Improving and Protecting Life for Chronic-stable Angina Patients

BIOTECH SHOWCASE™

The investor conference for innovators

JP Morgan Healthcare Conference Week 2024

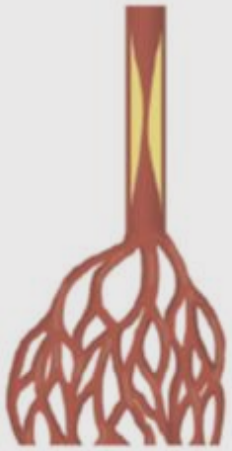
San Francisco Hilton, January 8th, 2024

Chronic-stable angina pectoris (CSAP) most often occurs on the basis of atherosclerotic coronary artery disease

Current angina treatments are not well suited, or even counterindicated, for MVA patients

Coronary Artery Disease

Coronary Vascular Dysfunction

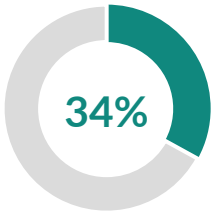
Microvascular Dysfunction	Vasospastic Disease	Coronary Artery Obstruction
		
Microvascular angina[1] (MVA)	**Vasospastic angina[1]** (rare)	**Macrovascular angina[1]**

1. Marinescu et al. *JACC Cardiovasc Imaging*. 2015;8(2)210-220. 2. Patel MR et al. *N Engl J Med*. 2010;362:886-95. 3. Bradly C, Berry C. *J Nucl Cardiol*. 2022;29;1763-75.
4. Taqueti VR, Di Carli MF. *J Am Coll Cardiol*. 2018;72(21):2625-2641. 5. Chen JW et al. *Am J Cardiol*. 1997;80;32-38. 6. Zhu H et al. *Clin Ther*. 2019;41(10)2137-2152.
7. Kaski JC et al. *Circulation*. 2018;138;1463-1480. 8.Knuuti, J et al. *Eur Heart J*. 2020;41,:407-477.

Chronic Stable Angina Pectoris (CSAP) is a highly prevalent condition taking a heavy toll on millions of Americans

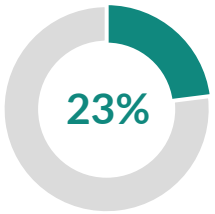
CSAP is the symptomatic side of coronary artery disease (CAD), typically manifesting as chest pain and shortness of breath

CSAP affects
11 M Americans
over the age of 20



Experience angina symptoms
five years after diagnosis
despite optimal treatment

Lifestyle, longevity, and life-saving cardiovascular procedures have contributed to a **rapidly growing, stable angina population**

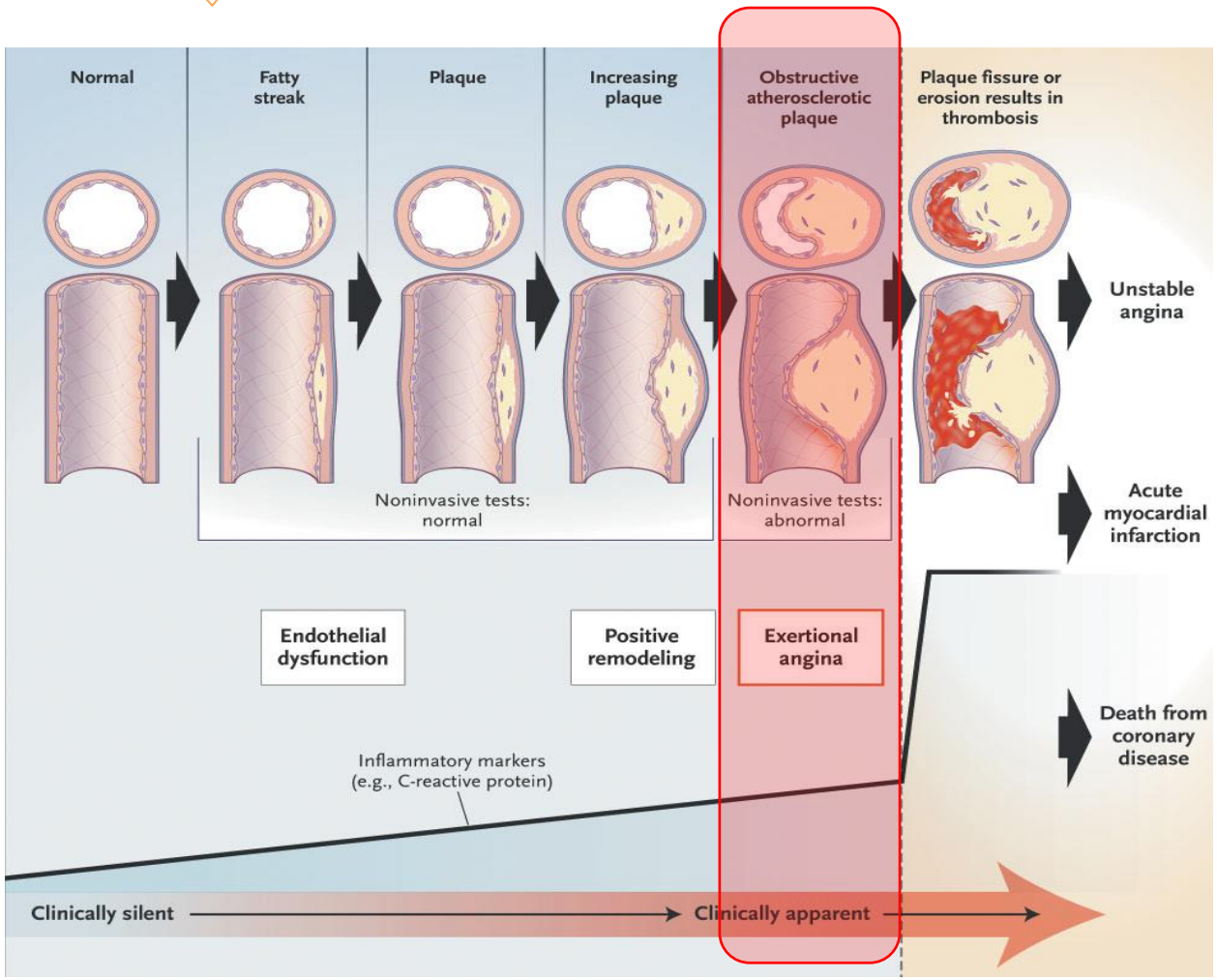


Report daily or weekly symptoms
despite taking multiple antianginal medications

Inadequately controlled angina reduces significantly patients' quality of life as they seek to avoid effort-induced angina

