



Novartis Investor Relations

Novartis Cardiovascular Update

Investor Presentation
May 18, 2021

 **NOVARTIS** | Reimagining Medicine

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Participants



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Novartis leading cardiovascular portfolio and capabilities

2015



Essential first choice for chronic heart failure

~15m patients

2020



Potential to tackle LDL-C related ASCVD at scale

~60m patients

~2025

pelacarsen (TQJ230)

Potential to lower CV risk for people with elevated Lp(a)

- High unmet need: CV disease leading cause of mortality
- Strong worldwide commercial and scientific** presence
- Deep understanding of customer needs across primary and specialty care

LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease CV – Cardiovascular Lp(a) – Lipoprotein(a) Note: Dates refer to first launch for Entresto® and Leqvio®, to submission for pelacarsen. Population numbers refer to US & EU5 (Germany, France, Spain, Italy, UK). Source: Decision Resources Group.

Entresto®



David Soergel MD

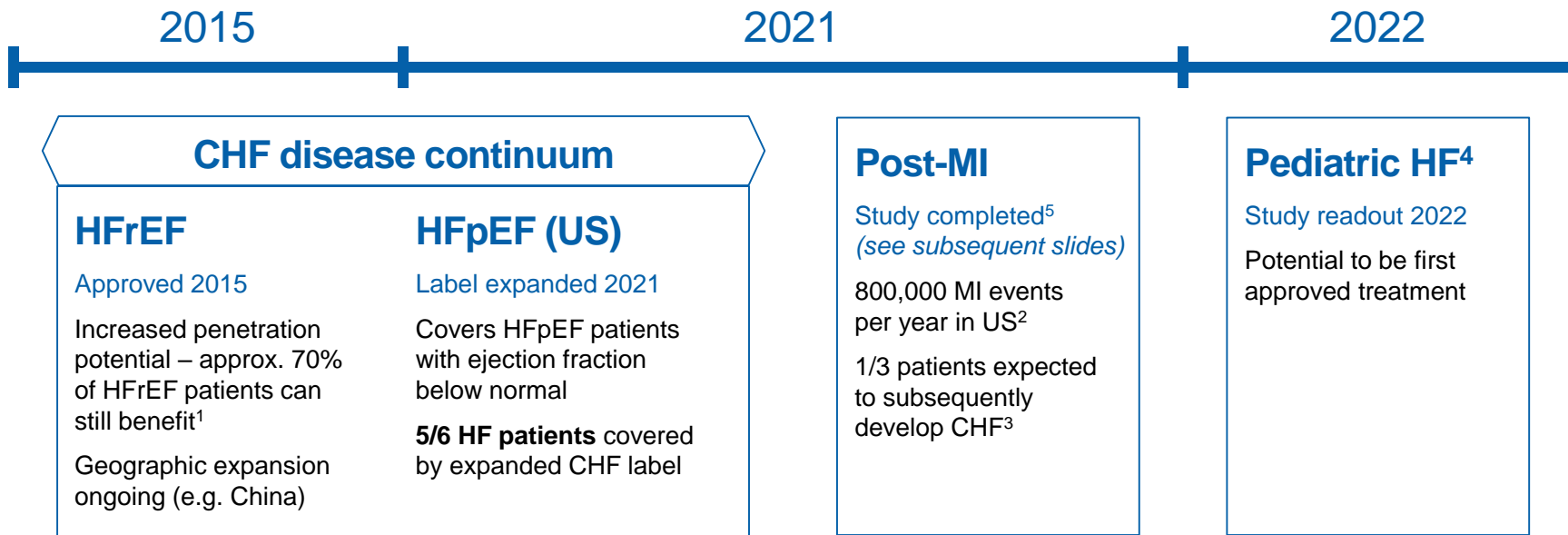
Global Head of Cardiovascular,
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Rod Wooten

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Entresto® development program across heart failure

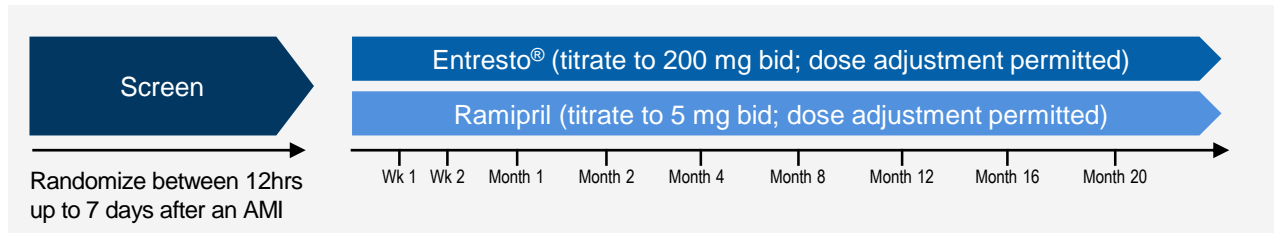


All pivotal studies with active comparator against standard of care

HFrEF – Heart Failure with reduced Ejection Fraction HFpEF – Heart Failure with preserved Ejection Fraction CHF – Chronic Heart Failure MI – Myocardial Infarction HF – Heart Failure 1. Eligible patients defined as prevalent HFrEF patients within each market's label. G7 = US, CA, JP, DE, FR, IT, UK. 2. Roth GA, et al. J Am Coll Cardiol 2017;70:1–25 3. Typically over 5 years. Source: Cahill T, Kharbanda R. World J Cardiol. 2017;9(5):396-469. DOI: 10.4330/wjc.v9.i5.407. 4. Approved in US in 2020. Primary endpoint not met. See subsequent pages for further details. 5. Virani S, Alonso A, Aparicio H, et al. Heart disease and stroke statistics—2021 update: a report from the American Heart Association. Circulation. 2021;143:e254–e743. doi: 10.1161/CIR.0000000000000950 .

PARADISE-MI a landmark trial in post acute MI patients

PARADISE-MI study design



Patients	5,669 patients without prior history of heart failure
Primary objective	Demonstrate superior efficacy , time to first composite event
Primary composite endpoint	CV death, HF hospitalizations, outpatient HF visits
Secondary endpoints	<ul style="list-style-type: none"> ▪ CV Death or HF hospitalization ▪ HF hospitalization or outpatient HF ▪ CV death, non-fatal MI or non-fatal stroke ▪ CV death and total hospitalizations for HF, MI or stroke ▪ All-cause death

Trial profile

Head-to-head **superiority** to **ramipril**, a current standard of care

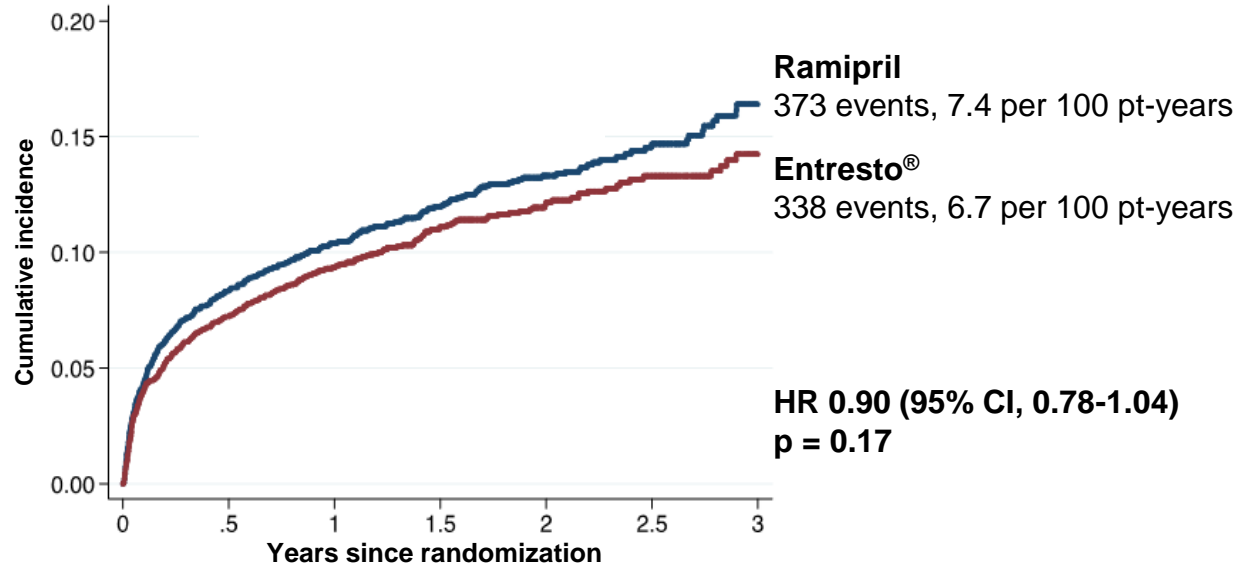
High risk patient population with recent MI

In-hospital/**early initiation** in fragile patients

This information is based on preliminary study data analysis and contain information that has not been approved by the regulatory authorities. MI – Myocardial Infarction AMI – Acute Myocardial Infarction CV – Cardiovascular HF – Heart Failure. Note: primary endpoint not met.

Positive trend against a high bar, though primary endpoint not met (1/2)

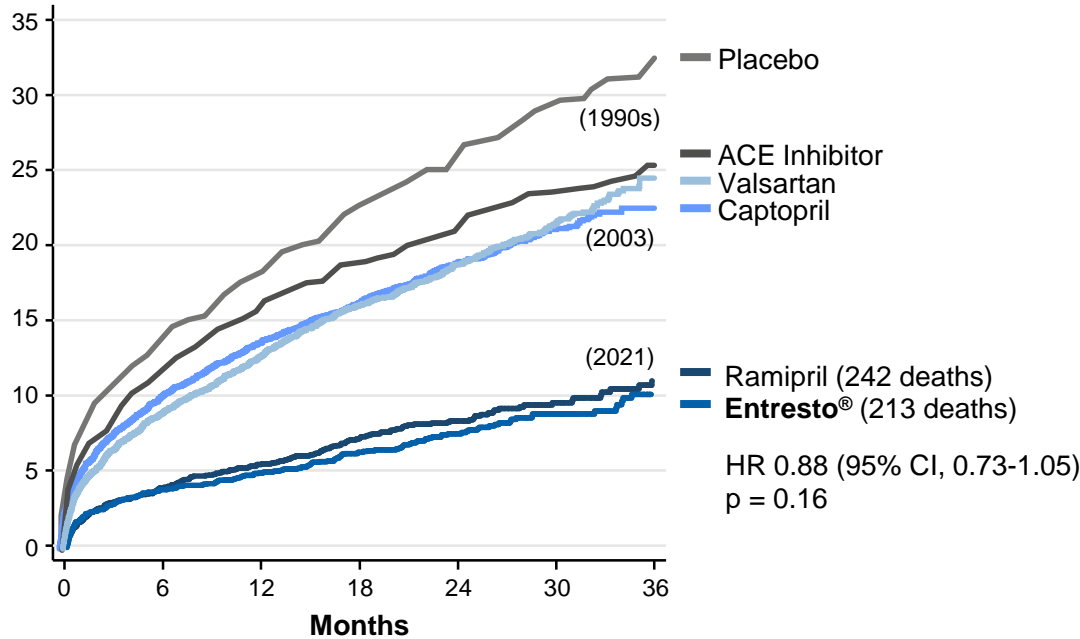
Entresto® vs. ramipril



This information is based on preliminary study data analysis and contain information that has not been approved by the regulatory authorities. HR – Hazard Ratio Source: Pfeffer, Angiotensin-Nepriylisin Inhibition Following Acute Myocardial Infarction: Primary Results of the PARADISE-MI Trial, presented at ACC (2021).

