



# Selatogrel (AMI)

Overview & Market  
Opportunity

---

November 2024



# Forward Looking Statements

---

This presentation contains “forward-looking statements”. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements may include, without limitation, statements about ongoing clinical trials and studies, or the outcome of clinical trials and studies; selatogrel has the potential to shift the treatment paradigm in AMI as a potent, reversible and highly selective P2Y12 receptor antagonist, with rapid uptake and fast onset of action and short duration; FDA fast-track designation; potential blockbuster as the first and only patient administered AMI treatment; information on the slide labeled “Selatogrel US Market Opportunity”, including but not limited to, potential launch in 2027, potential loss of exclusivity in 2038, mid-single to low-double digit percentage royalty rate on annual net sales; product margins expected to be higher than Viatriis average; the goals or outlooks with respect to the Company’s strategic initiatives, including but not limited to the Company’s two-phased strategic vision and potential, announced and completed divestitures, acquisitions or other transactions; the benefits and synergies of such divestitures, acquisitions, or other transactions, or restructuring programs; future opportunities for the Company and its products; and any other statements regarding the Company’s future operations, financial or operating results, capital allocation, dividend policy and payments, stock repurchases, debt ratio and covenants, anticipated business levels, future earnings, planned activities, anticipated growth, market opportunities, strategies, competitions, commitments, confidence in future results, efforts to create, enhance or otherwise unlock the value of our unique global platform, and other expectations and targets for future periods. Forward-looking statements may often be identified by the use of words such as “will”, “may”, “could”, “should”, “would”, “project”, “believe”, “anticipate”, “expect”, “plan”, “estimate”, “forecast”, “potential”, “pipeline”, “intend”, “continue”, “target”, “seek” and variations of these words or comparable words. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: the possibility that the Company may not realize the intended benefits of, or achieve the intended goals or outlooks with respect to, its strategic initiatives (including divestitures, acquisitions, or other potential transactions) or move up the value chain by focusing on more complex and innovative products to build a more durable higher margin portfolio; the possibility that the Company may be unable to achieve intended or expected benefits, goals, outlooks, synergies, growth opportunities and operating efficiencies in connection with divestitures, acquisitions, other transactions, or restructuring programs, within the expected timeframes or at all; with respect to divestitures, failure to realize the total transaction values or proceeds, including as a result of any purchase price adjustment or a failure to achieve any conditions to the payment of any contingent consideration; goodwill or impairment charges or other losses, including but not limited to related to the divestiture or sale of businesses or assets; the Company’s failure to achieve expected or targeted future financial and operating performance and results; the potential impact of public health outbreaks, epidemics and pandemics; actions and decisions of healthcare and pharmaceutical regulators; changes in relevant laws, regulations and policies and/or the application or implementation thereof, including but not limited to tax, healthcare and pharmaceutical laws, regulations and policies globally (including the impact of recent and potential tax reform in the U.S. and pharmaceutical product pricing policies in China); the ability to attract, motivate and retain key personnel; the Company’s liquidity, capital resources and ability to obtain financing; any regulatory, legal or other impediments to the Company’s ability to bring new products to market, including but not limited to “at-risk launches”; success of clinical trials and the Company’s or its partners’ ability to execute on new product opportunities and develop, manufacture and commercialize products; any changes in or difficulties with the Company’s manufacturing facilities, including with respect to inspections, remediation and restructuring activities, supply chain or inventory or the ability to meet anticipated demand; the scope, timing and outcome of any ongoing legal proceedings, including government inquiries or investigations, and the impact of any such proceedings on the Company; any significant breach of data security or data privacy or disruptions to our IT systems; risks associated with having significant operations globally; the ability to protect intellectual property and preserve intellectual property rights; changes in third-party relationships; the effect of any changes in the Company’s or its partners’ customer and supplier relationships and customer purchasing patterns, including customer loss and business disruption being greater than expected following an acquisition or divestiture; the impacts of competition, including decreases in sales or revenues as a result of the loss of market exclusivity for certain products; changes in the economic and financial conditions of the Company or its partners; uncertainties regarding future demand, pricing and reimbursement for the Company’s products; uncertainties and matters beyond the control of management, including but not limited to general political and economic conditions, inflation rates and global exchange rates; and inherent uncertainties involved in the estimates and judgments used in the preparation of financial statements, and the providing of estimates of financial measures, in accordance with U.S. GAAP and related standards or on an adjusted basis.

For more detailed information on the risks and uncertainties associated with Viatriis, see the risks described in Part I, Item 1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, as amended, and our other filings with the SEC. You can access Viatriis’ filings with the SEC through the SEC website at [www.sec.gov](http://www.sec.gov) or through our website and Viatriis strongly encourages you to do so. Viatriis routinely posts information that may be important to investors on our website at [investor.viatriis.com](http://investor.viatriis.com), and we use this website address as a means of disclosing material information to the public in a broad, non-exclusionary manner for purposes of the SEC’s Regulation Fair Disclosure (Reg FD). The contents of our website are not incorporated into this presentation or our filings with the SEC. Viatriis undertakes no obligation to update any statements herein for revisions or changes after the date of this presentation other than as required by law.