1. Heart Disease & Stroke Statistics. American Heart Association. *Circulation*. 2021;143(8):e254-e743. 2. Kureishi F et al. *Clin Cardiol*. 2017;40(1):6-10.
3. Mesnier et al. *Circulation*. 2021;144;512–523; 4. Angina Pectoris: Global Drug Forecast and Market Analysis to 2028, Global Data; 5. Eisen A et al. *J Am Heart Assoc*. 2016;5e004080.

Chronic-stable angina pectoris (CSAP) – Disease development and goal of therapy

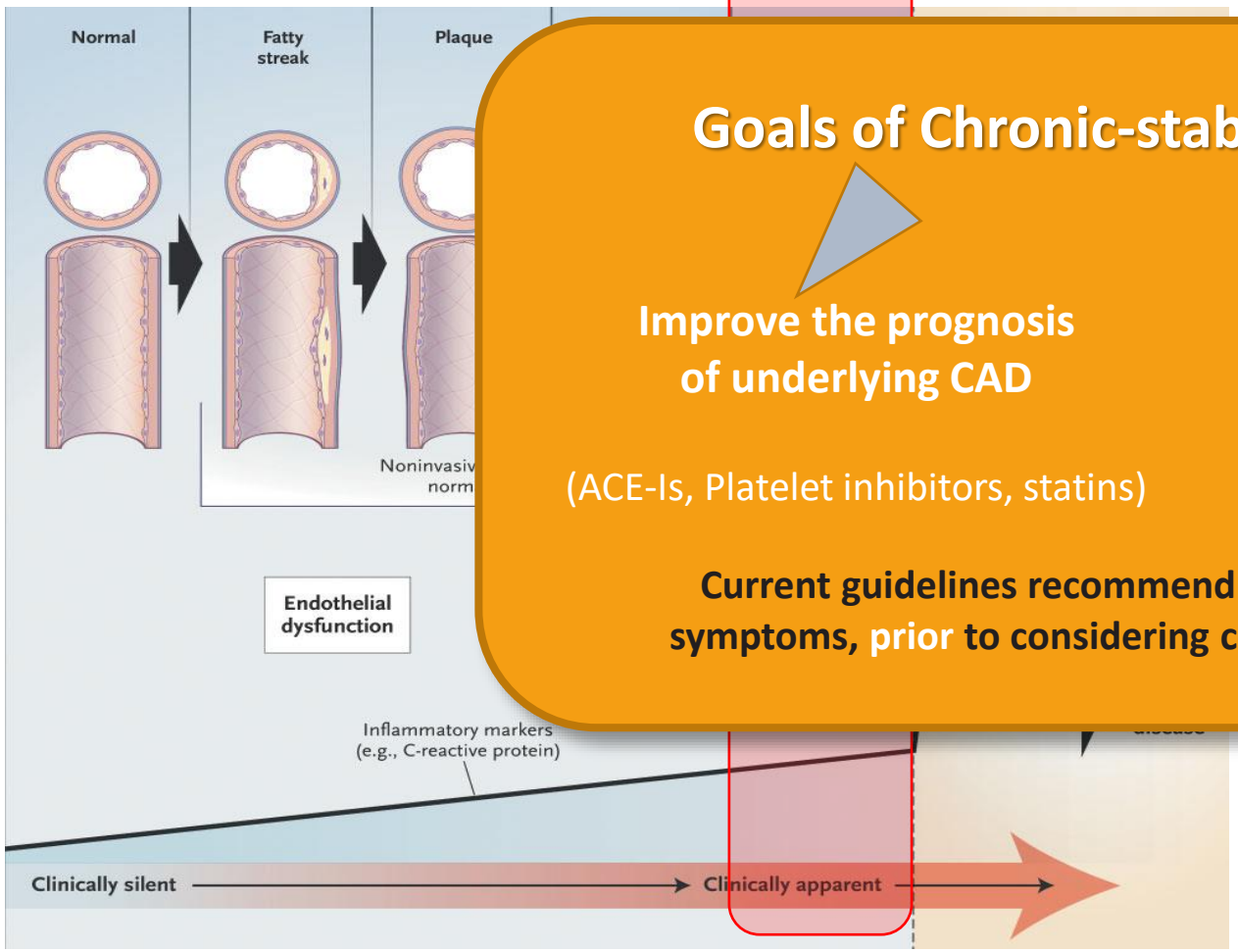


Typical Progression of Coronary Atherosclerosis.

- CSAP patients have atherosclerotic coronary artery disease (CAD) as the underlying disorder
- As the plaque burden increases, the atherosclerotic mass tends to stay external to the lumen, which allows the diameter of the lumen to be maintained positive remodeling.
- As plaque encroaches into the lumen, the coronary artery diameter decreases.
- **Myocardial ischemia** results from the mismatch of coronary blood supply and heart muscle oxygen demand
- Luminal narrowing of more than 65 to 75% may result in transient ischemia and angina.
- In acute coronary syndromes (i.e., heart attack), vulnerable plaque is a more important factor than is the degree of stenosis; acute coronary events result from ulceration or erosion of the fibrous cap, with subsequent intraluminal thrombosis.

1. Abrams J. *N Engl J Med*. 2005;352:2524-2533. 2. Virani et al. *Circulation*. 2023;148e9–e119. 3. Ferrari R et al. *Eur Heart J Suppl*. 2019;21(Suppl G): G1–G3.