Positive trend against a high bar, though primary endpoint not met (2/2)

Mortality (%)



MI mortality outcomes have improved over time through continuous improvement in MI care

This information is based on preliminary study data analysis and contain information that has not been approved by the regulatory authorities. ACE – Angiotensin Converting Enzyme HR – Hazard Ratio MI – Myocardial Infarction Source: Pfeffer, Angiotensin-Nepriylsin Inhibition Following Acute Myocardial Infarction: Primary Results of the PARADISE-MI Trial, presented at ACC (2021).

The positive trend was consistent across all secondary endpoints

Primary endpoint

HR

CV death, HF hospitalization, outpatient HF	0.88 (0.73-1.05)
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Secondary endpoints

HR

CV death or HF hospitalization	0.91 (0.78-1.07)
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HF hospitalization or outpatient HF	0.84 (0.70-1.02)
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CV death, MI or stroke	0.90 (0.77-1.05)
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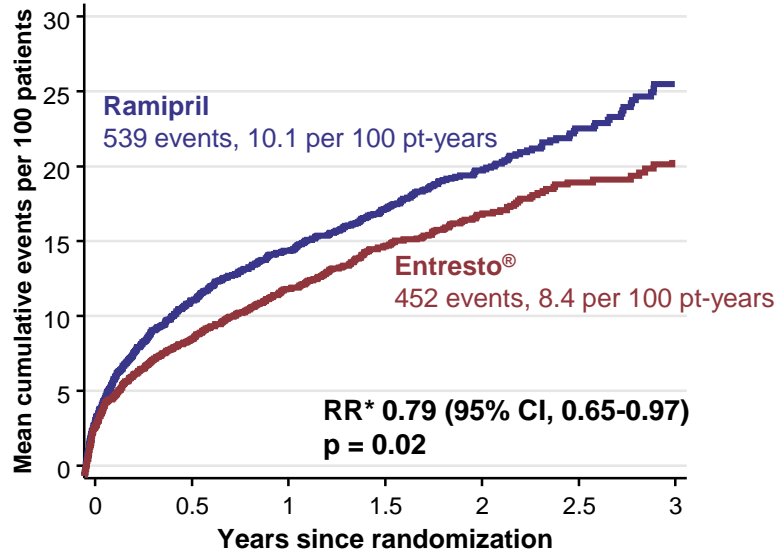
CV death and hospitalizations for HF, MI, stroke	0.84 (0.70-1.00)
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All-cause death	0.88 (0.73-1.05)
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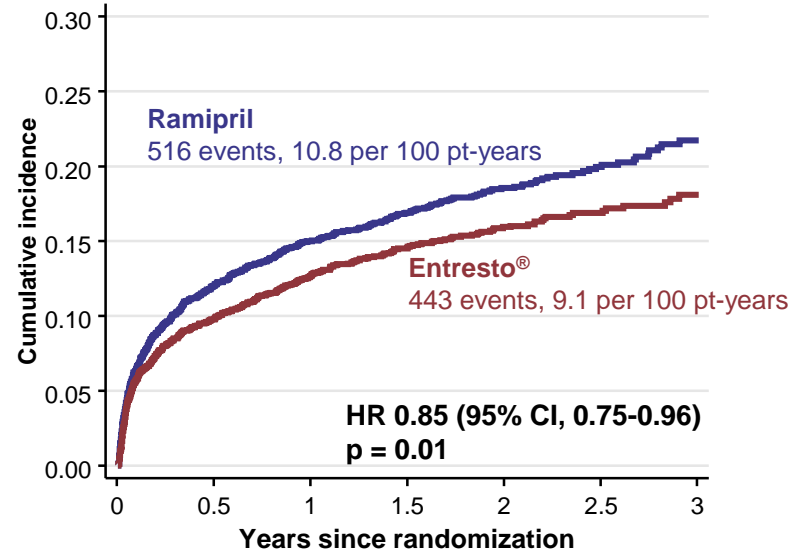
This information is based on preliminary study data analysis and contain information that has not been approved by the regulatory authorities. CV – Cardiovascular HF – Heart Failure MI – Myocardial Infarction HR – Hazard Ratio
Source: Pfeffer, Angiotensin-Nepriylsin Inhibition Following Acute Myocardial Infarction: Primary Results of the PARADISE-MI Trial, presented at ACC (2021).

Nominal significance in total recurrent adjusted primary events and investigator reported events (pre-specified)

Total (first and recurrent) CEC adjudicated primary events



Investigator reported primary endpoint



This information is based on preliminary study data analysis and contain information that has not been approved by the regulatory authorities. *Rate ratio derived from negative binomial regression with Weibull baseline intensity function
CEC – Clinical Events Committee RR – Relative Risk HR – Hazard Ratio Source: Pfeffer, Angiotensin-Nepriylsin Inhibition Following Acute Myocardial Infarction: Primary Results of the PARADISE-MI Trial, presented at ACC (2021).

Safety profile reassuring in this setting where treatment initiated early, in-hospital ...

Adverse Events (%)	Entresto® N=2830	Ramipril N=2831
Deaths	213 (8%)	242 (9%)
Angioedema (adjudicated)	14 (0.5%)	15 (0.5%)
Serious adverse events	1145 (40%)	1126 (40%)
Adverse events	2351 (83%)	2325 (82%)
Hypotension	802 (28%)*	620 (22%)
Cough	255 (9%)*	371 (13%)
Renal impairment	329 (12%)	326 (12%)
Hyperkalemia	301 (11%)	285 (10%)
Liver abnormalities	132 (5%)	167 (6%)

This information is based on preliminary study data analysis and contain information that has not been approved by the regulatory authorities. Note: balanced if not noted by *p<0.005. Source: Pfeffer, Angiotensin-Nepriylsin Inhibition Following Acute Myocardial Infarction: Primary Results of the PARADISE-MI Trial, presented at ACC (2021).

... with fewer adverse event related discontinuations on Entresto®

Reasons for treatment discontinuation	Entresto® N=2830, n (%)	Ramipril N=2831, n (%)	Total N=5661, n (%)
Completed	2210 (78.09)	2172 (76.72)	4382 (77.41)
Discontinued study treatment	610 (21.55)	644 (22.75)	1254 (22.15)
Primary reason for discontinuation of study treatment			
Adverse events	356 (12.58)	379 (13.38)	735 (12.98)
Hypotension	37 (1.31)	16 (0.57)	53 (0.94)
Cough	34 (1.20)	65 (2.30)	99 (1.75)
Renal impairment ¹	19 (0.67)	18 (0.64)	37 (1.31)
Hyperkalemia	12 (0.42)	14 (0.49)	26 (0.46)
Death	109 (3.85)	127 (4.49)	236 (4.17)
Physician decision	50 (1.77)	55 (1.94)	105 (1.85)
Subject/guardian decision	236 (8.34)	219 (7.74)	455 (8.04)
Never received study treatment	10 (0.35)	15 (0.53)	25 (0.44)

PARADISE-MI summary

Significance for primary endpoint was not met

Consistent, positive trends for Entresto® relative to ramipril in all endpoints

Nominal significance in total recurrent adjusted primary events and investigator reported events

Confirmed safety profile in fragile population

Data currently being evaluated

This information is based on preliminary study data analysis and contain information that has not been approved by the regulatory authorities. ¹ Renal impairment includes renal impairment, renal failure, acute kidney injury.

Source: Pfeffer, Angiotensin-Nepriylsin Inhibition Following Acute Myocardial Infarction: Primary Results of the PARADISE-MI Trial, presented at ACC (2021).

Entresto® comprehensive data across indications and treatment settings support first line use in chronic heart failure

Most comprehensive evidence of all HF therapies

Data from: >50,000 patients in clinical trials
>320,000 patients real world evidence (RWE)



HF _r EF	HF _p EF	In-hospital management	Post-MI	Real-world evidence
PARADIGM-HF Morbidity, mortality, QoL PROVE-HF, EVALUATE-HF NT-proBNP, cardiac remodeling, QoL OUTSTEP-HF/ACTIVITY-HF Functional/ exercise capacity	PARAGON-HF CV death, hospitalization, safety, QoL PARALLAX NT-proBNP, symptoms, functional capacity, QoL PARAGLIDE In-hospital initiation, NT-proBNP	TRANSITION <i>de novo</i> HF, ACEi/ARB naïve, AF, T2D, CKD PIONEER-HF <i>de novo</i> HF, ACEi/ARB naïve	PARADISE-MI¹ HF mortality/ morbidity prevention	ARIADNE EU treatment patterns CHAMP-HF US treatment patterns Systematic review (68 studies)² Efficacy, safety

Key characteristics supporting first line use of Entresto®

- **Improved mortality** in HFrEF vs. conventional RAAS inhibition
- Safe and effective in broad population including ACEi/ARB naïve patients
- **Easy and safe initiation in-hospital** or immediately after discharge
- Diverse study population based on global study footprint
- Well characterized reversal of cardiac remodelling based on MoA
- Effectiveness and safety confirmed by large body of RWE in clinical practice
- **Guideline support as SoC** in HFrEF

HF_rEF – Heart Failure with reduced Ejection Fraction HF_pEF – Heart Failure with preserved Ejection Fraction MI – Myocardial Infarction QoL – Quality of Life NT-proBNP - N-terminal prohormone of Brain Natriuretic Peptide
CV – Cardiovascular HF – Heart Failure ACEi – Angiotensin Converting Enzyme inhibitor ARB – Angiotensin II Receptor Blocker AF – Atrial Fibrillation T2D – Type 2 Diabetes CKD – Chronic Kidney Disease RAAS – Renin Angiotensin Aldosterone System MoA – Mechanism of Action RWE – Real World Evidence SoC – Standard of Care 1. Primary endpoint not met. 2. Proudfoot et al. (2021), Real-world effectiveness and safety of sacubitril/valsartan in heart failure: A systematic review. International Journal of Cardiology.

Entresto® could address hypertension in Asia, a remaining unmet need

Strong remaining unmet need in Asian population

- Higher sodium intake with 1.6m related CV deaths^{3,4}
- In China, **only 15%** of patients have controlled HTN⁵ vs. 52% in the US⁶

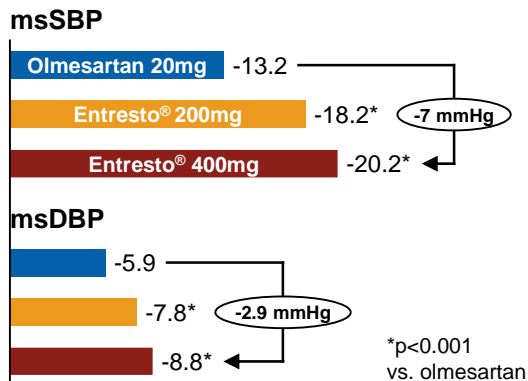
Comprehensive trial program

- 13 studies including ~7k patients across a broad population
- Regulatory review ongoing in Japan/ China

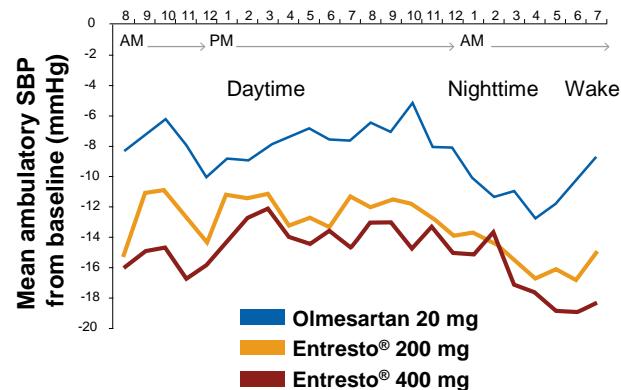
Entresto® superior to most potent ARB at the time with comparable safety¹

Entresto® superior at reducing BP at week 8²

BP Change from baseline, mmHg



Robust antihypertensive effects over 24 hours

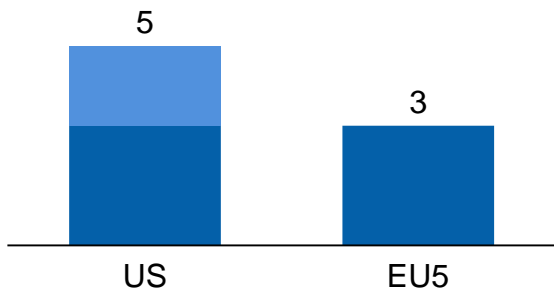


ARB - Angiotensin II Receptor Blocker HTN - Hypertension BP - Blood Pressure msSBP - mean seated Systolic Blood Pressure msDBP - mean seated Diastolic Blood Pressure SBP - Systolic Blood Pressure AM - Ante Meridiem PM - Post Meridiem 1. Study 1306 (one of two pivotal ph3 studies; results confirmed by A2315 study). 2. Results consistent across secondary endpoints (msDBP, msPP 24 hr BP and responder rates). 3. Powles J, et al. BMJ Open. 2013;3:e003733. 4. Mozaffarian D, et al. N Engl J Med. 2014;371:624-634. 5. Wang Z, et al. Circulation. 2018;137:2344-2356. 6. NCD Risk Factor Collaboration. Lancet. 2019;394:639-651.