# Outline

---

- Summary and market opportunity
- Background on epidemiology, current treatment paths and unmet need
- How our product works and why it is differentiated
- Clinical data
- Phase 3 design

# Summary and market opportunity

# Selatogrel (AMI) Summary

---

- Acute Myocardial Infarction (AMI) accounts for ~1/3 of all deaths in developed nations and there is a dire need for early intervention, as ~30% of deaths occur prior to hospital admission
- Selatogrel has the potential to shift the treatment paradigm in AMI as a potent, reversible and highly selective P2Y<sub>12</sub> receptor antagonist, with rapid uptake & fast onset of action and short duration
- In the phase 2 trial, > 90% of participants had > 80% IPA<sup>1</sup> within 15 minutes after dosing, there was reduced off-target interference of hemostasis compared to other P2Y<sub>12</sub> inhibitors and no difference in major bleeds compared to placebo on top of standard of care on top of dual anti-platelet therapy
- Comprehensive phase 3 study design with Special Protocol Assessment was agreed to with FDA and includes a fast track designation
- Currently in phase 3, we are on schedule for full enrollment / study expected to readout in 2026
- Potential blockbuster as the first and only patient administered AMI treatment

# Selatogrel US Market Opportunity

		US Opportunity Notes
<b>Epidemiology</b>	Prevalence	<ul style="list-style-type: none"> <li>• Large prevalent patient base of ~5.6M Acute Myocardial Infarction (AMI) survivors<sup>1</sup></li> <li>• ~800k Annual AMI incidents<sup>1</sup></li> </ul>
	Incidence	
<b>Demand</b>	Penetration & Access	<ul style="list-style-type: none"> <li>• Potential transformative results with mortality &amp; morbidity data</li> <li>• Leverage expertise in self-administered, acute rescue medications</li> <li>• Refills driven by product expiration (~18 months)</li> </ul>
	Refills	
<b>Value Proposition</b>	Value Proposition	<ul style="list-style-type: none"> <li>• Currently no treatments available for time between AMI onset and first medical contact</li> <li>• First and only patient administered AMI treatment</li> <li>• Potential for significant value proposition, similar to branded P2Y<sub>12</sub> therapies</li> </ul>
<b>Commercialization</b>	Field Force	<ul style="list-style-type: none"> <li>• Target specialty coverage across ~36k cardiologists (offices and hospitals)</li> <li>• Incremental sales, medical &amp; marketing to support US launch</li> <li>• Leverage existing infrastructure across reimbursement &amp; operations</li> </ul>
	Other SG&A	
<b>Other Assumptions</b>	Potential Launch & LOE*	<ul style="list-style-type: none"> <li>• Potential launch in 2027</li> <li>• Potential loss of exclusivity (LOE) in 2038</li> <li>• Mid-single to low-double digit percentage royalty rate on annual net sales</li> <li>• Product margins expected to be higher than VTRS average</li> </ul>
	Partnership & Profitability	

\*International opportunities: EU4 + UK: prevalence -7.8M incidence - 606k potential launch year 2028, LOE 2038, China: potential launch year - 2029, LOE - 2035

Notes: 1) per epiH data

Sources: epiH (Epidemiology and Health), British Heart Foundation Fact Sheet, Prevalence of myocardial infarction and coronary heart disease in adults aged 40–79 years in Germany, PubMed: Multivessel Disease



# Background on epidemiology, current treatment paths and unmet need

# Epidemiology of Acute Myocardial Infarctions (AMI)

Heart attacks can occur in:  
All ages, races, ethnicities, and sexes.

