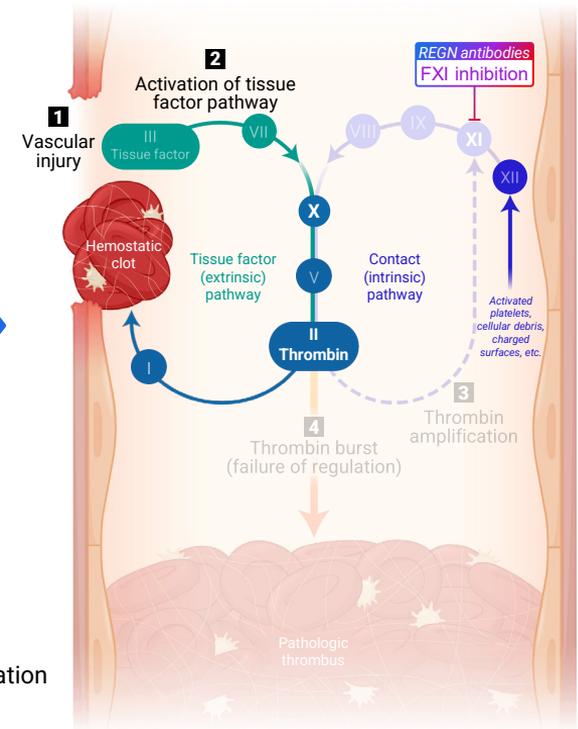
- More complete FXI inhibition demonstrated in aPTT and thrombin generation assays

Clinical data:

- TKR VTE studies demonstrated robust anticoagulation activity
- Beyond VTE, promising interim results demonstrated in Ph1/2 study in catheter-associated thrombosis

Patient-centric approach – two antibodies tailored to different risk-benefit profiles:

- **REGN7508^{Cat}** mimics FXI deficiency: potentially highest potency anticoagulation
- **REGN9933^{A2}** mimics FXII: potentially lowest bleeding risk



What is the unmet need?

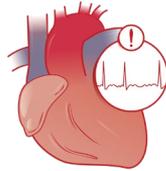
Currently >\$15B market in the U.S. alone, with room for growth in areas where bleeding risk has restricted standard-of-care usage



**Venous
Thromboembolism**

SoC: DOACs, LMWH

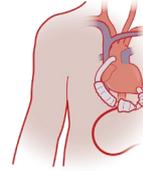
Use of aspirin or lack of adherence with guidelines for anticoagulation



**Cardioembolic
Stroke**

SoC: DOACs

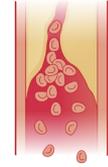
~50% of patients not treated because of bleeding concerns¹



**Contact-mediated
Thrombosis**

SoC: warfarin, heparin

Still dependent on older standard of care with high risk of bleeding



**Arterial
Thrombosis**

SoC: Anti-platelet therapy, DOACs

Limited use of approved anticoagulants due to bleeding concerns

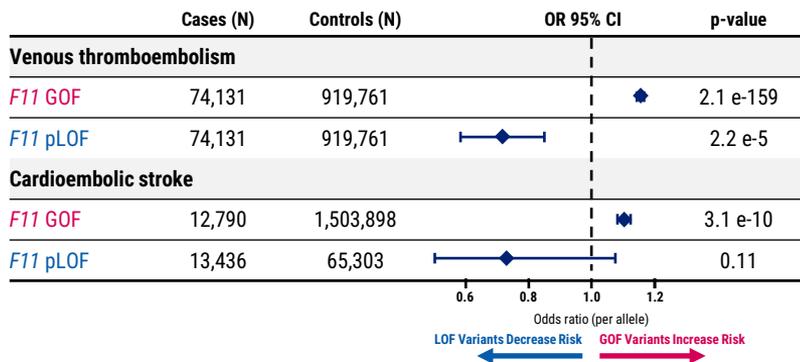
Two differentiated antibodies aim to unlock treatment opportunities in indications where anticoagulation is currently underutilized or not even considered

Genetics supports targeting Factor XI for anticoagulation therapy

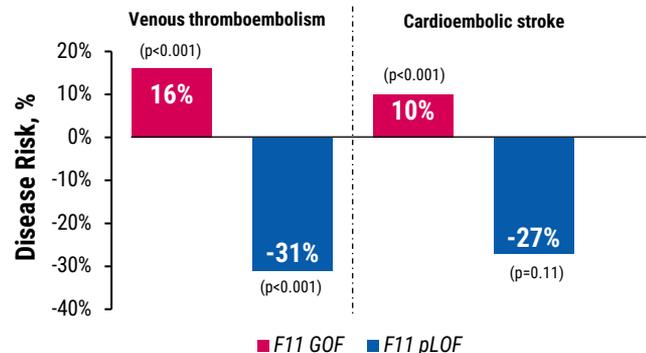
People with genetically lower FXI levels show reduced risk of VTE and cardioembolic stroke

- Epidemiological studies also show that FXI deficiency conveys protection from VTE and MACE¹, with a mild bleeding phenotype^{2,3}
- Our RGC analyses highlight *F11* gene variants as a significant contributor to **venous thromboembolism** (VTE) and **cardioembolic stroke** (figure below)
 - Analyses included people with a genetic mutation (***F11* gain-of-function, GOF**) that raises levels of FXI protein by ~8% and people with a different mutation (***F11* partial loss-of-function, pLOF**), which causes a ~50% decrease in FXI levels⁴
 - ***F11* GOF** was associated with **16% increased** risk for VTE and **10% increased** risk for **cardioembolic stroke**; while ***F11* pLOF** with **31% decreased** risk for VTE and **27% decreased** risk for **cardioembolic stroke**