1 in 3 post-MI patients likely to develop heart failure and enter labeled population for Entresto®

~8m CHF patients in US & EU5 can benefit from Entresto® today^{1,5}

■ HF-pEF patients (m)
■ HF-rEF patients (m)



~1.5m MI events in US and EU5 annually^{2,3,5}

US	EU5 ⁵	China	RoW
800k	630k	1.5m	4.4m



1/3 of post-MI patients likely to develop CHF⁴



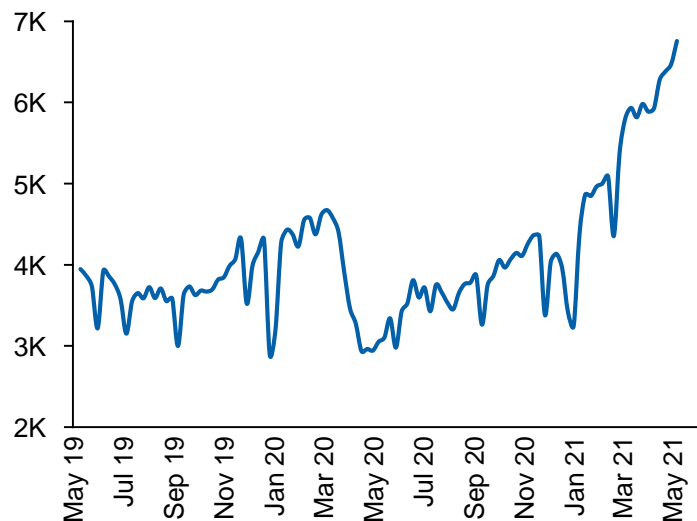
~500k post-MI patients who develop CHF may benefit from Entresto® over time

MI – Myocardial Infarction CHF – Chronic Heart Failure RoW – Rest of World 1. Based on label covering rEF in EU and CHF below normal in US; 60% of HF-rEF and 80% of HF-pEF patients have heart failure due to causes other than MI.
2. Roth GA, et al. J Am Coll Cardiol 2017;70:1–25 3. Virani S, Alonso A, Aparicio H, et al. Heart disease and stroke statistics—2021 update: a report from the American Heart Association. Circulation. 2021;143:e254–e743. doi: 10.1161/CIR.0000000000000950 4. Typically within 5 years. Source: Cahill T, Kharbanda R. World J Cardiol. 2017;9(5):396-469. DOI: 10.4330/wjc.v9.i5.407. 5. EU5: Germany, France, Spain, Italy, UK.

Entresto® trajectory continues; guideline support and label expansion drive above-market momentum

Weekly NBRx¹

New-to-brand prescriptions



Strong momentum in CHF

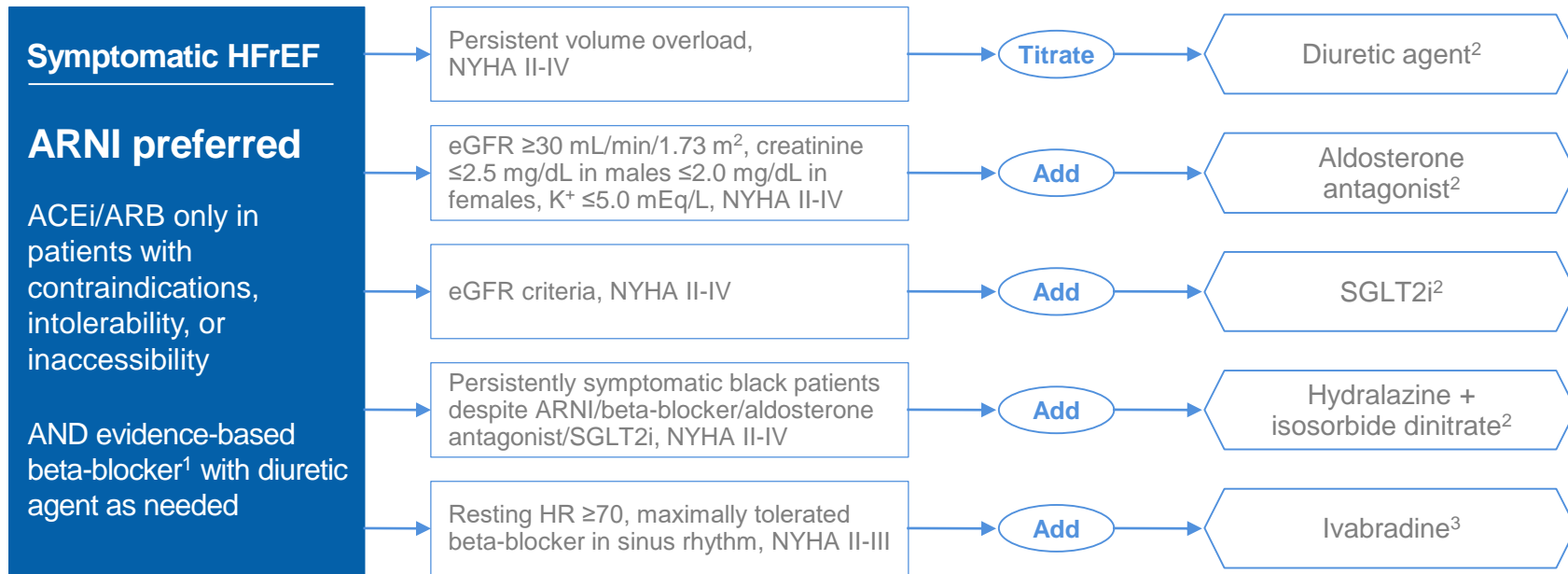
- ACC ECDP is supporting first-line use in HFrEF
- Adoption in HFpEF is gaining momentum in US²
 - Unaided awareness +25% (HFpEF)
 - Intent to prescribe +30% (HFpEF)
 - Increase of use by cardiologist +50% (CHF)

Confident in future growth globally

- ~30% of eligible HFrEF patients, ~15% of eligible US CHF patients currently treated³
- Expanded US label strengthens essential role of Entresto® across HF continuum
- PARADISE-MI reinforces safety in fragile hospitalized patients

NBRx – New-to-brand Prescriptions ACC – American College of Cardiology ECDP – Expert Consensus Decision Pathway HFrEF – Heart Failure with reduced Ejection Fraction HFpEF – Heart Failure with preserved Ejection Fraction
ACE – Angiotensin Converting Enzyme ARB – Angiotensin II Receptor Blocker CHF – Chronic Heart Failure HF – Heart Failure 1. IQVIA National Prescription Audit 2. Physician ATU February to April 2021. 3. Eligible patients defined as prevalent HFrEF patients within each market's label. G7 = US, CA, JP, DE, FR, IT, UK.

The ACC consensus (updated Jan 2021) recommends ARNI ahead of ACEi / ARBs for HFrEF



ACC – American College of Cardiology HFrEF – Heart Failure with reduced Ejection Fraction ARNI – Angiotensin Receptor Neprilysin Inhibitor ACEi – Angiotensin Converting Enzyme inhibitor ARB - Angiotensin II Receptor Blocker eGFR - estimated Glomerular Filtration Rate GDMT – Guideline-Directed Medical Therapy HR – Heart Rate NYHA – New York Heart Association SGLT2i – Sodium-Glucose Cotransporter-2 inhibitor 1. Carvedilol, metoprolol succinate, or bisoprolol. 2. Class I therapy from clinical practice guidelines. 3. Class II therapy. Source: Adapted from Maddox TM, Januzzi JL Jr, Allen LA, et al. J Am Coll Cardiol. 2021; 77:772–810.

Entresto® use supported by data / evidence from comprehensive and broad development program

PARADISE showed positive trend vs. comparator and confirmed safety profile in fragile population; 1 in 3 post-MI patients may enter label population and benefit from Entresto® over time

Strong in-market performance continues based on updated ACC consensus recommendations to use before ACE/ARB, and uptake in broader CHF population in US

Potential hypertension indication could accelerate momentum in select Asian markets

Leqvio[®]



David Soergel MD

Global Head of Cardiovascular,
Renal and Metabolism Development



Victor Bulto

Head of Novartis
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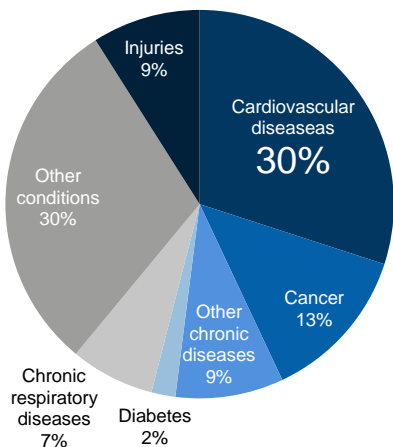
Matthew Whitty

CEO, Accelerated
Access Collaborative, NHS

Despite availability of effective treatments, the burden of cardiovascular disease on health systems is on the rise

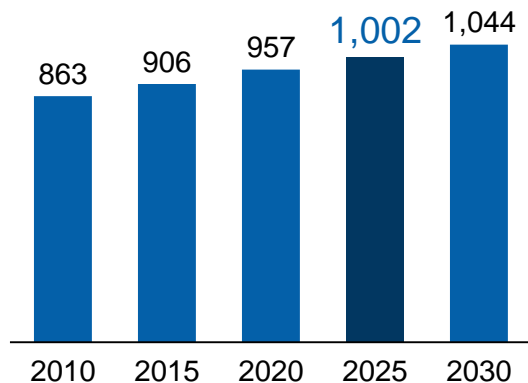
CVD accounts for more deaths than any other disease¹

% of deaths



Global CVD costs to surpass 1 trillion p.a. by 2025¹

USD billion



Total cost 2010-2030 = USD 20 trillion

18m lives lost globally to CVD²

After years of decline, number of lives lost is rising again³

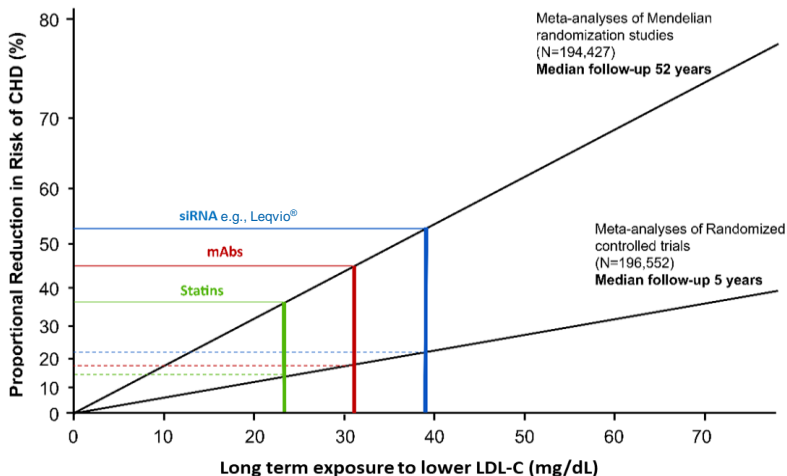
Disease burden is driven by healthcare costs (55%) and productivity loss (45%)¹

~60m patients with ASCVD in US and EU⁴

CVD – Cardiovascular Disease ASCVD – Atherosclerotic Cardiovascular Disease 1. Bloom, D.E., et al. (2011). The Global Economic Burden of Noncommunicable Diseases. Geneva: World Economic Forum. 2. World Health Organization. Cardiovascular diseases (CVDs). Available from: [https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)) [Last accessed: September 2020]. 3. McClellan M, Brown N, Califf RM, Warner JJ. Call to Action: Urgent Challenges in Cardiovascular Disease: A Presidential Advisory from the American Heart Association. *Circulation*. 2019;139(9):E44–E54. 4. Decision Resources Group, EU5: Germany, France, Spain, Italy, UK. Note: The effect of Leqvio® on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 trial.