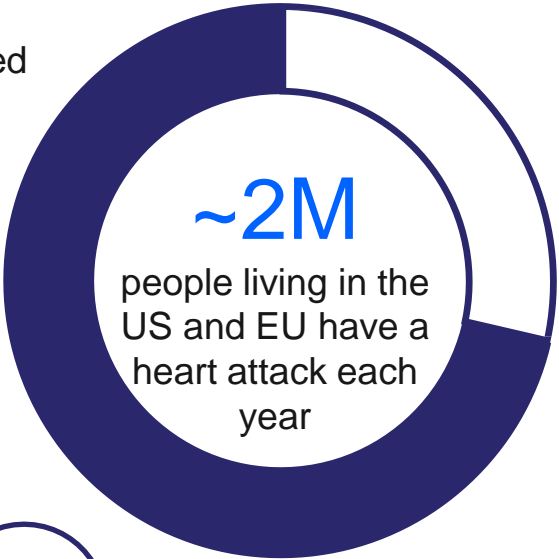


**80%** of deaths caused by cardiovascular disease are due to heart attack and stroke



**1/3** of deaths in developed nations can be attributed to heart attack

1<sup>st</sup> Heart Attack



Recurring Heart Attack

Patients with history of MI are at significantly higher risk of recurrent MI

**66**

Average age at first heart attack – risk increases with age



**72**



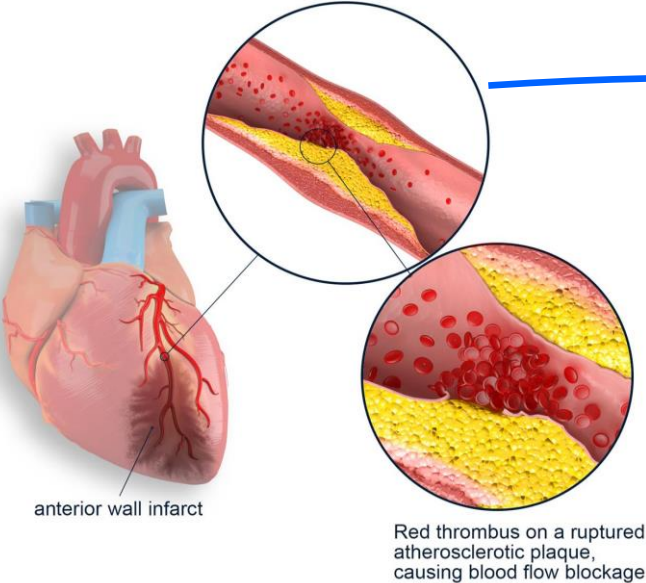
**9-10M**

Patients in US and EU have history of AMI within past 10 years

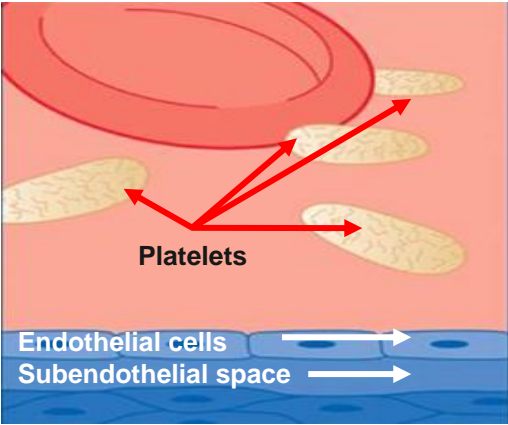