Chronic-stable angina pectoris (CSAP) – Disease development and goal of therapy



Goals of Chronic-stable Angina Therapy:[2,3]

Improve the prognosis of underlying CAD

(ACE-Is, Platelet inhibitors, statins)

Control or reduce angina symptoms and improve QoL

(BB, LANS, CCBs, ranolazine)

Current guidelines recommend antianginal therapy to control symptoms, prior to considering coronary artery revascularization

…erosclerosis.

…onary artery disease

…erosclerotic mass tends …ws the diameter of the …eling.

…e coronary artery

…ismatch of coronary …demand

…5% may result in

…t attack), vulnerable …an is the degree of stenosis; acute coronary events result from ulceration or erosion of the fibrous cap, with subsequent intraluminal thrombosis.

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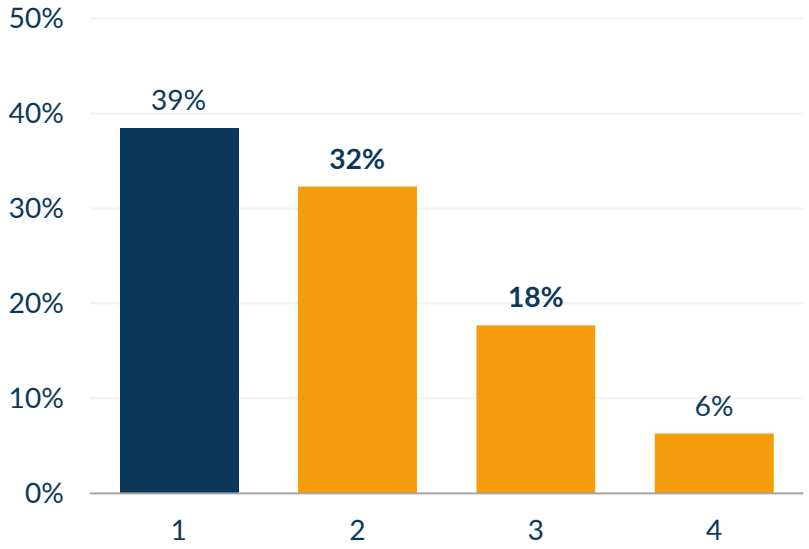
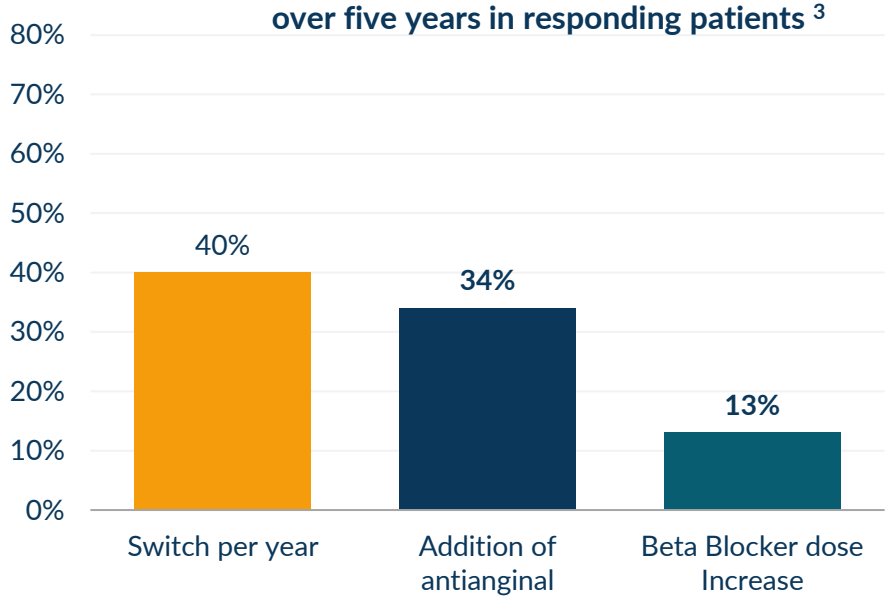
Most CSAP patients need ≥2 anti-angina medications yet remain symptomatic, underscoring a need for a new medication

Ample opportunity for introducing a new 1st line anti-anginal drug into a market of multiple drug use and frequent switching

Number of simultaneously used anginal drugs[1]



Annual frequency of adjusting angina medications over five years in responding patients [3]



- Among patients reporting angina, **23.3% report daily or weekly symptoms** [1,2]
- **56.3% of patients with frequent angina episodes need two or more** angina drugs to control their symptoms[1,3]

An average of **40% of patients switch** antianginal drugs each year[3]

1. Kureshi F, et al. *Clin Cardiol*. 2017;40:6–10. 2. Heart Disease & Stroke Statistics - 2019 Update. *Circulation*. 2019;139:e56–e528. 3. Mesnier et al. *Circulation*. 2021;144:512–523.

CSAP presents a large economic burden for the payors and society

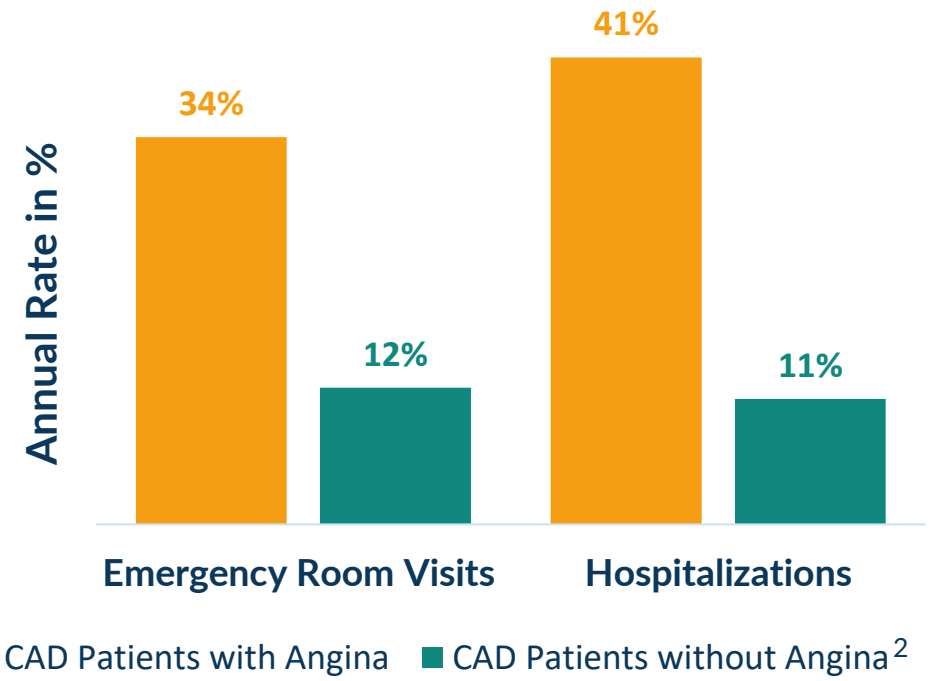
Hospital services utilization rates are much higher in chronic angina patients compared to CAD patients without chronic angina[1]