50 years of evidence demonstrate that effective and sustained LDL-C reduction improves cardiovascular outcomes*^{1,2}

Log-linear association per unit change in LDL-C and the risk of cardiovascular disease⁵



Each mmol/L reduction in LDL-C reduces the relative risk of ASCVD events by 20% after 3 years and 1.5% in each subsequent year³

Relationship between LDL-C and MACE is supported by clinical trials involving ~500k patients^{3,4}

Relation between LDL-C and outcomes is well established

LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease MACE - Major Adverse Cardiovascular Events CV – Cardiovascular
 1. Silverman MG, et al. JAMA. 2016;316(12):1289-1297. 2. CTT Collaboration. Lancet 2015;385:1397-1405. 3. Cholesterol Treatment Trialists' (CTT) Collaboration, et al. Lancet. 2010;376(9753):1670-1681. 4. Wang N, et al. Lancet Diabetes Endocrinol. 2020;8:36-49. 5. Figure adapted from Brandts J, et al. Circulation. 2020;141(11):873-876; Cholesterol Treatment Trialists(CTT) Collaboration European Heart Journal (2018) 39, 2540–2545 -doi:10.1093/eurheartj/ehx450. *The effect of Leqvio® on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 trial. Note: Leqvio® is approved in Europe, in the US Leqvio® has investigational status.

Guidelines recognize link between LDL-C and outcomes³; LDL-C reduction targets becoming more ambitious

AHA/ACC (2018)¹

Clinical ASCVD

Very high CVD risk

LDL-C reduction
by **≥50%**

LDL-C reduction
to **<70 mg/dL**
(1.8 mmol/L)

ESC/EAS (2019)²

High CV risk

Very high CV risk

LDL-C reduction
to **<70 mg/dL**
(1.8 mmol/L)

and

LDL-C reduction
by **≥50%**

LDL-C reduction
to **<55 mg/dL**
(1.4 mmol/L)

and

LDL-C reduction
by **≥50%**

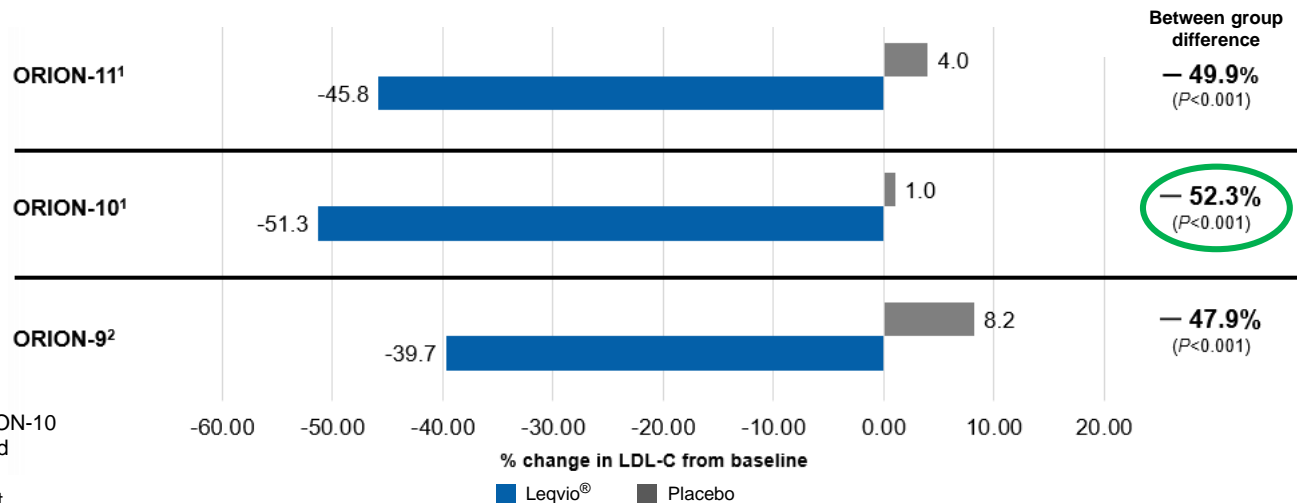
▼
In the real world, consistent and sustained LDL-C lowering is in many cases not achieved due to adherence, access, and affordability challenges

LDL-C – Low Density Lipoprotein Cholesterol AHA – American Heart Association ACC – American College of Cardiology ESC – European Society of Cardiology EAS - European Atherosclerosis Society ASCVD – Atherosclerotic Cardiovascular Disease CVD – Cardiovascular Disease CV – Cardiovascular 1. Grundy SM, et al. J Am Coll Cardiol. 2019;73(24):3237-3241. 2. Mach F, et al. Eur Heart J. 2020;41(1):111-188. 3. The effect of Leqvio[®] on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 trial.

Leqvio® delivers an effective and sustained³ LDL-C reduction of up to 52%^{1,2}

Leqvio® effected significant reductions in LDL-C vs. placebo at Day 510, on top of SoC

Range, -47.9% - 52.3%



LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease 1. Two Phase 3 Trials of Inclisiran in Patients with Elevated LDL Cholesterol Kausik K. Ray, M.D., M.Phil., R. Scott Wright, M.D., David Kallend, M.D., Wolfgang Koenig, M.D., Lawrence A. Leiter, M.D., Frederick J. Raal, Ph.D., Jenna A. Bisch, B.A., Tara Richardson, B.A., Mark Jaros, Ph.D., Peter L.J. Wijngaard, Ph.D., and John J.P. Kastelein, M.D., Ph.D., for the ORION-10 and ORION-11 Investigators*; March 18, 2020, at NEJM.org.DOI: 10.1056/NEJMoa1912387. 2. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia Frederick J. Raal, M.D., Ph.D., David Kallend, M.B., B.S., Kausik K. Ray, M.D., M.Phil., Traci Turner, M.D., Wolfgang Koenig, M.D., R. Scott Wright, M.D., Peter L.J. Wijngaard, Ph.D., Danielle Curcio, M.B.A., Mark J. Jaros, Ph.D., Lawrence A. Leiter, M.D., and John J.P. Kastelein, M.D., Ph.D., for the ORION-9 Investigators*; March 18, 2020, at NEJM.org.DOI: 10.1056/NEJMoa1913805. 3. Across the 6-month dosing interval. Note: Leqvio® is approved in Europe, in the US Leqvio® has investigational status.

Leqvio[®] well tolerated safety profile

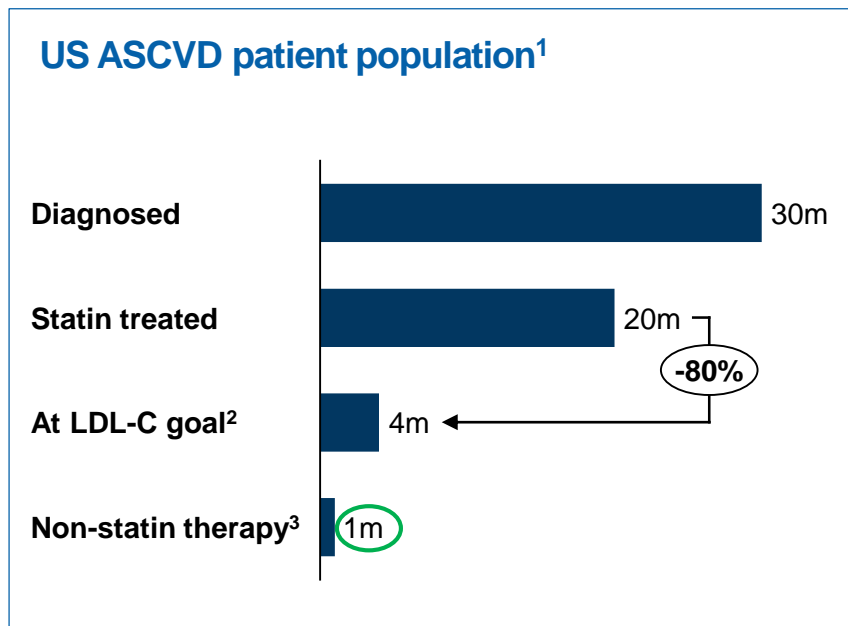
- No significant safety or tolerability concerns identified with the long-term administration of Leqvio[®]1,2*
- Most common adverse events occurred with similar frequency in Leqvio[®] and placebo groups
- Adverse events associated with Leqvio[®] include injection site reactions, all mild or moderate in severity, transient and resolved without sequelae

	ORION-9 (n=481) ¹				ORION-10 (n=1,559) ²				ORION-11 (n=1,615) ²			
Safety population	Leqvio [®] n=241		Placebo n=240		Leqvio [®] n=781		Placebo n=778		Leqvio [®] n=811		Placebo n=804	
	n	%	n	%	n	%	n	%	n	%	n	%
Patients with at least one serious TEAE	18	7.5%	33	13.8%	175	22.4%	205	26.3%	181	22.3%	181	22.5%
Pre-specified exploratory CV endpoint (MedDRA basket)	10	4.1%	10	4.2%	58	7.4%	79	10.2%	63	7.8%	83	10.3%

CV – Cardiovascular TEAE – Treatment Emergent Adverse Event * Over 18 months. 1. Inclisiran for the Treatment of Heterozygous Familial Hypercholesterolemia Frederick J. Raal, M.D., Ph.D., David Kallend, M.B., B.S., Kausik K. Ray, M.D., M.Phil., Traci Turner, M.D., Wolfgang Koenig, M.D., R. Scott Wright, M.D., Peter L.J. Wijngaard, Ph.D., Danielle Curcio, M.B.A., Mark J. Jaros, Ph.D., Lawrence A. Leiter, M.D., and John J.P. Kastelein, M.D., Ph.D., for the ORION-9 Investigators*; March 18, 2020, at NEJM.org.DOI: 10.1056/NEJMoa1913805. 2. Two Phase 3 Trials of Inclisiran in Patients with Elevated LDL Cholesterol Kausik K. Ray, M.D., M.Phil., R. Scott Wright, M.D., David Kallend, M.D., Wolfgang Koenig, M.D., Lawrence A. Leiter, M.D., Frederick J. Raal, Ph.D., Jenna A. Bisch, B.A., Tara Richardson, B.A., Mark Jaros, Ph.D., Peter L.J. Wijngaard, Ph.D., and John J.P. Kastelein, M.D., Ph.D., for the ORION-10 and ORION-11 Investigators*; March 18, 2020, at NEJM.org.DOI: 10.1056/NEJMoa1912387. Note: Leqvio[®] is approved in Europe, in the US Leqvio[®] has investigational status.