Associations of *F11* gene variants with VTE and cardioembolic stroke



Disease risk reduction/increase with *F11* gene variants

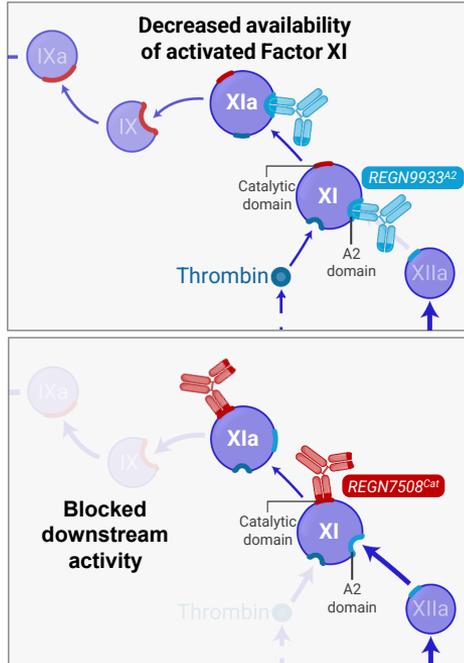


- RGC observed numerically lower but not statistically significant odds of myocardial infarction (MI) in *F11* pLOF carriers (OR: 0.88, p=0.17), likely due to MI more influenced by genes implicated in atherosclerotic disease, not thrombosis (data not shown)

¹Preis et al. Blood 2017; ²Peyvandi et al. JTH 2012; ³REGN CVD TFA & collaborators. SSVT 2021; ⁴In-house RGC data.
RGC: Regeneron Genetics Center; VTE: venous thromboembolism; MACE: major adverse cardiovascular events.

Why continued development of two Factor XI antibodies?

Patient-centric approach tailored to different risk-benefit profiles: **REGN9933^{A2}** for indications with low tolerance for bleeding risk, **REGN7508^{Cat}** broadly across Factor XI program indications



Anticipated therapeutic profile

	Anticoagulation potency	Bleeding risk	Most suitable for:
REGN9933^{A2}			Patients with highest bleeding risk Indications: AF DOAC NC, patients on background dual antiplatelet therapy (PAD)
REGN7508^{Cat}			Patients requiring maximal anticoagulation Indications: VTE, AF DOAC Candidates
DOACs			Approved for several anticoagulation indications

For illustrative purposes only

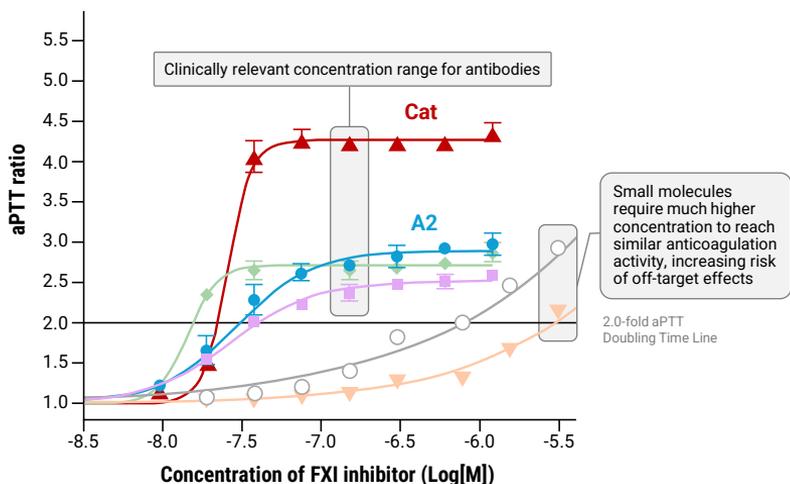
Preclinical data support differentiated profile for REGN's FXI antibodies

In preclinical assays, **REGN7508^{Cat}** and **REGN9933^{A2}** demonstrate more robust aPTT prolongation and stronger inhibition of thrombin generation compared to other FXI inhibitors, suggesting Regeneron's antibodies may be more complete FXI inhibitors

Activity of Regeneron's Antibodies and Competitor FXI Agents in Preclinical Assays of Anticoagulation

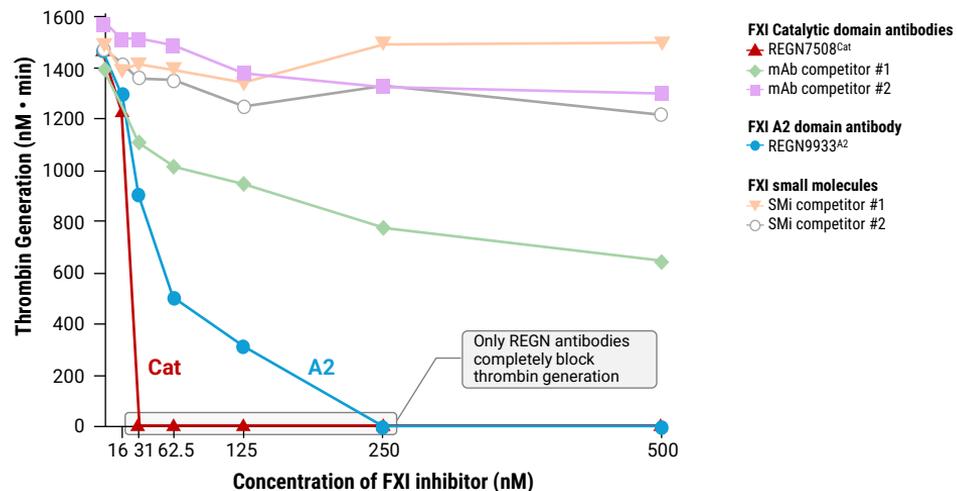
Concentration-response with aPTT assay in human plasma

(evaluation of intrinsic and common pathways of blood coagulation)



Concentration-response with Thrombin Generation Assay using intrinsic pathway trigger in human plasma

(assessment of ability of blood to form thrombin, a key enzyme in the blood clotting process)