# Major Role of Platelets in Acute MI

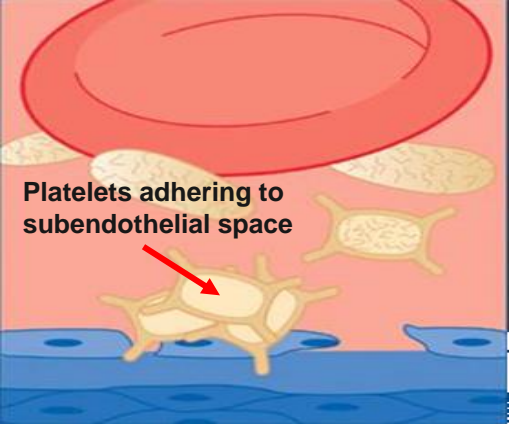
## Myocardial Infarction



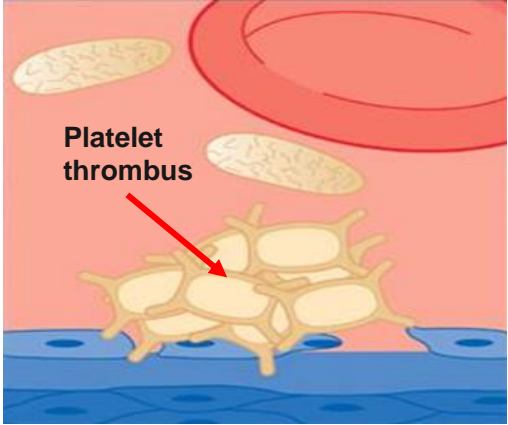
Normal platelets in flowing blood



Platelets adhering to damaged endothelium and undergoing activation



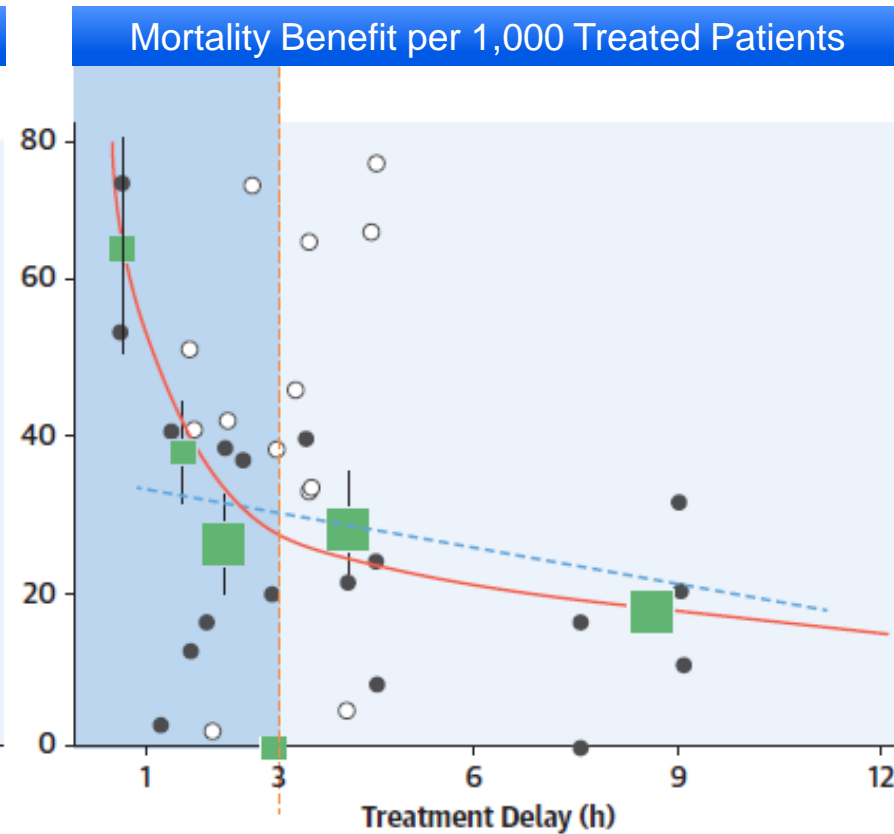
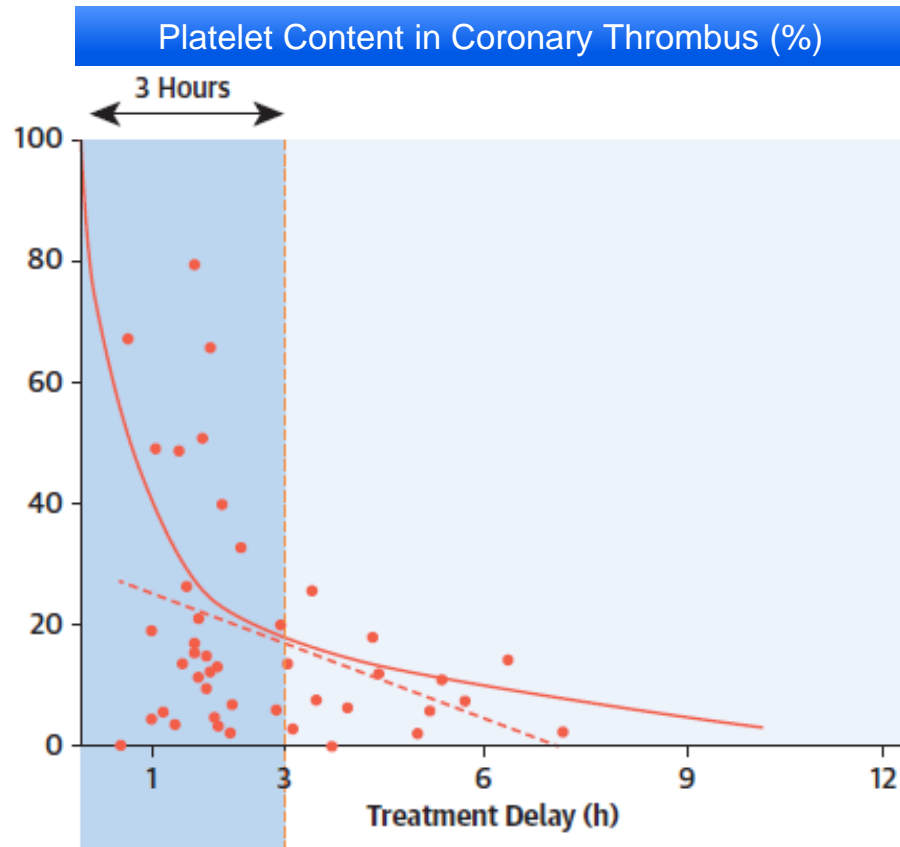
Aggregation of platelets into a thrombus



Adapted from: Ferguson JJ. In: Ferguson JJ, Chronos N, Harrington RA (Eds). *Antiplatelet Therapy in Clinical Practice*. London: Martin Dunitz; 2000: 15–35.