In the US, Leqvio[®] positioned to meet the needs of 80% of statin-treated ASCVD patients who are not at LDL-C goal



Factors driving unmet need

- A1 Adherence
- A2 Access
- A3 Affordability

Leqvio[®] has the potential to offer:

- Effective and sustained⁵ LDL-C reduction with two doses a year⁴
- Medical benefit reimbursement
- Reduced affordability challenges

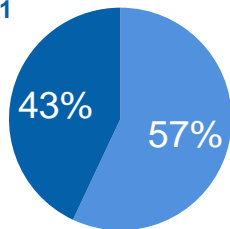
ASCVD – Atherosclerotic Cardiovascular Disease LDL-C – Low Density Lipoprotein Cholesterol 1. Data on file; American Heart Association. Center for Health Metrics and Evaluation. Accessed at: <https://healthmetrics.heart.org/prevalence-and-number-of-us-adults-eligible-for-and-currently-using-statin-therapy-nhanes-2011-2014/>; Wong ND. Journal of Clinical Lipidology. 2016;10(5):1109–1118; American Heart Association/American Stroke Association. Cardiovascular Disease: A Costly Burden. 2. <70mg/dL. 3. Non-statin lipid lowering therapies include ezetimibe and PCSK9i mAbs. 4. After an initial dose, again at 3 months, and again every six months thereafter. 5. Across the 6-month dosing interval. Note: Leqvio[®] is approved in Europe, in the US Leqvio[®] has investigational status



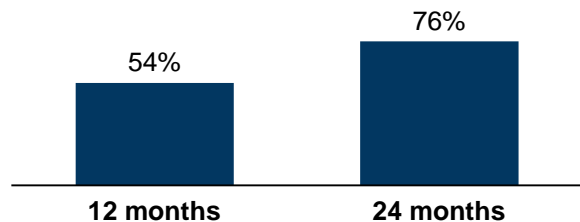
Adherence – real-world challenges compromise outcomes⁴

Statin adherence in secondary prevention¹

Not adherent²
Adherent

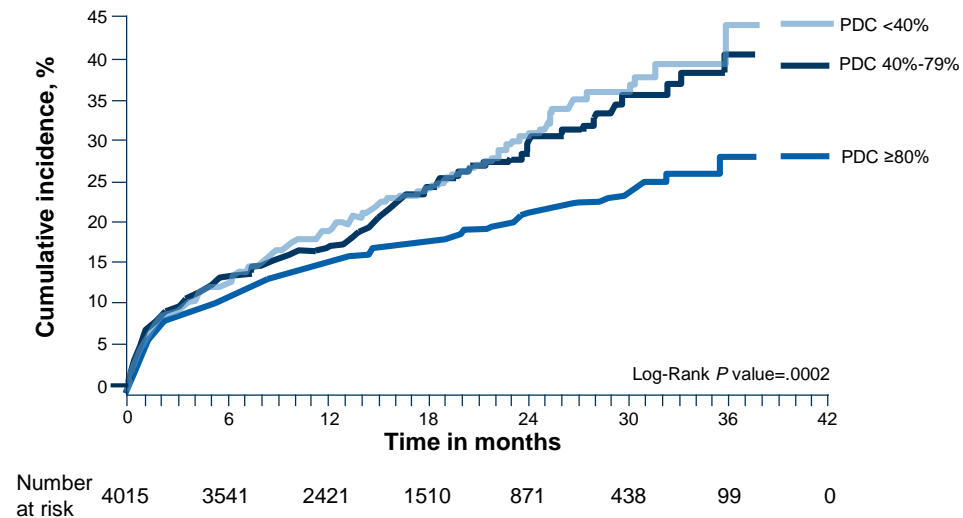


Non-adherent PCSK9i patient share³



Sustained lipid lowering reduces CV risk¹

MACE according to adherence categories in secondary prevention



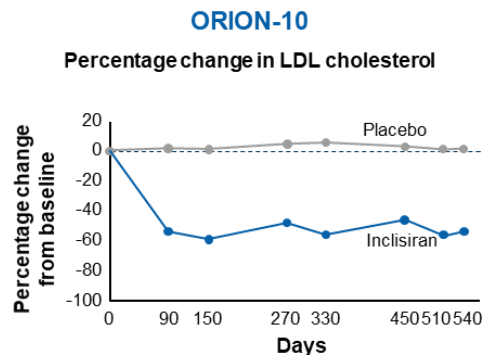
CV – Cardiovascular MACE – Major Adverse Cardiovascular Event PCSK9i - Proprotein convertase subtilisin/kexin type 9 inhibitor. PDC – Percent Days Covered 1. Bansilal S, et al. J Am Coll Cardiol. 2016;68:789-801. 2. Not adherent or not fully adherent within 6 months. 3. Data on file. 4. The effect of Leqvio® on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 trial. Note: Leqvio® is approved in Europe, in the US Leqvio® has investigational status.



A1

Adherence – Leqvio® has the potential to address adherence challenges

Effective and sustained⁴ LDL-C reduction^{1,3}

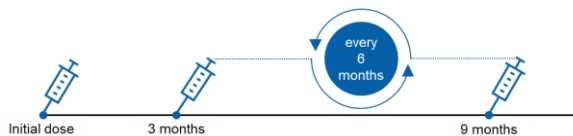


No. of patients

Placebo	780	762	745	724	715	698	666	670
Inclisiran	781	758	757	737	731	721	691	705

Twice-yearly dosing^{1,2}

Dosing scheme³



May integrate seamlessly into a patient's health care routine

HCP administered



No patient education on administration required

L'DL-C – Low Density Lipoprotein Cholesterol HCP – Healthcare Professional 1. Ray KK, et al. N Engl J Med. 2020;382(16):1507-1519. 2. After an initial dose, again at 3 months, and again every six months thereafter. As a strong complement to a maximally tolerated statin. 3. LDL-C reduction was maintained during each 6-month dosing interval. 4. Across the 6-month dosing interval. Note: Leqvio® is approved in Europe, in the US Leqvio® has investigational status.



Access – majority of Leqvio[®] patients will be covered by medical benefit, reducing access hurdles

Patient benefit	Leqvio [®]			PCSK9i mAbs
	Part B FFS (39%)	Medicare Advantage (19%)	Commercial (34%)	Pharmacy benefit
Administration	←	HCP-administered	→	Self-administered
Acquisition	Buy-and-bill	Buy-and-bill, specialty pharmacy	Buy-and-bill, specialty pharmacy	Specialty or retail pharmacy
Access restrictions (step edits, prior authorizations)	●	●	●	●
Reimbursement of administrative effort	←	●	→	●
		<i>Efforts reimbursed (medical benefit)</i>		<i>Efforts not reimbursed</i>
CV outcomes evidence as driver of access decisions	●	←	●	→
	<i>Access mirrors FDA label</i>	<i>Focus on efficacy, safety, cost</i>		

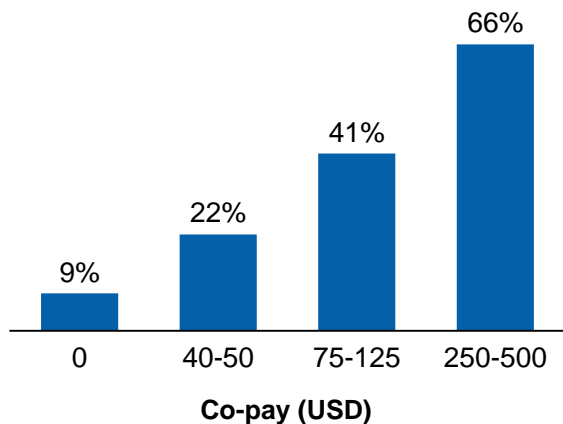
More favorable  Less favorable

CV – Cardiovascular FFS – Fee For Service HCP – Healthcare Professional PCSK9i – Proprotein convertase subtilisin/kexin type 9 inhibitor mAbs – monoclonal Antibodies FDA – Food and Drug Administration Note: Leqvio[®] is approved in Europe, in the US Leqvio[®] has investigational status.



Affordability – medical benefit coverage for Leqvio® creates opportunity for 0 USD co-pay for 2/3 patients at launch

PCSK9i abandonment rate by OOP cost¹



Anticipated payer mix and co-pay for Leqvio® at launch

	% of eligible population	Anticipated co-pay
Medicare Part B	39%	80% pay as little as 0 USD
Medicare Advantage	19%	Varies; 0-20% co-insurance
Commercial	34%	Eligible patients pay as little as 0 USD
Other (Medicaid, federal)	8%	<10 USD

PCSK9i - Proprotein convertase subtilisin/kexin type 9 inhibitor OOP – Out Of Pocket 1. LAAD; IQVIA US Market Access Strategy Consulting. Note: Leqvio® is approved in Europe, in the US Leqvio® has investigational status.



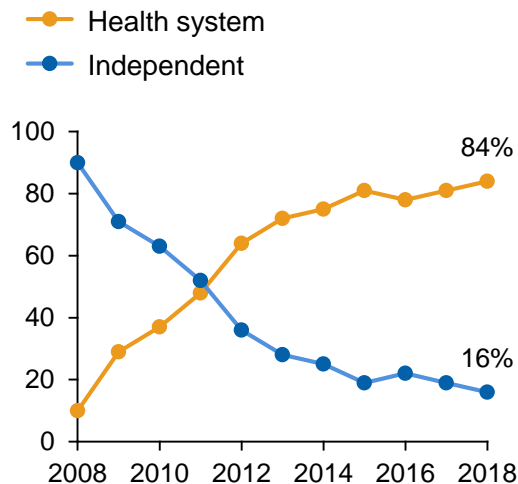
To comprehensively manage non-clinical barriers, our US launch focuses on partnering with health systems

Health systems as primary customer

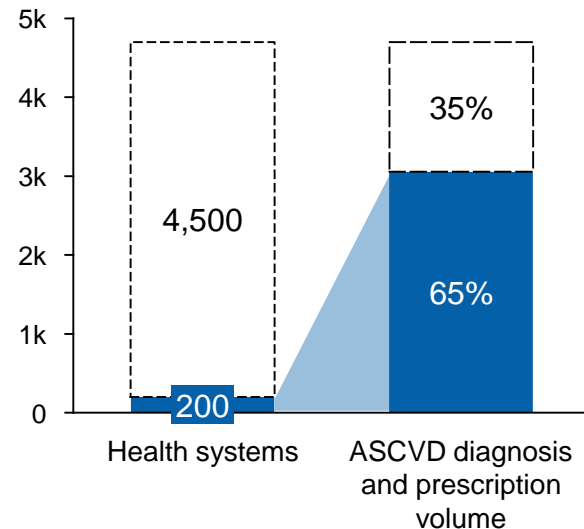
- Buy-and-bill infrastructure implemented
- Centralized prescribing influence
- Centralized EHR enables patient identification
- Established processes for product adoption

45% of target customers currently prioritize ASCVD

Majority of US cardiologists employed by health systems¹



~200 systems represent 2/3 of prescription volume^{1,2,3}

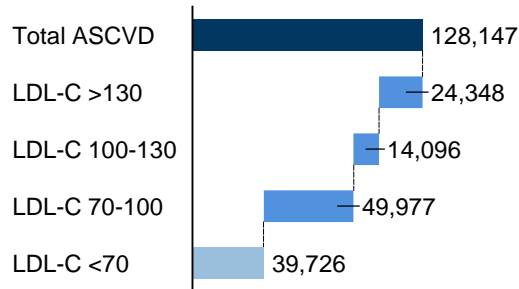


EHR – Electronic Health Record ASCVD – Atherosclerotic Cardiovascular Disease 1. American College of Cardiology. Has employment of cardiologists been a successful strategy? – Part 1. 2. Xponent Plan Trak (October 2019). 3. IQVIA Rx Claims (August 2019). Note: Leqvio® is approved in Europe, in the US Leqvio® has investigational status.