CAD patients' annual care costs **are twice as high** when they suffer from chronic angina[1]

$ ~29k vs **~14k**

In addition, CSAP is still frequently treated with **costly elective invasive** revascularization procedures, such as:

~$150k[3] **CABG** or **~$15k**[2] **STENTING** (uncomplicated PCI)



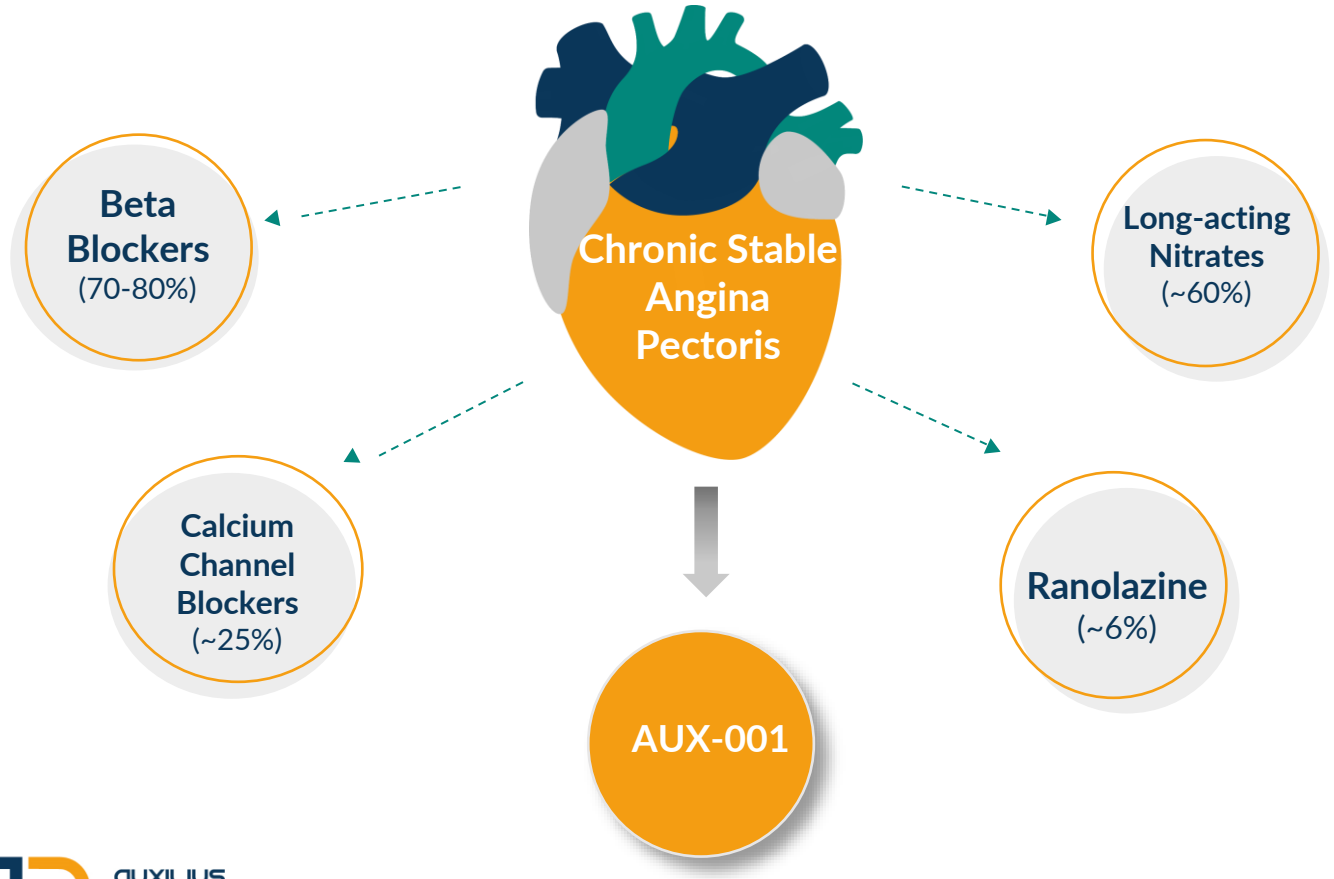
Above figures represent mean cost
CAD – Coronary Artery Disease

1. Kempf J et al. *Am Health Drug Benefits*. 2011;4(6):353-61. 2. Dehmer GJ, Mirza MA. *J Am Coll Cardiol Intv*. 2019;12(4):332-34. 3. Giacomino BD et al. *Am J Cardiol*. 2016;117(7):1101-06.