# “Time is Muscle!” - Early Intervention is an Opportunity for Myocardial Salvage

## Early Coronary Thrombus is Platelet-rich, Early Treatment is Key

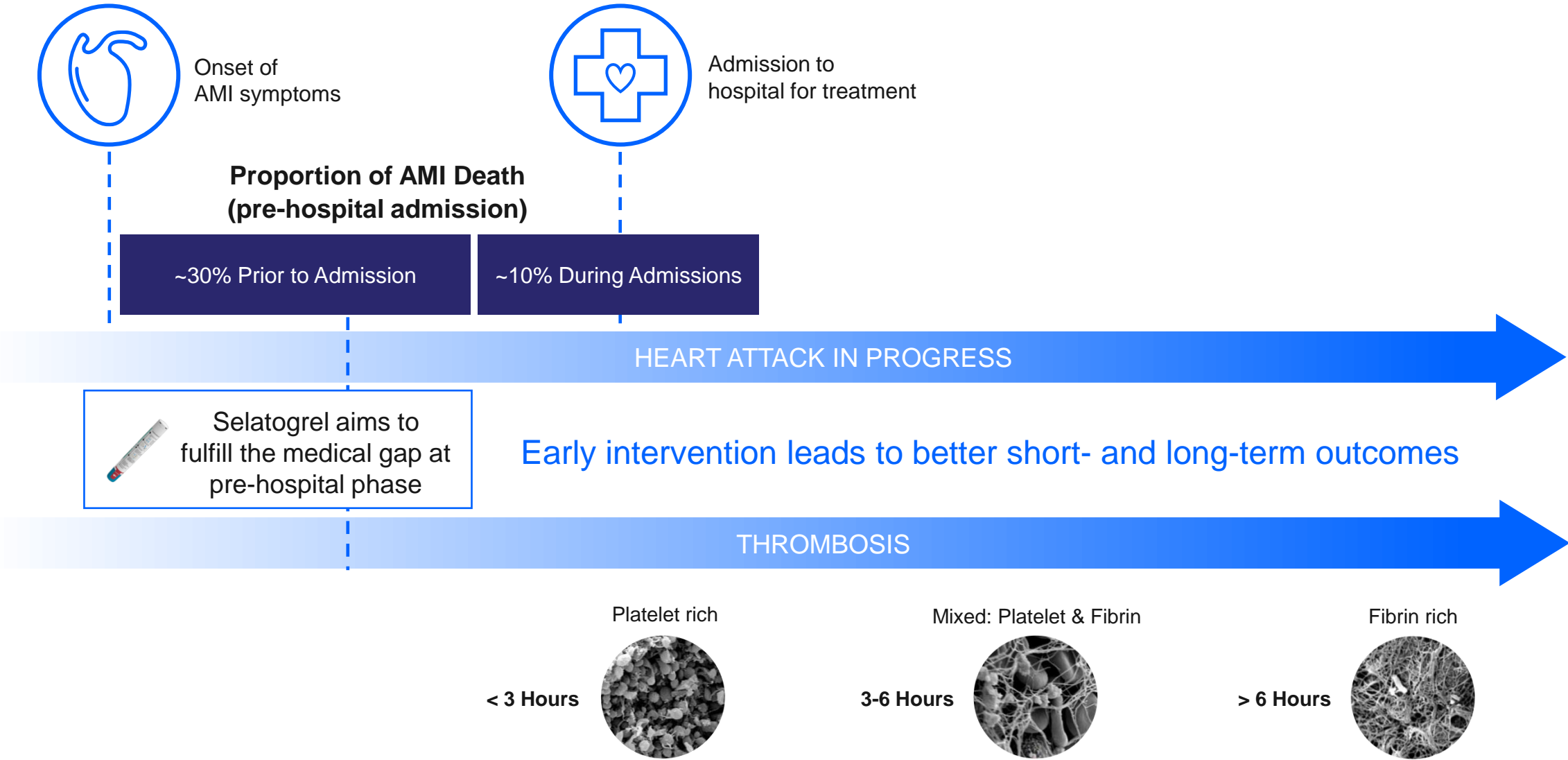


- ▶ Thrombus compositions changes over time from **platelet-rich to fibrin-rich**<sup>1</sup>
- ▶ Beneficial effect of therapy in mortality reduction is **substantially higher in the first hours of symptom onset**<sup>2</sup>

<sup>1</sup>Silavail J et al JACC 2011, <sup>2</sup>Boersma et al Lancet 1996  
Adapted from: Silvain J et al JACC 2020

# How our product works and why it is differentiated

# Dire Need for Early Intervention at Onset of Acute Myocardial Infarctions



# Multiple P2Y12 Inhibitors are Already Approved, But Only Selatogrel is Suitable for Emergency Treatment

Name	Clopidogrel	Prasugrel	Ticagrelor	Cangrelor	Selatogrel
Group	Thienopyridine	Thienopyridine	ATP-analog	ATP-analog	2-phenylpyrimidine-4-carboxamides
Administration	Oral (qd)	Oral (qd)	Oral (bid)	Intravenous	subcutaneous
Receptor Blockade	irreversible	irreversible	reversible	reversible	reversible
Prodrug	yes	yes	no	no	no
Suitable for subcutaneous injection	no	no	no <sup>1</sup>	no <sup>2</sup>	yes
Time to peak effect	2-6 h	2-4 h	2 h	2 min	15-30 min
Offset for effect	5-10 d	7-10 d	3-5 d	~0.5 h	~24 h
Preclinical profile					
Potency IPA (20 μM ADP)	na	na	398 nM <sup>3</sup>	45 nM <sup>4</sup>	14 nM
Off-target effects	yes	yes	yes	yes	no
Efficacy/Safety window	**	**	***	***	****

ADP: Adenosine diphosphate, ATP: Adenosine triphosphate, IPA: Inhibition of platelet aggregation

<sup>1</sup> Solubility in water limited to 10 ug/ml, <sup>2</sup> Stability in aqueous solution limited to 12 h

<sup>3</sup> Nylander and Schulz, 2016, PMID: 26758983, <sup>4</sup> NDA 204958 Cangrelor



# Selatogrel Has the Potential to Shift Treatment Paradigm in AMI

## Selatogrel



### Potent, reversible and highly selective P2Y<sub>12</sub> receptor antagonist

- ▶ With reduced off target interference of hemostasis compared to other P2Y<sub>12</sub> in preclinical setting