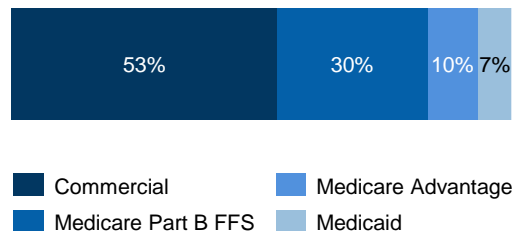
Account teams focused on identifying unmet needs within systems and enhancing the customer experience

System of care account example

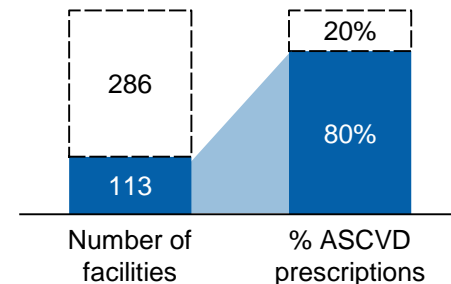
ASCVD population



Payer mix



Prescriber concentration



Account overview

- Highly integrated IDN
- 23 hospitals, 1 dedicated lipid center, 7 advanced cardiac hospitals
- 40 owned cardiology groups
- >10,000 affiliated HCPs
- 800 outpatient sites
- 10 outpatient infusion centers
- Own specialty pharmacy

IDN – Integrated Delivery Network | LDL-C – Low Density Lipoprotein Cholesterol | HCP – Healthcare Professional | FFS – Fee For Service | ASCVD – Atherosclerotic Cardiovascular Disease | Source: Data on file. | Note: Leqvio® is approved in Europe, in the US Leqvio® has investigational status.

Leqvio[®] has the potential to become the leading choice for ASCVD patients³ by providing effective and sustained⁴ LDL-C reduction

Leqvio[®] is uniquely positioned to address unmet needs in ASCVD

A1 Adherence

Effective and sustained⁴ LDL-C reduction with **two doses per year**,* generally well-tolerated^{1,2}

A2 Access

Medical benefit coverage for majority of patients at launch

A3 Affordability

0 USD co-pay for 2/3 patients at launch

Novartis is pursuing a customer-centric go-to-market model to address non-clinical barriers to adoption

Focused on ~200 prioritized health systems at launch

Developing a robust alternate injection center network to provide acquisition & administration flexibility

Deploying a best-in-class field team to help systems and HCPs navigate early reimbursement complexity

45% of field access & reimbursement team with 5+ years of buy-and-bill experience

ASCVD – Atherosclerotic Cardiovascular Disease LDL-C – Low Density Lipoprotein Cholesterol HCP – Healthcare Professional *After an initial dose, again at 3 months, and again every six months thereafter. 1. Khvorova A, et al. N Engl J Med. 2017;376:4-7. 2. Fitzgerald K, et al. N Engl J Med. 2017;376:41-51. 3. On maximally tolerated statins. 4. Across the 6-month dosing interval. Note: Leqvio[®] is approved in Europe, in the US Leqvio[®] has investigational status.

The Accelerated Access Collaborative

Objectives

- The Accelerated Access Collaborative brings together industry, government, regulators, patients and the NHS to remove barriers and accelerate the introduction of ground-breaking innovations which can transform care
- Innovations include **medicines, diagnostics, devices and digital products**
- Our work supports the NHS to **more quickly adopt clinically and cost-effective innovations**, to ensure patients get access to the best new treatments and technologies

Partners



In the UK, the NHS and Novartis are partnering on a population health approach to impact CVD at scale

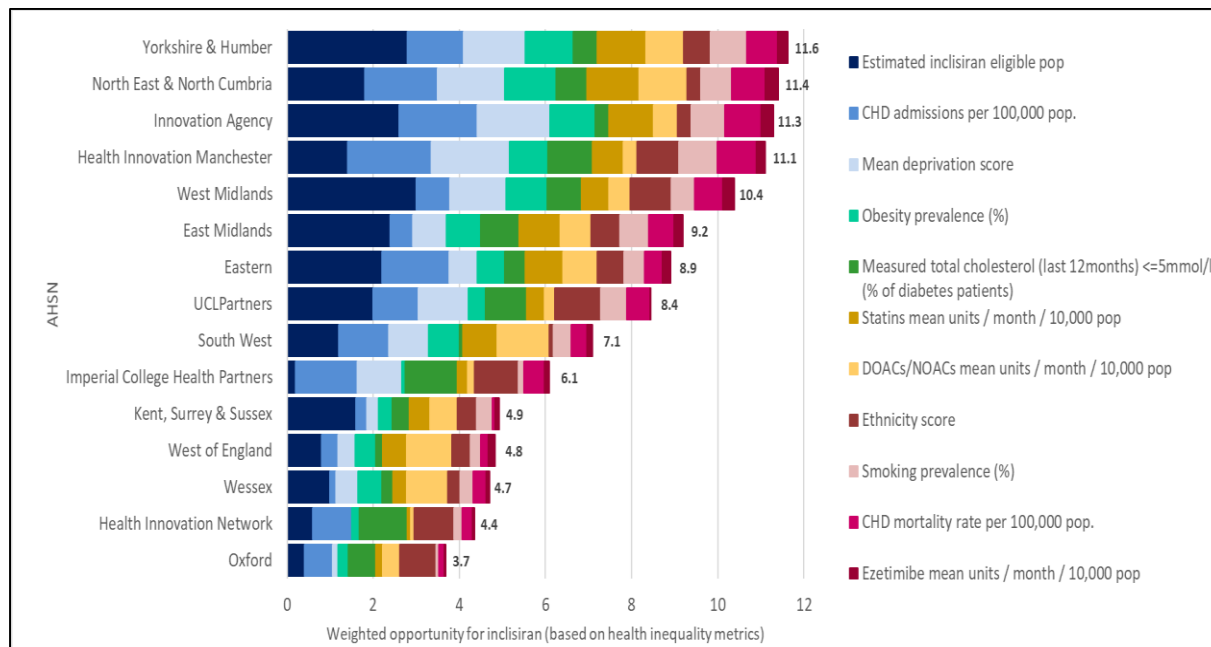
The population-level agreement aims lower LDL-C by ~50% in a high-risk population of people with cardiovascular disease, supporting the Long Term Plan (LTP) ambition of preventing 150,000 heart attacks, strokes and dementia cases over the next 10 years

To achieve this the implementation is focused in three areas:

Primary Care Mobilisation	Patient Identification	Stakeholder Engagement & Consultation
<p>A co-created integrated care system-based strategy led by the AAC. A combination of specialist knowledge in lipid management with an oversight of the local population needs forming the basis of a PHM service pathway focused on achieving an at-scale, primary care-based, secondary prevention programme in CVD; including access to Inclisiran for ~300,000 patients by 2024</p>	<p>Collaboration with NHS Digital, working with GP software & systems provides, that enables the use of data to easily identify and manage the 'at risk' populations within primary care networks of 30,000-50,000 people</p>	<p>Transferring responsibility to a primary care-based population approach requires full system support</p> <p>A co-created comprehensive stakeholder engagement and consultation strategy, spanning across all parts of the health care system, to support with development and implementation of the integrated care system-based strategy primary care by the AHSNs</p>



Focus by the NHS and Novartis collaboration will have a major impact on CV deaths and health inequalities in the UK



- The programme breaks from a traditional approach and aims to ‘level up’ cholesterol services ensuring access to the full eligible population
- Co creation with the AAC and AHSN of shared patient uptake targets with a consideration for improving health inequalities in CVD
- Mutually agreed KPIs for each of the AHSN’s for the adoption and uptake of Inclisiran, monitored throughout implementation



Implementation of NHS-Novartis collaboration is geared to impact CV outcomes at scale

Objective setting

1

- NHS and Novartis mutually agreed draft commercial agreement fully aligned to national CVD & PHM goals
- Implementation of ASCVD secondary prevention programme by the NHS through the AHSNs
- Patient uptake trajectories and tracking KPIs to be agreed with all AHSNs
- Implementation toolkits per geography; including targeted roll-out approach

HCP education

2

- Novartis & NHSE joint education programme aimed at primary care HCPs: 'Cholesterol Now'
- Comprehensive NHS driven communications programme; including internal NHS 'Townhall' meetings and external events
- Full repository of materials available via NHS channels to support inclisiran initiation & management

Patient identification

3

- Collaboration with NHS Digital to create a national ASCVD patient identification and stratification tool directly integrated into primary care GP systems
- Approach allows for proactive and reactive patient identification and inclisiran initiation

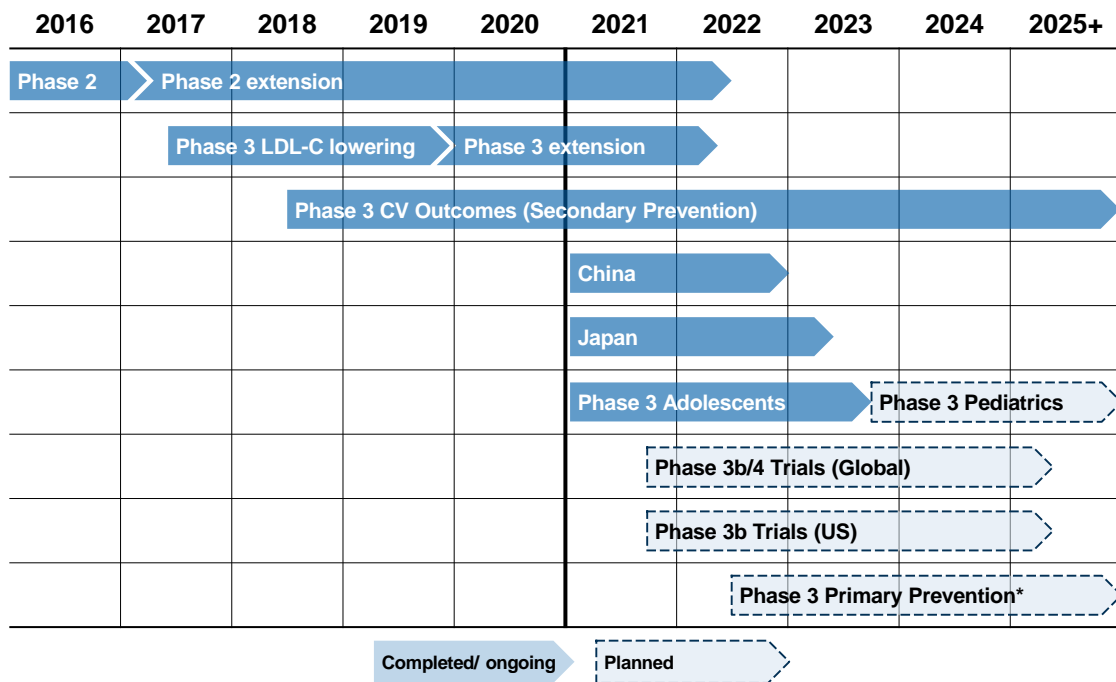
Adherence support

4

- NHS Digital collaboration includes system prompts for patient recall for all patients that have been initiated on inclisiran
- The approach builds on the strengths that the NHS have used for patient recall in other national programmes, e.g. Breast screening, Flu vaccine, etc.