REGENERON ROUNDTABLE – Factor XI

Regeneron's Hematology Pipeline

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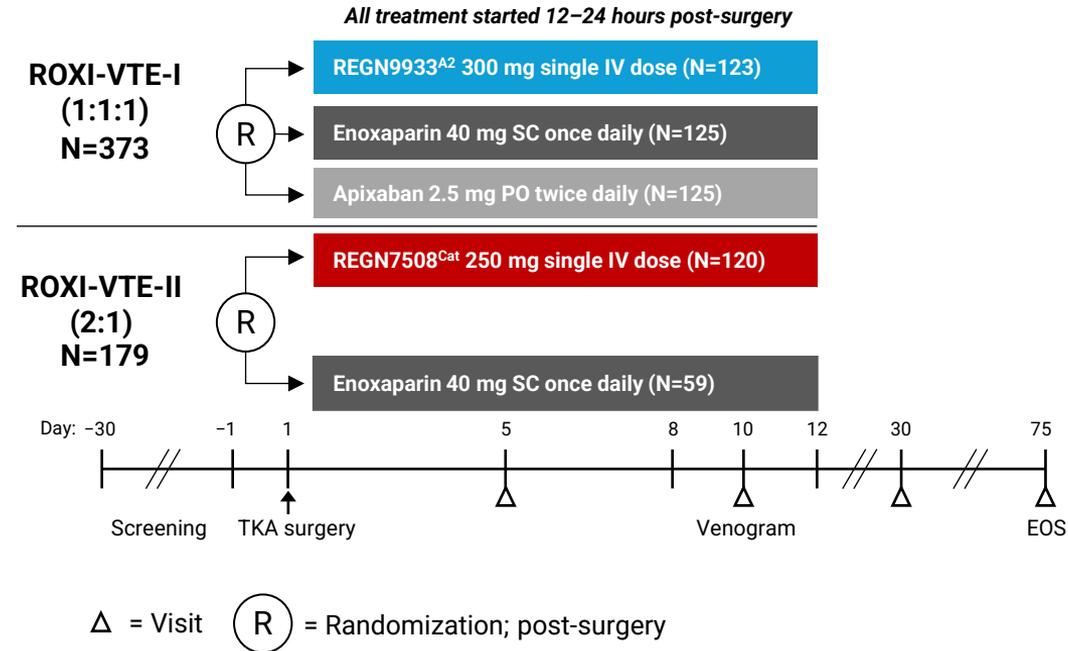
Factor XI Development Plan

Commercial Opportunity

Closing Remarks and Q&A

AHA 2025: ROXI-VTE-I and -II Study Design

Randomized, Open-Label, Active-Control, Phase 2 studies in patients undergoing Total Knee Replacement



Primary efficacy outcome:

- Incidence of adjudicated, confirmed VTE through day 12 (REGN9933^{A2}/REGN7508^{Cat} vs. enoxaparin)

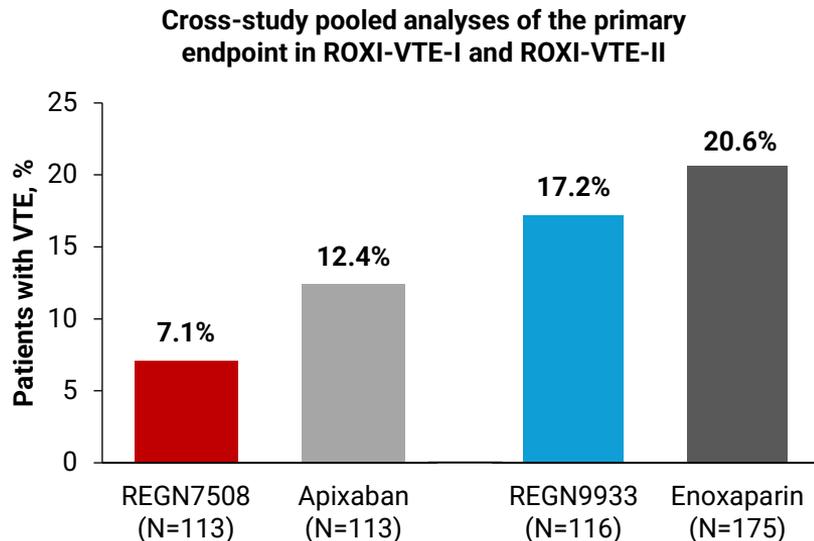
Principal safety outcome:

- Incidence of major and clinically relevant nonmajor bleeding through time of venography (or day 12, whichever was earlier)

AHA 2025: data in VTE prevention post-knee replacement surgery support broad Phase 3 development

REGN7508^{Cat} demonstrated numerically lowest VTE rate while REGN9933^{A2} demonstrated numerically lower VTE rate vs. enoxaparin

THE LANCET



Risk difference in VTE incidence, % (95% CI)

REGN7508^{Cat} vs pooled enoxaparin: -13.6 (-21.1 to -6.0)

REGN9933^{A2} vs pooled enoxaparin: -3.5 (-12.7 to 5.7)

REGN7508^{Cat} vs apixaban: -5.3 (-13.2 to 2.4)

Key Efficacy Findings:

- **REGN7508^{Cat}** – single infusion demonstrated superior efficacy vs. Lovenox (enoxaparin, SC daily) and demonstrated numerically lower VTE rate vs. Eliquis (apixaban, orally twice daily)
- **REGN9933^{A2}** – single infusion demonstrated numerically lower VTE rate vs. Lovenox (enoxaparin, SC daily)

AHA 2025: Safety Outcomes of ROXI-VTE-I and ROXI-VTE-II

There were no major or clinically relevant nonmajor bleeds in any arm in either study; none of the serious adverse events were related to any of the study drugs

	ROXI-VTE-I			ROXI-VTE-II	
Safety	REGN9933 ^{A2} 300 mg IV (N=123)	Enoxaparin 40 mg SC (N=125)	Apixaban 2.5 mg PO (N=125)	REGN7508 ^{Cat} 250 mg IV (N=120)	Enoxaparin 40 mg SC (N=59)
Major or clinically relevant nonmajor bleeding, n (%)					
Major bleeding	0	0	0	0	0
Clinically relevant nonmajor bleeding	0	0	0	0	0
Minor bleeding	0	1 (0.8)	0	0	0
Blood transfusion, n (%)	1 (0.8)	4 (3.2)	3 (2.4)	0	0
Adverse events, n (%)					
≥1 Adverse event	27 (22.0)	26 (20.8)	31 (24.8)	26 (21.7)	17 (28.8)
Serious adverse event	4 (3.3)	1 (0.8)	2 (1.6)	2 (1.7)	0

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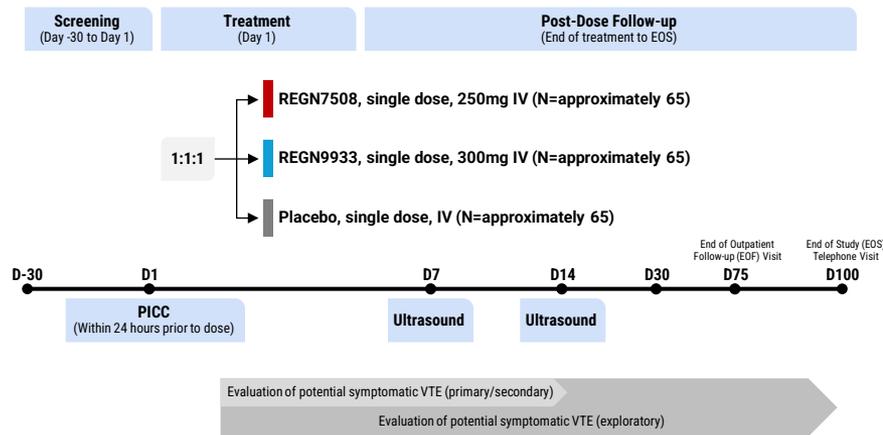
Closing Remarks and Q&A