### Rapid uptake and fast onset of action

- ▶ In phase 2 trial, > 90% of participants have > 80% inhibition of platelet aggregation (IPA) 15 minutes after dosing



### Short duration of action

- ▶ IPA effect lasted about 6 to 8 hours, with platelet recovery within 24 hours



### Suitable safety profile

- ▶ No difference in major bleeds compared to placebo on top of standard of care in phase 2 trial



## Auto Injector



### Designed for emergency use



### Safe

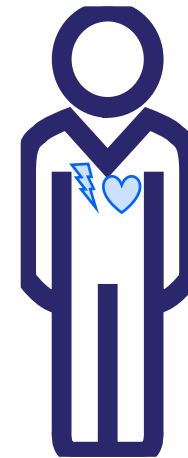


### Easy to use, carry and store

- ▶ Storage at room temperature



### Insights into commercialization of injectors for emergency treatment



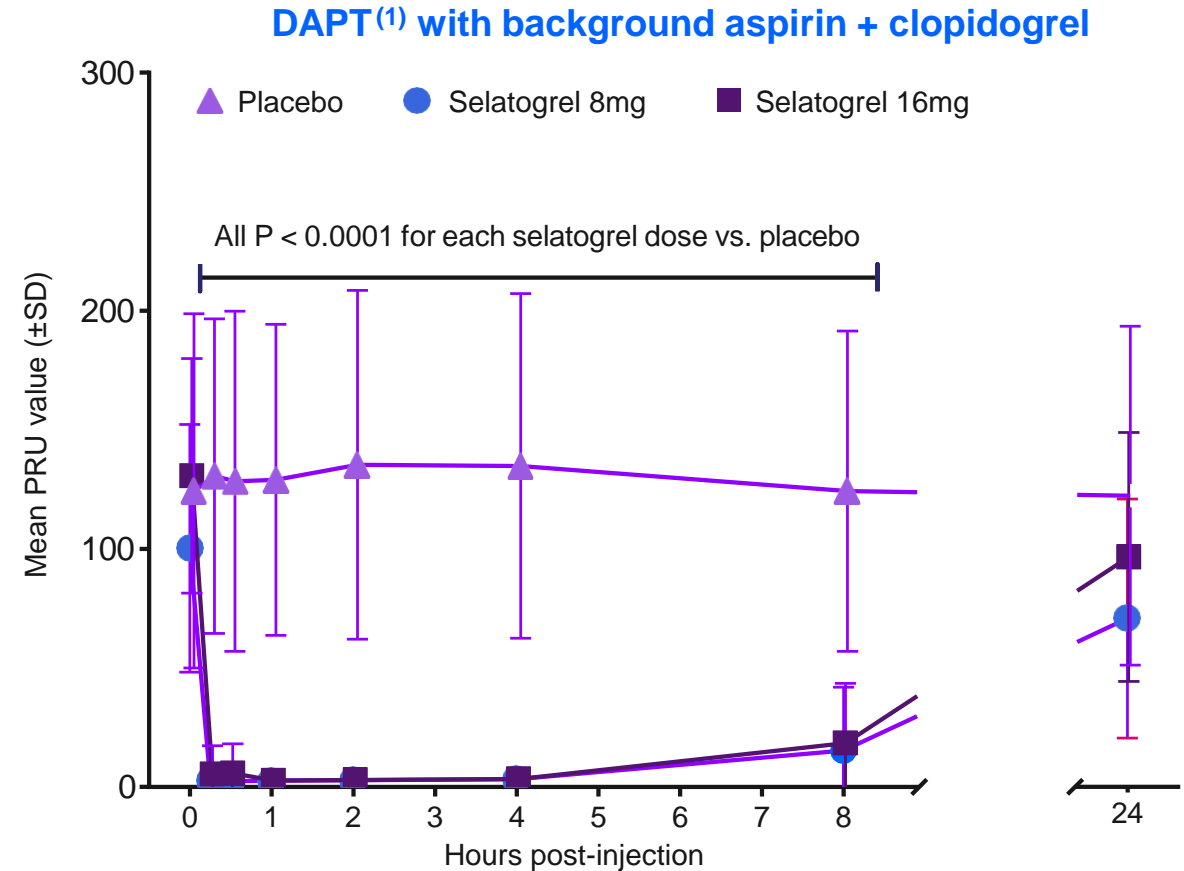
# Clinical data

# Robust and Rapid Effect Observed in Phase 2 Program in Acute Coronary Syndrome (N=345) and Acute MI (N=47)

## Differentiated Profile vs Other P2Y12 Inhibitors

- ▶ **Robust and rapid effect:** >80% IPA **within 15 minutes**
- ▶ **Short Duration:** Height of IPA effect **extended over 8 hours**, with **platelet recovery within 24 hours**
- ▶ **IPA was faster, more pronounced, and more consistent with 16 mg**
- ▶ **Effect also obtained on top of background dual anti-platelet therapy (P2Y12 inhibitor + aspirin)**

Data from chronic coronary syndrome study – consistent with results from AMI study  
(1) DAPT: dual anti-platelet therapy