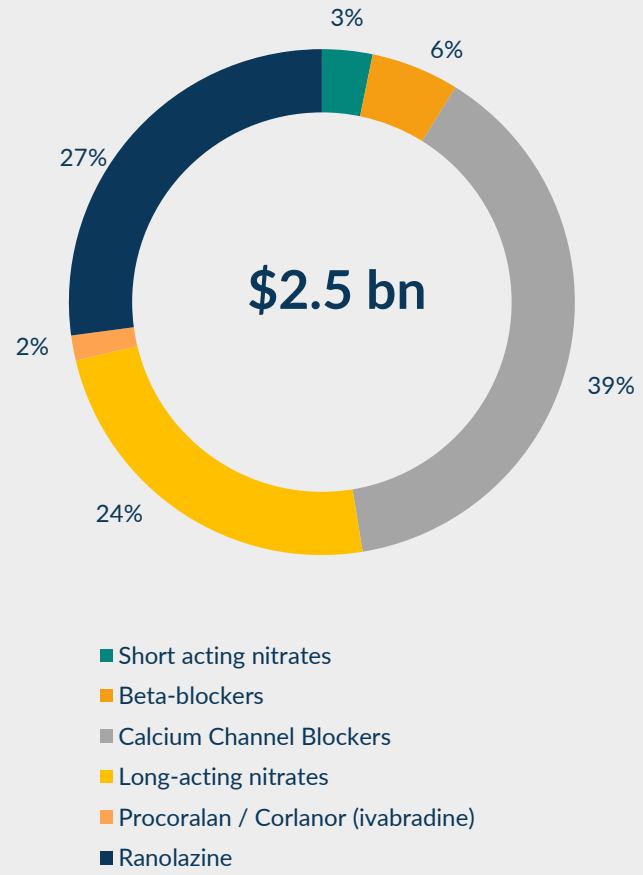
Chronic Angina Medication Market: How we currently treat CSAP in the US

US angina patients use on average 2.5 anti-anginal drugs to control their symptoms

Angina medication classes used in CSAP management



US Angina Drug Sales in 2020

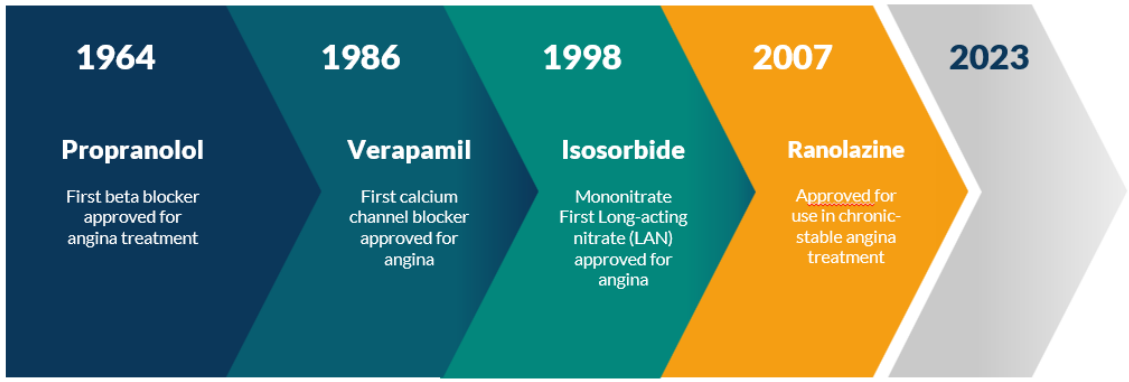


Source: GlobalData. Angina Pectoris: Global Drug Forecast and Market Analysis to 2028; GDHC197PIDR.Published: April 2020; Grand View Research, Angina Pectoris Drugs Market Analysis 2018-2030 ; Bloomberg data; Auxilius Pharma. Internal analysis

Why do we need a new and effective antianginal medication now?

Increasing focus on revascularization procedures stifled R&D of innovative antianginal medications in the US

US ANGINA DRUG PORTFOLIO IS DECADES OLD



- Last anti-anginal drug was introduced in **2006/2007**
- None of the current anti-angina medications demonstrated the ability to reduce risk in underlying CAD
- Many antianginals put a high pill burden on patients

ELECTIVE REVASCULARIZATION DOES NOT ELIMINATE ANGINA SYMPTOMS

COURAGE → ISCHEMIA

2007[1] (N=2,287)

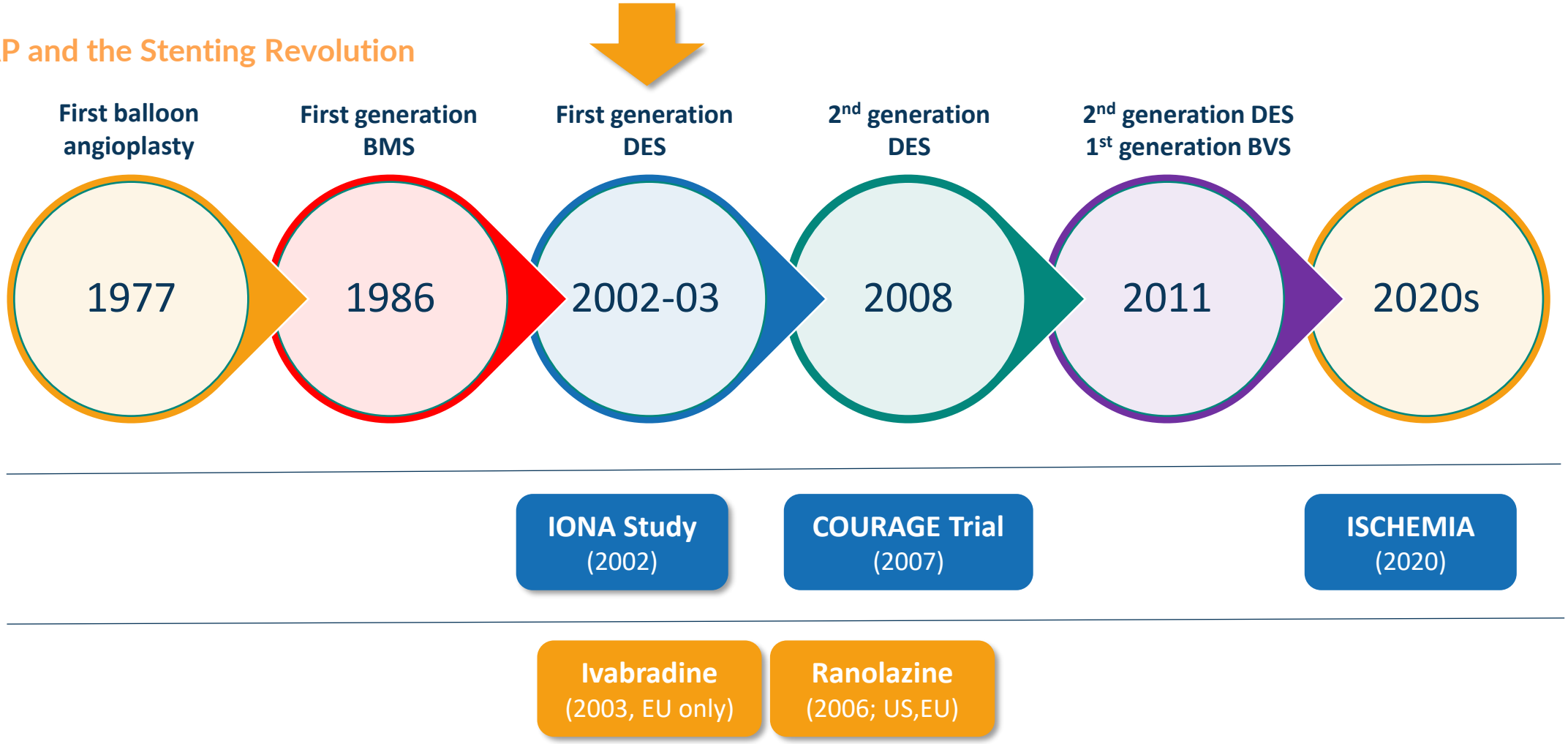
2020[2] (N=5,179)