Phase 2 ROXI-CATH in catheter-associated thrombosis: promising interim results for Regeneron's Factor XI inhibitors beyond VTE

Results support Phase 3 development for Cancer-Associated VTE prevention and PICC-associated thrombosis
Avoiding replacement of long-term indwelling catheters (e.g., PICC lines for chemotherapy) is a critical unmet need

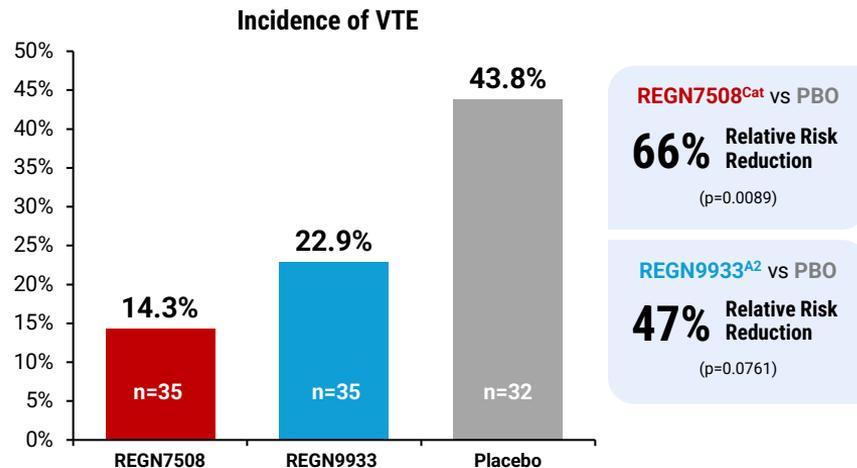
Phase 2 ROXI-CATH schema & rationale

- Study looked at patients with catheters inserted for various reasons; 55% of patients in this analysis were cancer patients
- Catheters increase risk of blood clotting (VTE)



Results of the interim analysis (50% enrollment)

- Factor XI antibodies are efficacious for clot prevention in patients with catheter-associated thrombosis
- No new safety signals were observed with FXI antibodies



Phase 1 GI bleed study: Factor XI antibodies demonstrate a favorable bleeding profile in a healthy volunteer provoked bleeding model

These results support antibodies' safety profile (bleeding risk) for all planned Phase 3 indications

Proof-of-mechanism study schema

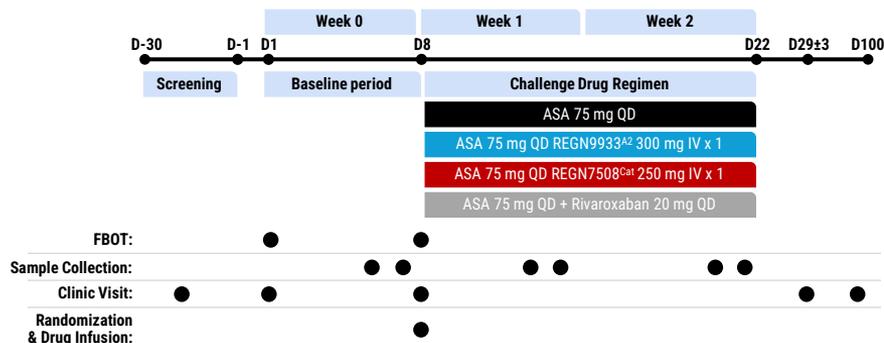
Study tested how bleeding profile on background aspirin therapy changes with **REGN9933^{A2}** and **REGN7508^{Cat}** compared to rivaroxaban (Xarelto, DOAC)

- Aspirin (ASA) causes a generally non-concerning increase of detected blood in the stool; anticoagulants can further increase this risk

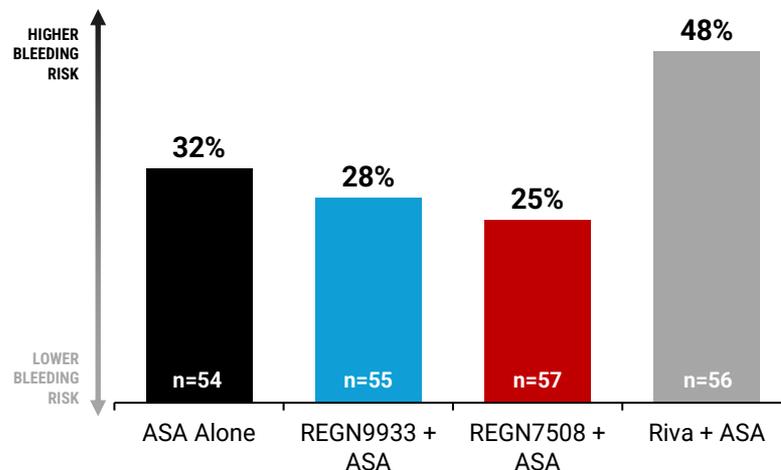
Preliminary results

- Pooled analysis: REGN7508/REGN9933 resulted in **14% less bleeding risk** comparing to Riva+ASA ($p=0.0497$)
- No new safety signals were observed

Phase 1b, randomized, open-label study in healthy volunteers at low risk for bleeding to quantitate increase in subclinical GI blood loss



Increase in subclinical GI bleeding over baseline (week 2)



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Factor XI Development Program