# Selatogrel: Reduced Off-target Interference of Hemostasis Compared to Other P2Y12 Inhibitors

## No Off-Target Effects Interfering with Hemostasis due to Selatogrel High Selectivity

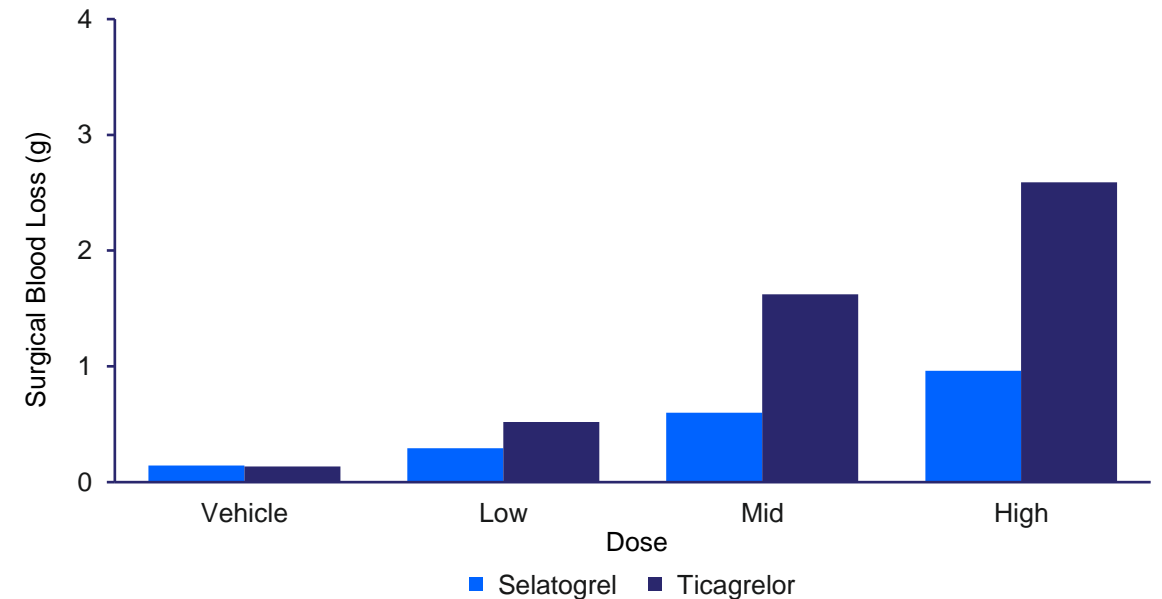
No activity on multiple signaling pathways (including P2Y1)<sup>(1)</sup>

Impact on key-elements of hemostasis at same anti-thrombotic effect level	Control	Selatogrel	Ticagrelor	Clopidogrel
Calcium signaling in endothelial cells	Functional	No decrease	Partial decrease	N/D
Vasoconstriction	Functional	No decrease	Partial decrease	N/D
Neutrophil adhesion	Functional	No decrease	Decrease	Decrease
Fibrin generation	Functional	No decrease	Partial decrease	Decrease
Stability of platelet-seal	Functional	No decrease	Partial decrease	Decrease

Data summarized from: Crescence et al. 2021; Rey et al. 2012

(1) No activity on 120 GPCRs (incl. P2Y1) @10 mM  
No effect on: ENT1, A3, PDE5, GPR17, P2Y1

## Selatogrel Causes Less Blood Loss than Ticagrelor at Equivalent Efficacy in Anesthetized Wistar Rats



Rat thrombosis model. Dose dependent surgical blood loss after standardized punch biopsy of the spleen. Drugs administered by continuous infusion to achieve low-, intermediate-, and high-level inhibition of platelet aggregation. Selatogrel doses; 0.06, 0.2, 0.6 µg/kg/min. Ticagrelor doses; 2, 6, 20 µg/kg/min. After surgical wounding of the spleen, blood was collected for 30 min and the weight of lost blood determined. Data are presented as means ± SEM, n = 9-35. \*P < 0.05. \*\*P < 0.01.