- Two large outcomes studies demonstrated no benefit in angina symptom control of elective revascularization over optimal drug therapy alone along with no outcome benefits
- Revascularization caries additional mortality risk

1. Boden W et al. *N Engl J Med.* 2007;356(15):1503-16. 2. Maron DJ et al. *N Engl J Med 2020*;382;1395-407.

The decades long bet on revascularization delayed the R&D for new effective CSAP medications

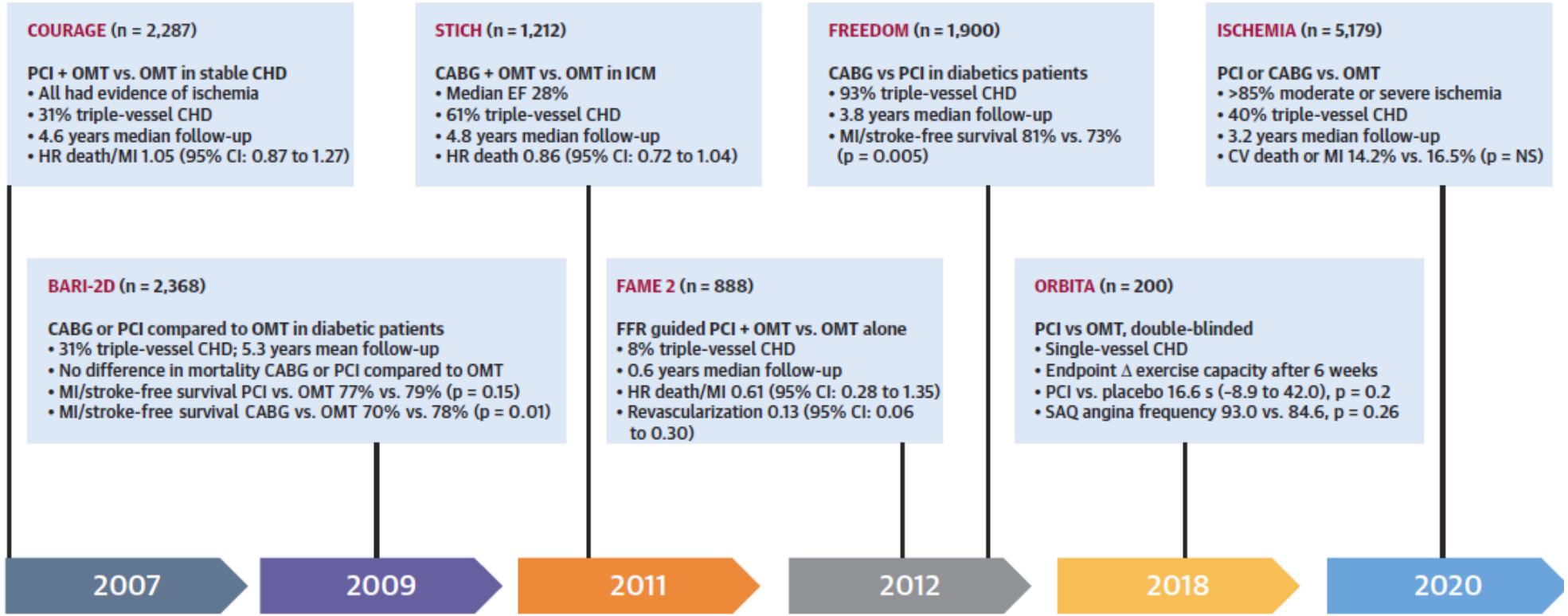
CSAP and the Stenting Revolution



BMS – bare metal stents; **DES** – drug eluting stents; **BVS** – bioresorbable vascular scaffolds

Adapted from: Scafa Udris A. et al. *Materials*. 2021;14:2498.