Genetics, preclinical, and clinical data support broad Factor XI development

	Patient Segment	Study	Target Enrollment	Treatment Period	Est. Study Start	Est. Primary Completion	
	Post-Total Knee Replacement (TKR) VTE U.S. ~2M	ROXI-APEX (Cat vs. apixaban vs. enoxaparin)	~2,000	Single dose	enrolling	1Q 2027	
		ROXI-ASPEN (Cat vs. aspirin)	~2,000	Single dose	Nov 2025	2027	
	Primary prevention 100k	ROXI-CAT I (Cat vs. placebo)	~850	6 mos	1H26	2029 +	
	Secondary prevention 850k	ROXI-CAT II (Cat vs. apixaban)	~1,500	6 mos +	1H26	2029 +	
	Stroke Prevention in Atrial Fibrillation (SPAF) U.S. ~8M	DOAC candidates ~6.4M (80%)	ROXI-ATLAS Ph2* (Cat vs. A2 vs. apixaban)	~1,200	3 mos	enrolling	2Q 2027
			ROXI-EVEREST (Cat vs. apixaban)	~12,400	16-36 mos	2026	2029 +
	DOAC non-candidates ~1.6M (20%)	ROXI-INCLINE (Cat vs. A2 vs. placebo)	~2,650	12-36 mos	1H26	2028 +	
	Peripherally Inserted Central Catheter (PICC)-Associated Thrombosis	ROXI-PEAK (Cat and A2 vs. placebo)	~2,050	Duration of PICC line	2026	2028 +	
	Peripheral Artery Disease (PAD) Post-Revascularization U.S. ~310k	ROXI-PALISADE (Cat vs. A2 vs. rivaroxaban or placebo)	~7,050	~19 mos	1H26	2029 +	

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Regeneron's Factor XI Program, which consists of two antibody candidates, is targeting several indications

REGN7508^{Cat} pursued in all listed indications, **REGN9933^{A2}** in indications with lowest bleeding risk tolerance



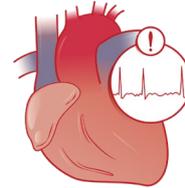
**Post-TKR
VTE**

R7508



**Cancer
VTE**

R7508



**Stroke Prevention
in AF**

R7508

R9933



**Peripheral Artery
Disease**

R7508

R9933

Depending on the benefit-risk profile, use could ultimately extend to broader patient populations in need of safer anticoagulation options

Commercial Opportunity: Post-TKR and Cancer VTE

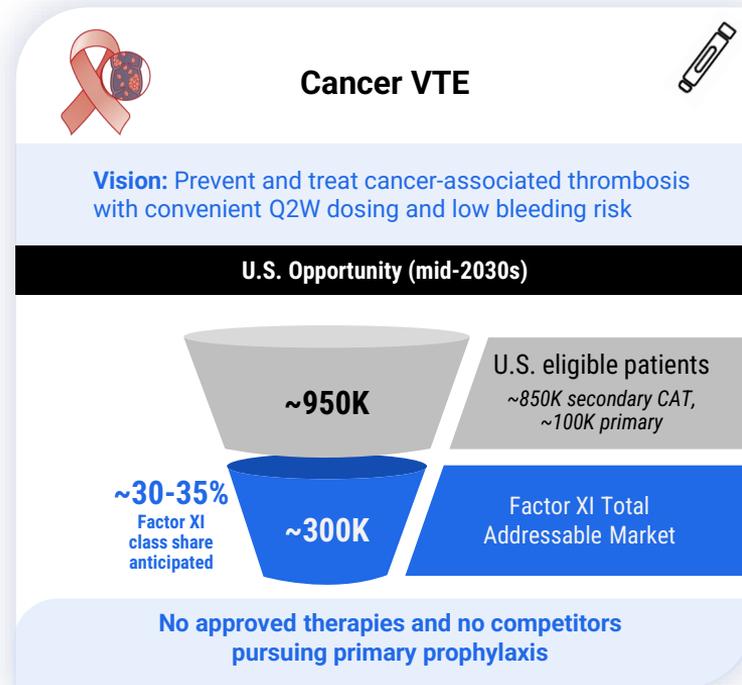
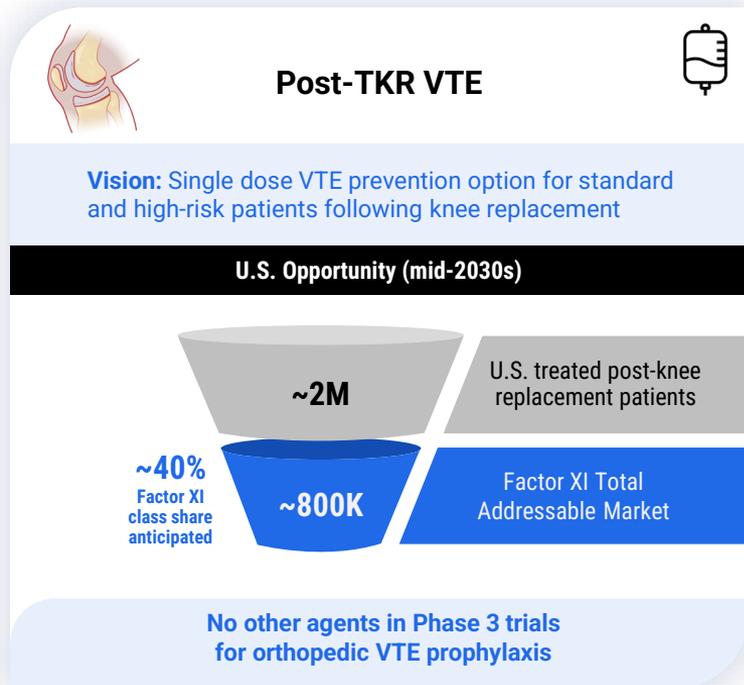
Differentiated Factor XI inhibitors designed to potentially reduce bleeding risk, deliver strong efficacy, and simplify treatment with convenient SC Q2W dosing for chronic disease management