# Differentiated Safety Profile and No Difference in Major Bleeds Compared to Placebo on Top of Standard of Care

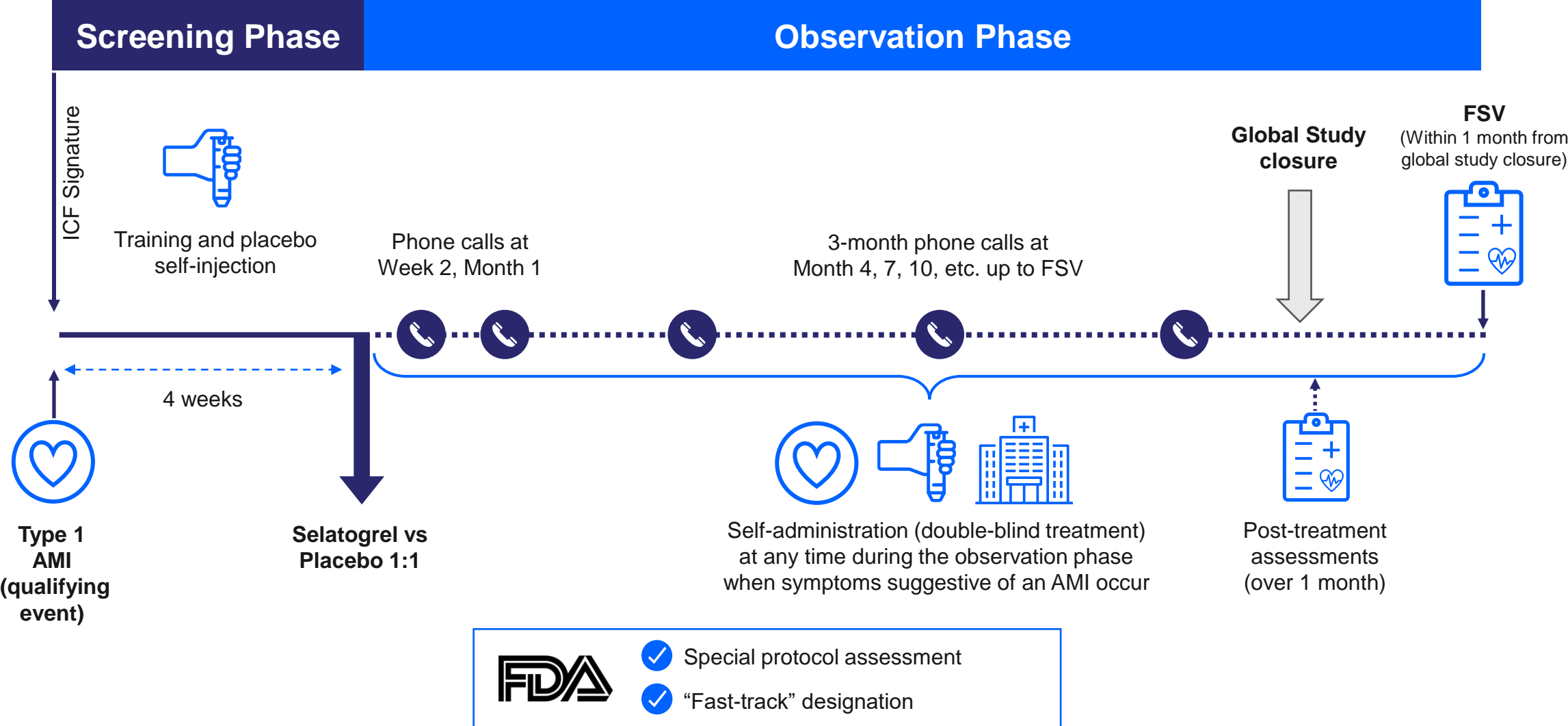
Treatment-emergent AEs <sup>(1)</sup> , n (%)	8 mg selatogrel (N=114)	16 mg selatogrel (N=115)	Placebo (N=116)
<b>Patients with ≥1 AE</b>	36 (32)	26 (23)	25 (22)
<b>Patients with serious AEs</b>	0	0	0
<b>Most frequent AEs (≥3 subjects)</b>			
Dyspnoea	6 (5)	10 (9)	0
<i>Median duration, h</i>	2.4	0.8	-
Dizziness	5 (4)	4 (4)	1 (1)
Headache	3 (3)	3 (3)	5 (4)
Injection site bruising	3 (3)	2 (2)	0
Diarrhea	4 (4)	1 (1)	0
Vessel puncture site bruise	4 (4)	0	3 (3)
Contusion	1 (1)	1 (1)	3 (3)
<b>Patients with ≥1 bleeding event</b>	11 (10)	5 (4)	8 (7)
Major bleeding events	0	0	0

Data from chronic coronary syndrome study – consistent with results from AMI study

(1) Treatment-emergent was defined as any AE occurring up to 48 h after treatment administration

# Phase 3 design

# Phase 3 Study Design



# Phase 3 Assumptions & Key Endpoints

Special Protocol Assessment in coordination with KOLs and the FDA to develop a composite endpoint

- Event Driven Study: ~4,500 Events Needed (Patients Treated)
- Relative Risk Reduction ~20%; Type I Error Set to 5%



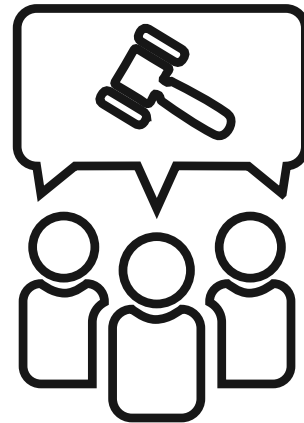
**Primary efficacy endpoints:** Death, AMI (up to 7 days)



**Secondary efficacy endpoint:** Death, AMI or HF (30 days)



**Primary safety endpoints:** Treatment Emergent Severe Bleedings



**Clinical Event Committee  
(Blinded Independent  
Adjudication)**



**Ranking by severity using 6-point scale from “no event” up to “death”**

**Ranking of bleeding by severity according to BARC<sup>(1)</sup> definition**