Major Trials in Chronic-stable Angina with CAD

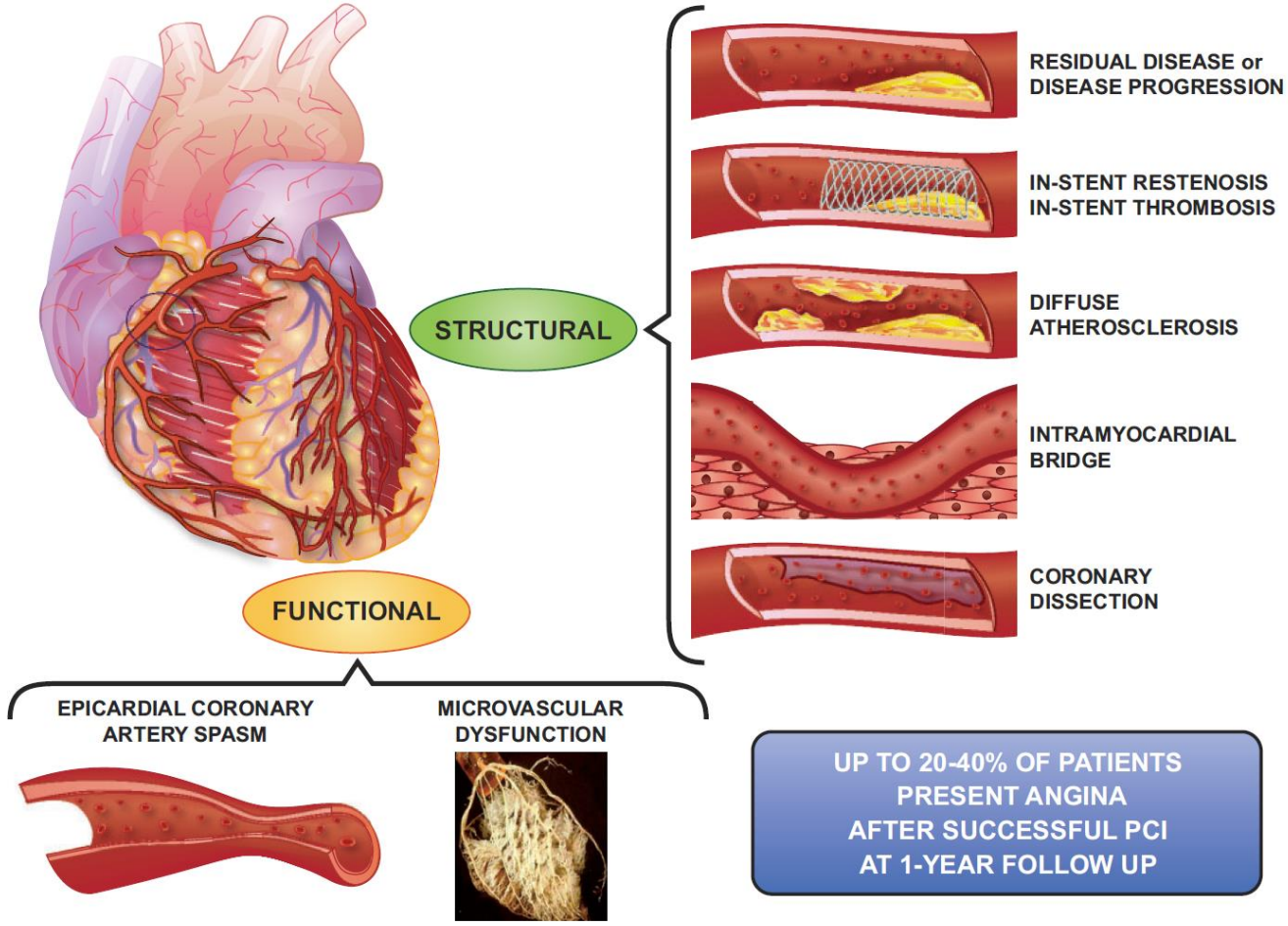


CABG = coronary artery bypass grafting; CHD = coronary heart disease; PCI ¼ percutaneous coronary intervention; OMT = optimal medical therapy; MI = myocardial infarction; NS = not significant; SAQ = Seattle Angina Questionnaire.

Ferraro R et a. *J Am Coll Cardiol*. 2020;76(19):2252-66.

Causes of Persistent Angina after Revascularization

Up to 40% of CSAP patients present with angina symptoms 1 year after successful PCI



- Coronary microvascular dysfunction (CMD) is a major functional contributor to persistent angina after PCI
- Patients who underwent PCI with second-generation DES, impaired coronary blood flow (CBF) response to both ACh (an endothelium-dependent stimulus) and adenosine (mostly an endothelium-independent stimulus) was found.
- Overall, CMD was found in **59% of patients** with previous PCI and residual angina symptoms

1. Crea F et al. *Eur Heart J*. 2019;40:2455-2462. 2. Hokimoto S et al. *Int J Cardiol*. 2016;222:185-194.

Our solution – effective angina symptom-controlling agent with proven hospitalization reduction effect [AUX-001]

AP is actively working to bring AUX-001 to the US as a first-line, once-daily version of a well-known reference drug used in Europe and Asia

An efficient antianginal agent with a unique mechanism of action, **able to address both macro and microvascular angina**

First US anti-angina agent which controls chronic angina symptoms AND **reduces cardiovascular risk and frequency of hospitalization**

Convenient **once-daily dosing with no risk of tachyphylaxis** (drug tolerance) frequently observed with long-acting nitrates

Interviews with US commercial payors indicated their willingness to reimburse AUX-001 due to its hospitalization reduction effect

AUX-001 QD offers outcome benefits, cardioprotection, no drug tolerance at no extra cost

AUX-001 Comparative Target Product Profile

	Beta Blockers	Calcium Channel Blockers	AUX-001	Long-acting Nitrates	Ranolazine
Antianginal efficacy	✓	✓	✓	✓	✓
Outcomes benefits in angina patients with CAD	No	No	✓	No	No
Safety	✓	✓	✓	✓	✓
Dosing	QD/BID	QD/BID	QD	QD/BID/TID	BID
Tachyphylaxis	No	No	No	Yes	No
Cardioprotection in angina	No	No	✓	No	No
Ischemic preconditioning	No	No	✓	No	No
Reduction in angina-related hospital admission	No	No	✓	No	No

CAD – coronary artery disease; QD – once daily dosing; BID – twice daily; TID – three-times daily dosing