Robust clinical trial program to support Leqvio®



- **Current submissions** supported by completed ORION-9/10/11 trials
 - US planned Q2-Q3 2021
- **CV outcomes** expected 2026
- **Phase 3b/4** studies to support access and drive demand
 - Bridging implementation gaps
 - Expanding on benefit/risk profile and selected patient populations
- **Primary prevention** program to be announced H2/2021

* Expected timelines LDL-C – Low Density Lipoprotein Cholesterol

Burden of Atherosclerotic Cardiovascular Disease (ASCVD) rising, despite effective treatments

Link between LDL-C reduction and outcomes firmly established¹; **suboptimal outcomes in real world** setting mainly due **adherence, access and affordability** challenges (non-clinical barriers)

US launch focuses on **partnering with health systems** to manage non-clinical barriers

In UK, **NHS and Novartis are partnering on a population health** approach to impact CVD at scale

LDL-C – Low Density Lipoprotein Cholesterol NHS – National Health Service ASCVD – Atherosclerotic Cardiovascular Disease CVD – Cardiovascular Disease 1. The effect of Leqvio[®] on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 trial.

Pelacarsen (TQJ230)



David Soergel MD

Global Head of Cardiovascular,
Renal and Metabolism Development



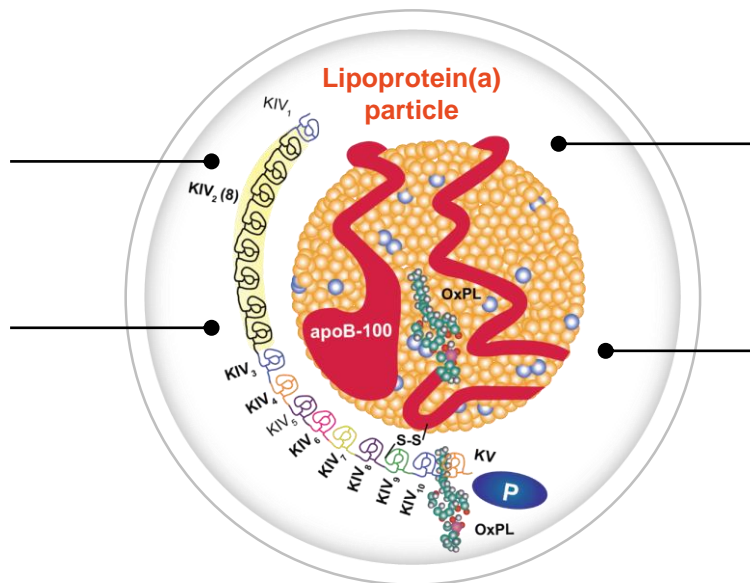
Rod Wooten

Global Head of Marketing
Novartis Pharmaceuticals

Lp(a) is an independent risk factor for ASCVD¹ that cannot currently be treated

Lp(a) is an **independent, inherited and causal risk factor** for CVD, with elevated Lp(a) mediating MI, stroke, and PAD

Lp(a) consists of an **LDL-like particle** which is covalently bound to apo(a)



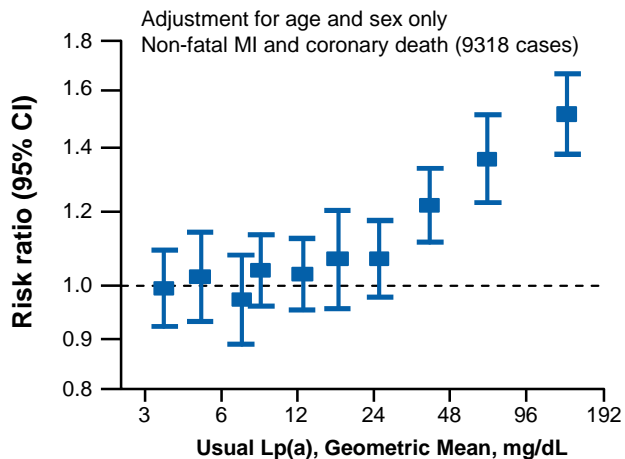
Lp(a) levels are primarily **genetically determined** and not influenced by diet or exercise

There are currently **no approved therapies** to treat elevated Lp(a)

ASCVD – Atherosclerotic Cardiovascular Disease Lp(a) – Lipoprotein a CVD – Cardiovascular Disease LDL – Low Density Lipoprotein MI – Myocardial Infarction PAD – Peripheral Artery Disease Apo(a) – Apolipoprotein(a)
ApoB-100 – Apolipoprotein B-100 KIV – Kringle IV. Lp(a) figure adapted from Tsimikas S. J Am Coll Cardiol 2017;69:692–711. 1. The effect of pelacarsen on cardiovascular morbidity and mortality is currently being studied in the HORIZON trials. Note: pelacarsen is an investigational product.

Elevated Lp(a) increases cardiovascular risk⁵ ~2-fold, a level similar to LDL-C

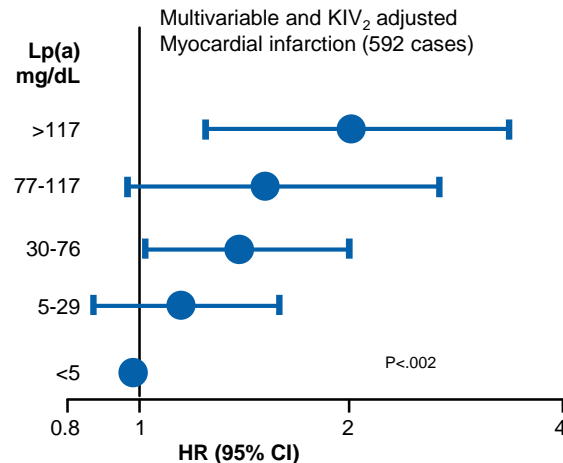
Lp(a) is an independent, genetic and causal risk factor for MI, stroke and PAD^{1,2,3}



Emerging Risk Factors Collaboration

Individual records of 126,634 participants in 36 long-term, prospective epidemiological studies

Elevated Lp(a) increases risk for CV-events ~2-fold^{1,3,4}



Emerging Risk Factors Collaboration

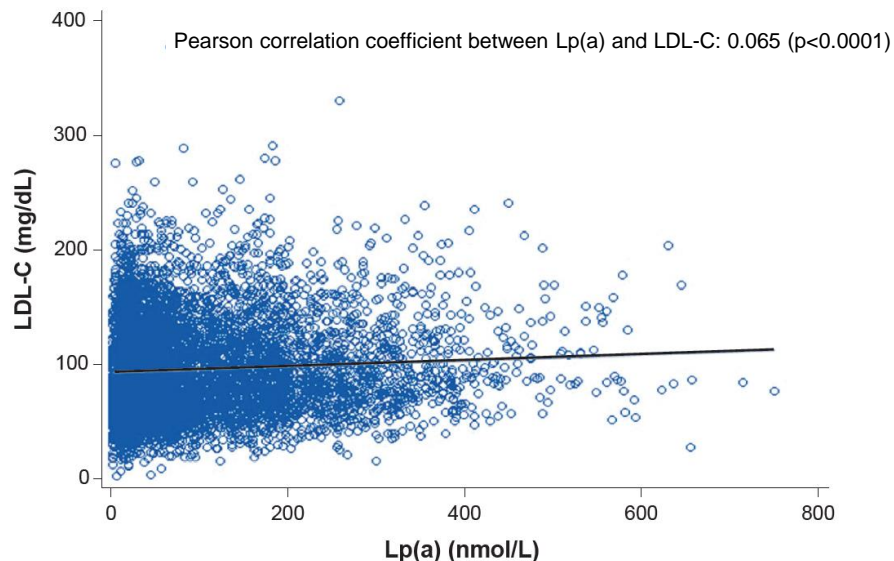
Individual records of 126,634 participants in 36 long-term, prospective epidemiological studies

CI – Confidence Interval CV – Cardiovascular KIV – Kringle IV Lp(a) – Lipoprotein(a) 1. Tsimikas S. J Am Coll Cardiol. 2017;69:692-711; 2. Erquo S et al. JAMA. 2009;302(4):412-23; 3. Kamstrup PR et al. JAMA. 2009;301(22):2331-9; 4. 2x fold increase if considering 50 mg/dL as high. 5. The effect of pelacarsen on cardiovascular morbidity and mortality is currently being studied in the HORIZON trials. Note: pelacarsen is an investigational product.

The correlation between Lp(a) and LDL-C is weak, thus separate treatment approaches are required

ACC.21

Correlation between Lp(a) and LDL-C values is weak



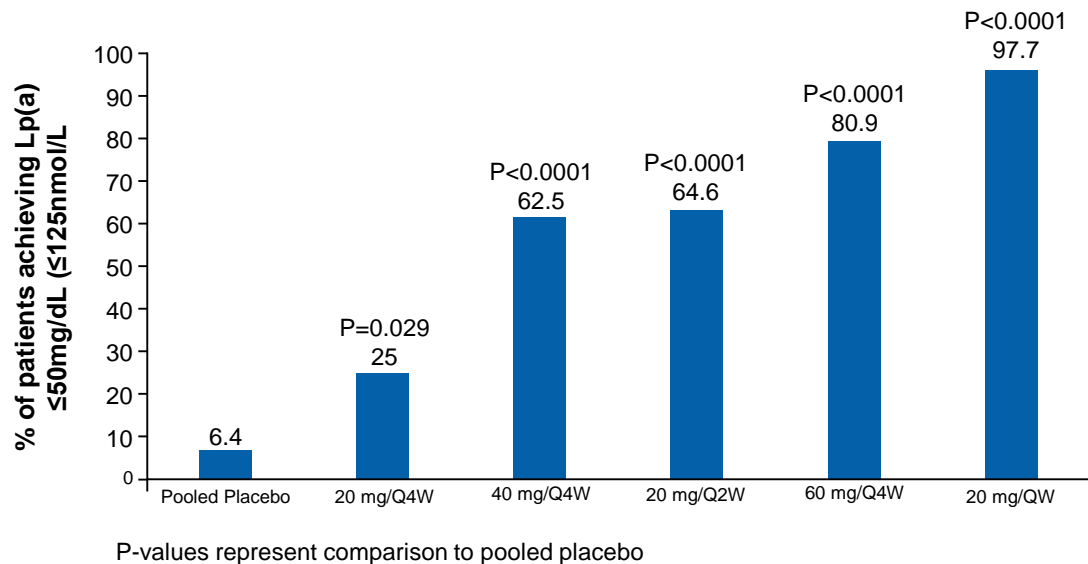
- In the US, Lp(a) is elevated in more than **25% of patients with ASCVD**
- However, **Lp(a) is rarely measured (0.4%)** in routine clinical practice
- The **weak association of Lp(a) and LDL-C** suggests it is not possible to impute Lp(a) levels by measuring LDL-C
- Reinforces **need for separate Lp(a) testing** in ASCVD patients as part of the CV risk profile assessment¹

LP(a) – Lipoprotein a LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease CV – Cardiovascular Source: Lahoz Lp(a) distribution and correlation with LDL-C in patients with atherosclerotic cardiovascular disease (ASCVD) in the US. 1. The effect of pelacarsen on cardiovascular morbidity and mortality is currently being studied in the HORIZON trials. Note: pelacarsen is an investigational product.

In Phase 2b, pelacarsen significantly reduced Lp(a) in CVD patients

Ph2b results – pelacarsen vs. placebo

NEJM Tsimikas, et al. 2020



Ph2b data showed:

- Lp(a) levels were reduced to ≤50mg/dL in 98% of CVD patients following treatment with pelacarsen 20mg once a week
- Dose-dependent Lp(a) reductions up to 80%
- Good tolerability and safety profile

80mg monthly is being evaluated in Ph3

Lp(a) - Lipoprotein a CVD - Cardiovascular Disease QW - once a week Source: Tsimikas, et al. N Engl J Med. 2020;382(3):244-255. Note: pelacarsen is an investigational product.