OVERVIEW

DATA

DEV PLAN

COMMERCIAL



Commercial Opportunity: SPAF and PAD

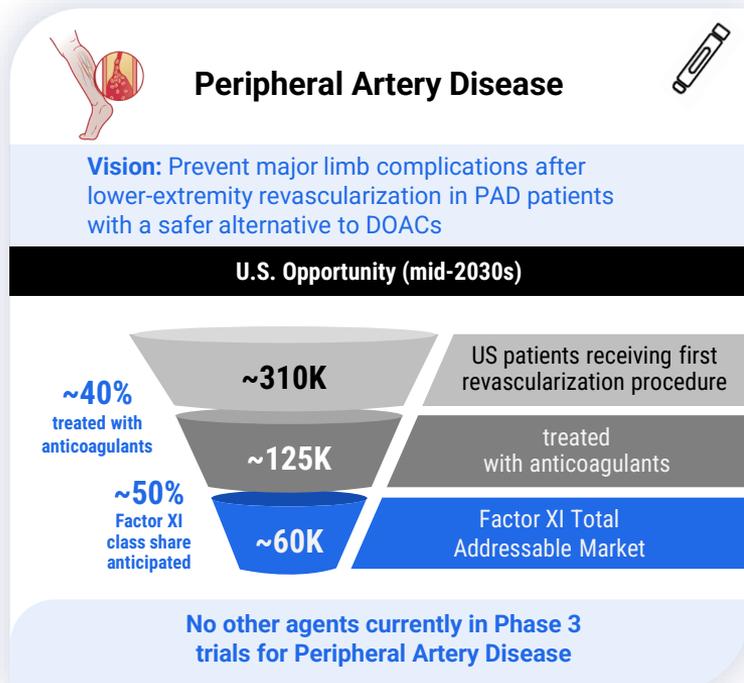
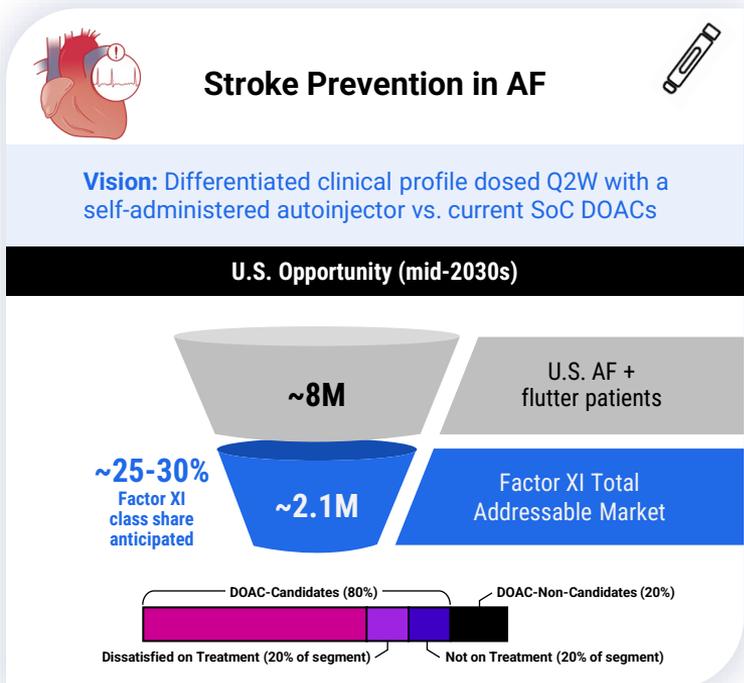
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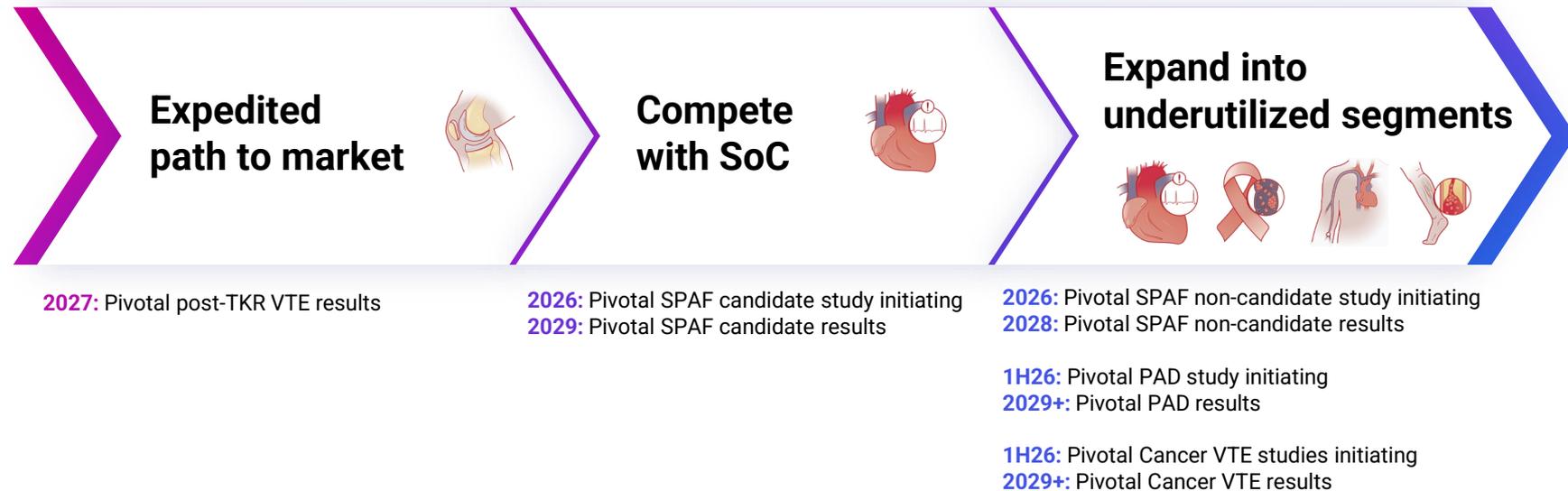
Factor XI Development Plan

Commercial Opportunity

Closing Remarks and Q&A

Regeneron's Factor XI antibodies to provide tailored approach to anticoagulation to meet patient-specific needs

Unique Factor XI development approach at Regeneron aims to address unmet need and build future market



Depending on the benefit-risk profile, use could ultimately extend to broader patient populations in need of safer anticoagulation options

Q&A Session

Regeneron Roundtable – Factor XI



George Yancopoulos

Board co-Chair
President
Chief Scientific Officer

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Andres Sirulnik

Senior Vice President
Clinical Development Unit Head
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David Gutstein

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Ryan Crowe

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Investor Relations &
Strategic Analysis

REGENERON

Appendix Slides

REGENERON[®]

Post-Total Knee Replacement (TKR) VTE Background



Post-TKR VTE

Condition

- Patients undergoing total hip and total knee replacement (TKR) are at an increased risk of venous thromboembolism (VTE) – a blood clot that can occur in the legs or lungs, with rates between 0.9% and 1.6%¹
- Bleeding-related wound complications can cause major morbidity in these patients; patients on more aggressive anticoagulation are at a higher risk¹