De-risked development plan

Reformulation of an effective cardiovascular twice-daily agent into a convenient, once-daily drug to be launched in the US

AP has **reformulated** the product from twice-daily to **once-daily** extended-release capsule

AP has filed and received a **patent** for the once-daily formulation

AP initiated collaboration with the **FDA** which **green-lighted** 505(b)2 pathway approach to obtain fast-track market approval in the US

AP will run **low-cost** / **time efficient** preclinical and clinical studies

First-in-human PK study in 2023; IND in 2024; NDA filing anticipated in 2026

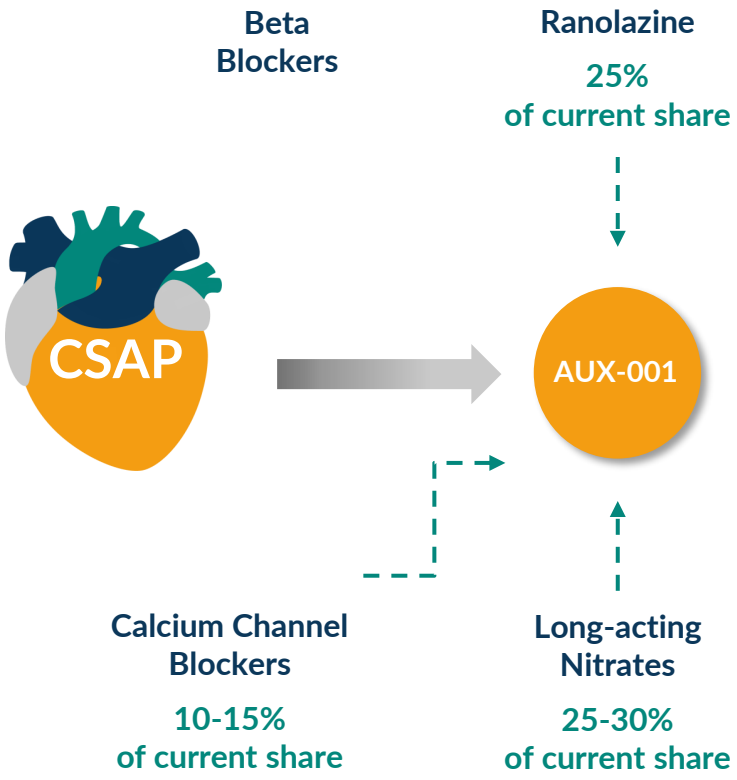
AUX-001 – US market potential

Market entry strategy based on high volume and conservative pricing

Planned AUX-001 launch as a first-line agent

- We anticipate the take-up of AUX-001 will be the largest among the following patient groups:
  - Long-acting nitrates
  - Calcium channel blockers and ranolazine
  - New patients (annual incidence of CSAP is 650,000)
  - Treatment refractory and/or microvascular angina
- **Based on our initial discussion with the US payors, we anticipate a pricing of AUX-001 in the range of $100 per month.**
- **Expected share of 10-15% treated patients, i.e. 600K to 900K CSAP patients by year 4**

Estimated take-up by drug classes



Accelerated regulatory pathway confirmed by the FDA

At the pre-IND meeting, the FDA confirmed:

- **Phase 1 PK study** design
- **No need for Phase 2** studies
- **Single Phase 3 study** for NDA – efficacy of AUX-001 **vs. placebo**

Phase 3 study expected to start in 2025
US launch of the product anticipated in 2027

Typical Value-Added medication development pathway

NEW DRUG APPLICATION PATHWAY	NEW CHEMICAL ENTITY	CLINICAL STUDY REQUIREMENTS	DEVELOPMENT TIMELINE	REVIEW TIMELINE	MARKET EXCLUSIVITY	INVESTMENT AVERAGE
505(b)2 Value-Added medication	+	partial	3-6 years	10-12 months	3-7 years	<$15MM

Source: Berenberg report | Hyloris Pharmaceuticals estimates | Auxilius Pharma estimates

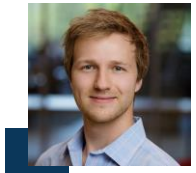
Leadership

Versatile Team with multifunctional experience in both the US and EU

Jed Litwiniuk, MHA
Chief Executive Officer

Healthcare Executive and Corporate Finance Professional

- Head of M&A of Lux Med (the largest healthcare provider in CEE)
- Investment Director at Enterprise Venture Fund and PZU
- CEO of orthopedics and spine surgery inpatient clinic (CM Gamma)
- Co-founder of Picket Pharmaceuticals, NYC based start-up
- Executive MHA at Columbia University Mailman School of Public Health



Dawid Chabowski, PhD
Science and Operational Manager

A biomedical scientist with experience in basic science research in areas of cardiovascular physiology, microvascular function, and lipid signaling.

- Research experiences from institutions such as St. John's University, Wake Forest University, and Mayo Clinic
- PhD from the Department of Pharmacology and Toxicology at the Medical College of Wisconsin

Uwe Tigör, MD
Chief Medical Officer

Extensive marketing and product launch experience

- Chief Medical Officer and Medical Director in healthcare marketing and communications agencies from IPG, WPP, HAVAS Health to InventivHealth
- Consultant to Pharmaceutical Industry
- Medical training in EU and US, MD from Humboldt University, Berlin
- Cardiovascular research experience, including a research fellowship at Mount Sinai Hospital, NY

Pascal St-Laurent
Pharmaceutical Development Consultant

- Over 25 years of experience in research and development and quality assurance. Experienced analytical chemist and manager
- Extensive knowledge of dissolution method development and validation (USP I, II, III and IV)
- Prior experiences include J&J Consumer Healthcare, Cephalon, Wyeth Pharmaceuticals, Schering and Merck

Key Advisors

Len S. Smith
Chief IP and Legal Counsel

Prof. Michael Weber, MD
Cardiology Advisor

Julie Warneck
Non-clinical development consultant

Prof. Juan-Carlos Kaski, DSc, MD
Cardiology Advisor

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THANK YOU

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