Prevalence study and Ph3 outcome study ongoing with expected readouts in 2021 and 2024

Prevalence study



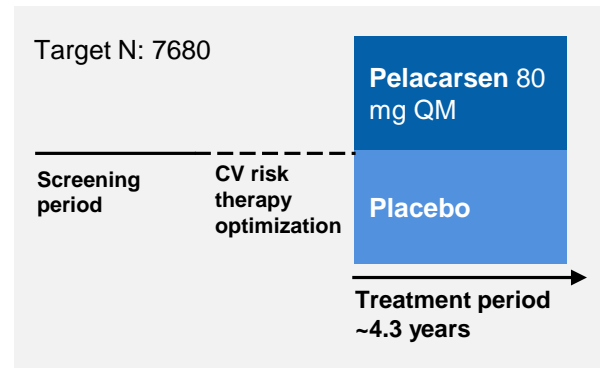
- Study to evaluate prevalence of elevated Lp(a) levels in patients with established CVD
- ~45,000 patients, > 900 sites in 48 countries
- Study initiated April 2019
- Study results expected 2021

Phase 3 outcome study



- CV outcome trial to assess effect of pelacarsen on MACE in patients with established CV disease and elevated Lp(a) on optimal therapy for other risk factors¹
- Pioneering trial to evaluate impact of Lp(a) lowering on CV outcomes
- Study initiated December 2019
- Primary outcome: 2024

Trial design



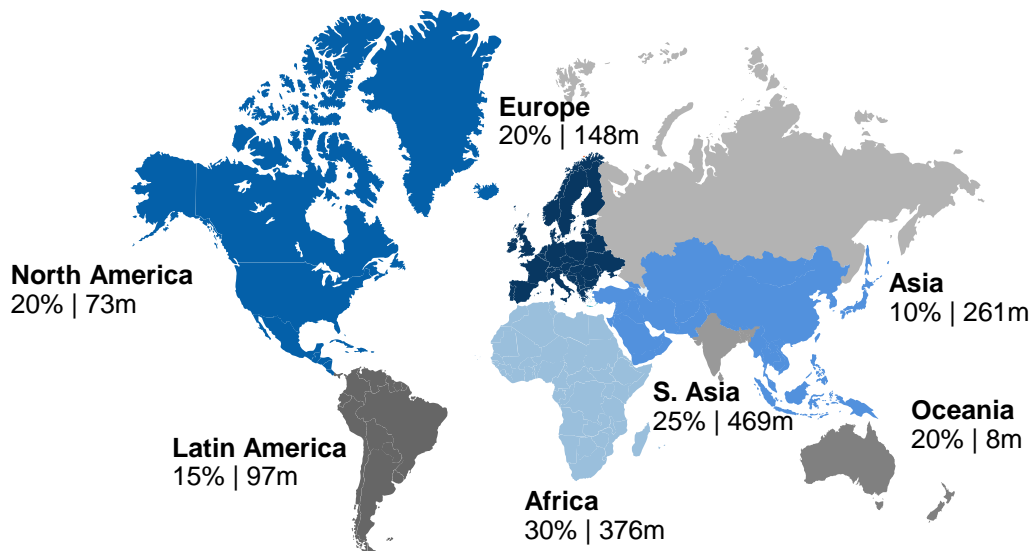
CV – Cardiovascular MACE - Major Adverse Cardiovascular Event Lp(a) – Lipoprotein a 1. <https://clinicaltrials.gov/ct2/show/NCT04023552>. Note: pelacarsen is an investigational product.

Elevated Lp(a) is highly prevalent and one of the strongest genetic CVD risk factors¹⁻⁶

1 in 5 people worldwide have elevated Lp(a)^{*1,2}

- 1.4 billion people have elevated Lp(a)^{*}, increasing their ASCVD risk^{1,2}
- Lp(a) is both the **most common monogenic CVD risk factor** and one of the strongest genetic CVD risk factors²⁻⁵

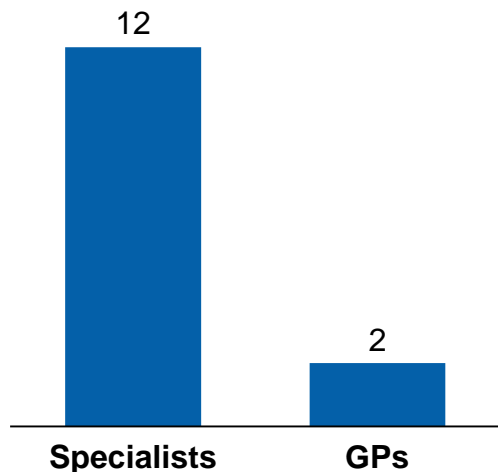
The prevalence of elevated Lp(a)^{*} varies by geography



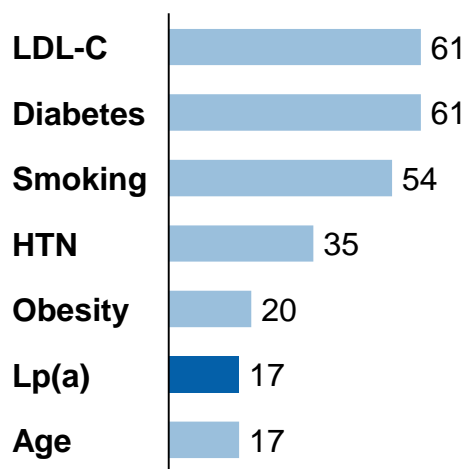
LP(a) – Lipoprotein a CVD – Cardiovascular Disease *LP(a) >50 mg/dL or >125 nmol/L. 1. Tsimikas S et al. J Am Coll Cardiol. 2018;71(2):177–192. 2. Tsimikas S, Stroes ESG. Atherosclerosis 2020;300:1–9. 3. Nordestgaard BG, Langsted A. J Lipid Res. 2016;57:1953–75. 4. Tsimikas S. J Am Coll Cardiol. 2017;69(6):692–711. 5. Clarke R et al. N Engl J Med. 2009;361(26):2518–2528. 6. The effect of pelacarsen on cardiovascular morbidity and mortality is currently being studied in the HORIZON trials. Note: pelacarsen is an investigational product.

Awareness of Lp(a) and testing are low among ASCVD patients

Unaided awareness of Lp(a) as CV risk factor (%)

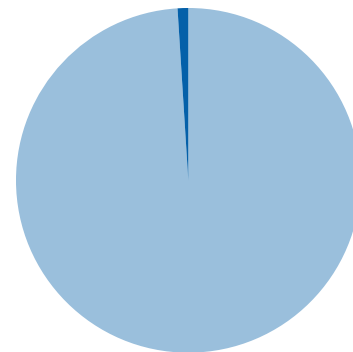


Perceived relative importance of CV risk factors (%)



Share of ASCVD patients tested for Lp(a) in US

Not tested: >99%
Tested: <1%



Lp(a) – Lipoprotein a CV – Cardiovascular LDL-C – Low Density Lipoprotein Cholesterol HTN – Hypertension ASCVD – Atherosclerotic Cardiovascular Disease Source: Physician ATU report (2020)

Need to test for Lp(a) is growing in clinical guidelines



NLA

- **Lp(a) screening:** All adults with personal or family history of premature ASCVD, severe hypercholesterolemia, suspected FH
- **Lp(a) threshold:** **>50** mg/dL (>100 nmol/L) for ASCVD
- **Treatment:** Consider intensification of treatment of LDL and other risk factors



ESC/ EAS

- **Lp(a) screening:** All adults once in a lifetime
- **Lp(a) threshold:** None for ASCVD. Primary prevention patients with **>180** mg/dL (>430 nmol/L) CV risk equivalent to HeFH
- **Treatment:** Consider intensification of treatment of LDL and other risk factors

Lp(a) – Lipoprotein a NLA – National Lipids Association ASCVD – Atherosclerotic Cardiovascular Disease LDL-C – Low Density Lipoprotein Cholesterol ESC/ EAS – European Society of Cardiology/ European Atherosclerosis Society
FH – Familial Hypercholesterolemia CV – Cardiovascular HeFH - Heterozygous Familial Hypercholesterolemia. Note. The effect of pelacarsen on cardiovascular morbidity and mortality is currently being studied in the HORIZON trials.
Pelacarsen is an investigational product.

Synergies with Leqvio® and Entresto® commercially

Synergy at the customer level, building on existing strong presence

Cardiologists, endocrinologists, lipid specialists and PCPs who manage LDL-C also expected to treat Lp(a)

Leqvio® medical teams can provide **education** on Lp(a) early on

Leqvio® commercial teams can generate **health system insights** on comprehensive ASCVD management

Ongoing close **dialogue with medical societies** issuing CV guidelines

There is overlap in patients as well as a unique pool for pelacarsen¹

Like the overall ASCVD population, **~50% of Lp(a) patients** have LDL>100 mg/dL²

HCP – Healthcare Professional Lp(a) – Lipoprotein a LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease CV – Cardiovascular 1. Arterioscler Thromb Vasc Biol. 2016;36:2239-2245. DOI: 10.1161/ATVBAHA.116.308011. 2. Arterioscler Thromb Vasc Biol. 2016;36:2239-2245. DOI: 10.1161/ATVBAHA.116.308011. Note: pelacarsen is an investigational product. The effect of pelacarsen on cardiovascular morbidity and mortality is currently being studied in the HORIZON trials.

Pelacarsen summary

Lp(a) is a causal, **independent risk factor** for ASCVD

Currently, **no specific pharmacologic treatments**, but access to Lp(a) levels can guide HCPs to optimize the management of other risk factors

Awareness of Lp(a) is low and the **rate of testing is low** among ASCVD patients

In Phase 2b, **pelacarsen significantly reduced Lp(a)** in CVD patients

Potentially **commercial synergies** with Leqvio[®] and Entresto[®]

ASCVD – Atherosclerotic Cardiovascular Disease CVD – Cardiovascular Disease Lp(a) – Lipoprotein a HCP – Healthcare Professional Note: pelacarsen is an investigational product. The effect of pelacarsen on cardiovascular morbidity and mortality is currently being studied in the HORIZON trials.

Novartis leading cardiovascular portfolio and capabilities

2015



Essential first choice for chronic heart failure

~15m patients

2020



Potential to tackle LDL-C related ASCVD at scale

~60m patients

~2025

pelacarsen (TQJ230)

Potential to lower CV risk for people with elevated Lp(a)

- ✓ High unmet need: CV disease leading cause of mortality
- ✓ **Strong worldwide commercial and scientific** presence
- ✓ Deep understanding of customer needs across primary and specialty care

LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease CV – Cardiovascular Lp(a) – Lipoprotein(a) Note: Dates refer to first launch for Entresto® and Leqvio®, to submission for pelacarsen. Population numbers refer to US & EU5 (Germany, France, Spain, Italy, UK). Source: Decision Resources Group.

Q&A session



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Appendix

Cardio, Renal, Metabolism pipeline

Phase 1

Code	Name	Mechanism	Indication(s)		
MBL949	MBL949	-	Obesity related diseases		

Phase 2

Code	Name	Mechanism	Indication(s)		
CFZ533	iscalimab	CD40 inhibitor	Lupus nephritis	T1DM	
HSY244	HSY244	-	Atrial fibrillation		
LMB763	nidufexor	FXR agonist	Diabetic nephropathy		
LNP023	iptacopan	CFB inhibitor	C3G	iMN	aHUS

Phase 3

Code	Name	Mechanism	Indication(s)		
KJX839	Leqvio®	siRNA (regulation of LDL-C)	CVRR-LDLC	Ped Hyperlipidemia	
LCZ696	Entresto®	Angiotensin receptor/neprilysin inhibitor	Post-AMI	Pediatric CHF ³⁾	
LNP023	Iptacopan	CFB inhibitor	PNH	IgAN	
TQJ230	Pelacarsen	ASO targeting Lp(a)	CVRR-Lp(a)		

In registration

Code	Name	Mechanism	Indication(s)		
KJX839	Leqvio®	siRNA (regulation of LDL-C)	Hyperlipidemia		