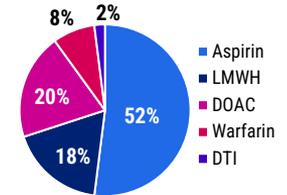
Patient Population

- ~2M U.S. patients undergoing TKR in 2030
 - ~85% considered at standard-risk for a post-op VTE
 - ~15% are high risk due to prior VTE/other predisposing factors
- There is a growing trend toward outpatient procedures

Current Management

- In the U.S., nearly all patients are given drug prophylaxis for VTE prevention
- Standard risk patients: typically managed with **aspirin** (2-6 weeks)
- High-risk patients: treated with a **low-dose LMWH or DOAC** (12-14 days)

U.S. Patient Share*
(2024)



Unmet Need

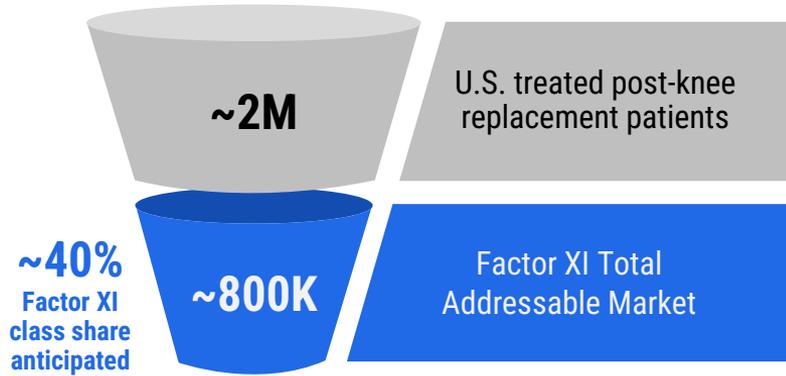
- In high-risk patients, the low doses of DOACs are considered sufficient for VTE prevention, but bleeding is a concern

¹Anil, Utkarsh et al. *The Journal of Arthroplasty* 2023. *Note: considerable geographical variation. LMWH: low-molecular-weight heparin; DOAC: direct oral anticoagulants.

Post-Total Knee Replacement (TKR) VTE



U.S. Opportunity (mid-2030s)



No other agents in Phase 3 trials for orthopedic VTE prophylaxis

Differentiation and Positioning

Vision: Single dose VTE prevention option for standard and high-risk patients following knee replacement

- **Only agent in Phase 3 development for this patient segment in the U.S.**
- **Potential one-and-done prophylaxis** option may drive uptake and improve compliance
- **vs. aspirin** (standard risk patients): Phase 3 program testing single dose of **REGN7508^{Cat}** for VTE risk reduction and bleeding risk vs. aspirin
- **vs. DOACs/LMWH** (high-risk patients): Phase 3 program testing single dose of **REGN7508^{Cat}** for VTE risk reduction and bleeding risk vs. apixaban

Cancer-Associated VTE Prevention Background



Cancer VTE

Condition

- Cancer-associated thrombosis is the second leading cause of death in patients with malignant disease, behind only cancer progression
- VTE incidence is 50x higher than the average person

Patient Population

- **Primary Prophylaxis:** ~500k patients estimated to have solid tumors susceptible to cancer associated thrombosis
- **Treatment & Secondary Prevention:** ~900k patients with solid tumors will have a VTE event in mid-2030s

Current Management

- Guidelines recommend use of LMWH or DOAC for treatment and secondary prevention; primary prophylaxis highly underused
- No approved therapies and no competitors pursuing primary prophylaxis

SoC

- **LMWH/UFH**
Prevention in high-risk inpatient only
- **DOACs: Xarelto, Eliquis Treatment**

Unmet Need

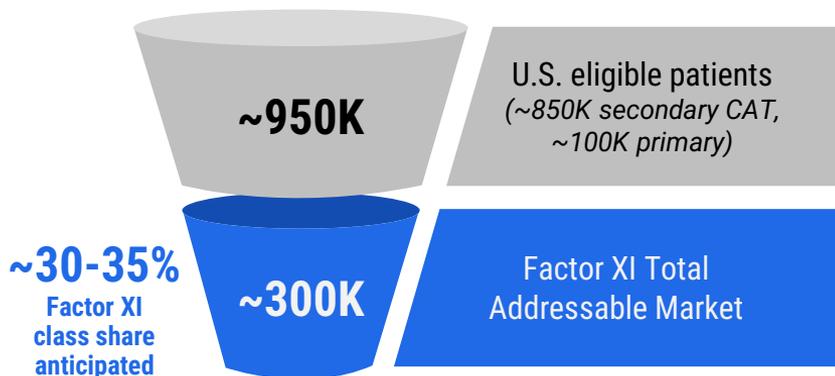
- **Primary prophylaxis** remains highly underused despite guidelines recommendation – an opportunity for an agent with DOAC-like efficacy, with an improved safety profile
- While **secondary prevention** with DOACs or LMWH is adequate, cancer patients experience higher rates of VTE recurrence and a higher risk of major bleeding



Cancer-Associated VTE Prevention

Opportunity for Factor XI to address ~1M patients (estimated \$1.4Bn future U.S. market)

U.S. Opportunity (mid-2030s)



Differentiation and Positioning

Vision: Prevent and treat cancer-associated thrombosis with convenient Q2W dosing and low bleeding risk

- Potential for only Factor XI inhibitor indicated for **both primary prophylaxis and secondary prevention** of VTE in cancer patients
- **vs. DOACs:** Phase 3 program testing Q2W **REGN7508^{Cat}** VTE risk reduction and bleeding risk vs. apixaban

Stroke Prevention in Atrial Fibrillation (SPAF) Background



Stroke Prevention in Atrial Fibrillation

Condition

- Atrial fibrillation (AF) is a type of irregular heartbeat that can lead to blood clots, stroke, heart failure, and other heart-related complications
- Stroke is caused by a blood clot that forms in the heart due to AF, then travels to the brain and blocks an artery
- People with AF are up to 5x more likely to have a stroke vs. general population

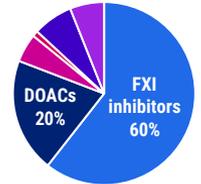
Patient Population

- Estimated 8.4M AF patients in the U.S. in mid-2030s, the majority of whom are at risk of stroke
- Of the patients eligible for anticoagulation, HCPs consider 20% non-candidates for a DOAC

Current Management & Development

- Current standard of care is a **direct oral anticoagulant** (DOAC, once or twice daily)
- Several competing FXI inhibitors in development for AF

G7 Atrial Fibrillation Market (2032) = \$20.7B



Unmet Need

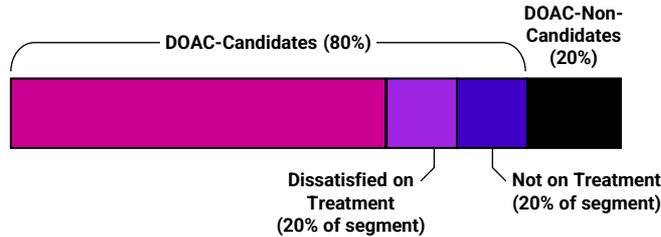
- Only 50-60% of patients with AF are on anticoagulants, remainder untreated generally due to bleeding concerns
 - Other reasons include vascular disease, anemia, severe renal disease, treatment at non-tertiary care centers, aspirin use, atrial flutter¹
- DOAC non-candidates: need anticoagulant with lower bleeding risk than DOACs
- DOAC candidates: **DOACs carry risk of major bleeding**, unmet need for maintaining DOAC efficacy with reduced bleeding risk



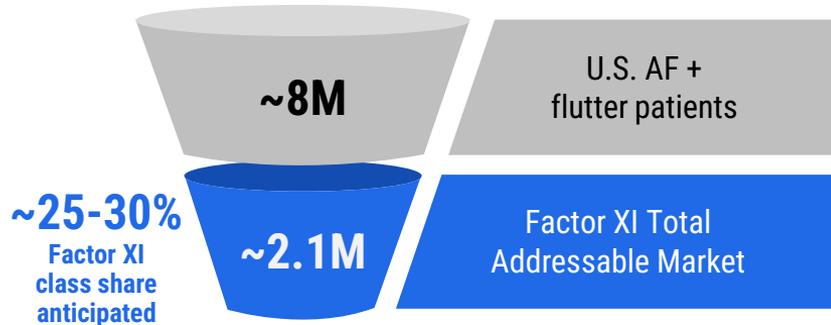
Stroke Prevention in Atrial Fibrillation (SPAF)

Large market opportunity for Factor XI if less bleeding vs. DOACs and similar efficacy on stroke prevention is demonstrated (estimated \$12.6Bn future U.S. market)

SPAF Patient Segmentation



U.S. Opportunity (mid-2030s)



Differentiation and Positioning

Vision: Differentiated clinical profile dosed Q2W with a self-administered autoinjector vs. current standard of care (DOACs)

Opportunity for expanding patient population

- ~40% of patients with AF currently do not receive anticoagulation therapy because of bleeding risk

Differentiation against other FXIs

- Exploring treatment options for both DOAC-candidate and DOAC-non-candidate patients
- Potential better compliance with Q2W dosing vs. BID oral Factor XI competitor milvexian

Peripheral Artery Disease (PAD) Post-Revascularization Background



Peripheral Artery Disease

Condition

- Peripheral Artery Disease (PAD) is caused by a buildup of plaque in the arteries (atherosclerosis), reducing circulation to the limbs and leading to pain, numbness, non-healing wounds
- Lower extremity revascularization (LER) – procedure for restoring proper blood flow in the legs and feet affected by PAD

Patient Population

- U.S.: ~400,000 lower extremity revascularizations annually, most of which are endovascular procedures
- 1 in 6 patients who undergo an LER experience a MALE within 1 year
- 40% of all patients with an LER will require a subsequent revascularization procedure

Current Management

- Most patients are on anti-platelet therapy only
- Xarelto (DOAC) combination is approved, but use remains low (~4%) due to a fear of bleeding risk
- Xarelto likely to remain the only approved anticoagulant
- No other FXI inhibitors in current development

Unmet Need

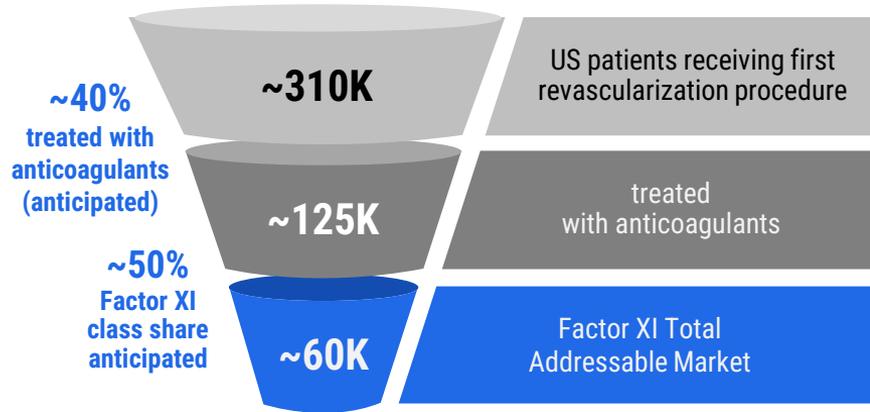
- Due to a fear of bleeding risk, anticoagulation with DOAC use remains persistently low
- Reduction of MALE outcomes over SoC



Peripheral Artery Disease (PAD) Post-Revascularization

Estimated \$1-1.5Bn future U.S. market

U.S. Opportunity (mid-2030s)



Regeneron's FXI mAbs are the only FXI inhibitors being evaluated in the PAD post-revascularization setting

Differentiation and Positioning

Vision: Prevent major limb complications after lower-extremity revascularization in PAD patients with safer alternative to DOACs

- **vs. Anti-platelet Therapy (Aspirin/DAPT):** Phase 3 program testing Q2W **REGN7508^{Cat}** and **REGN9933^{A2}** for preventing cardiovascular and limb outcomes as well as bleeding risk vs. placebo on top of anti-platelet SOC
- **vs. Anti-platelet + DOAC (Xarelto):** Phase 3 program testing Q2W **REGN7508^{Cat}** and **REGN9933^{A2}** for preventing cardiovascular and limb outcomes as well as bleeding risk vs. rivaroxaban on top of anti-platelet SOC