Novartis Investor Relations

Leqvio® FDA approval

Investor call
December 23, 2021

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Agenda

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Samir Shah, Global Head of Investor Relations

Overview
Marie-France Tschudin, President of Novartis Pharmaceuticals

Leqvio® clinical data and label
David Soergel, MD, Head of Global Drug Development Cardio Renal Metabolism

US market and launch readiness
Victor Bulto, Head of Novartis Pharma US

Q&A
Samir Shah, Global Head of Investor Relations

Overview

Marie-France Tschudin
President of Novartis Pharmaceuticals

We are building on our strength in cardiovascular to fundamentally improve and extend patients' lives

2015

Entresto® sacubitril/valsartan

Essential first choice for chronic heart failure

~15m patients

2021

LEQVIO® inclisiran

Potential to tackle LDL-C in ASCVD at scale

~60m patients

~2025

pelacarsen (TQJ230)

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

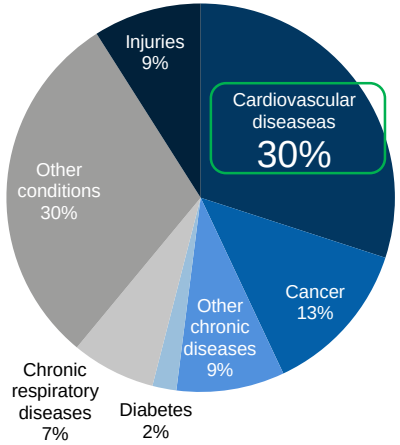
- ☑ High unmet need: CV disease leading cause of mortality
- ☑ Strong worldwide commercial and scientific presence
- ☑ Deep understanding of customer needs across primary and specialty care

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

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

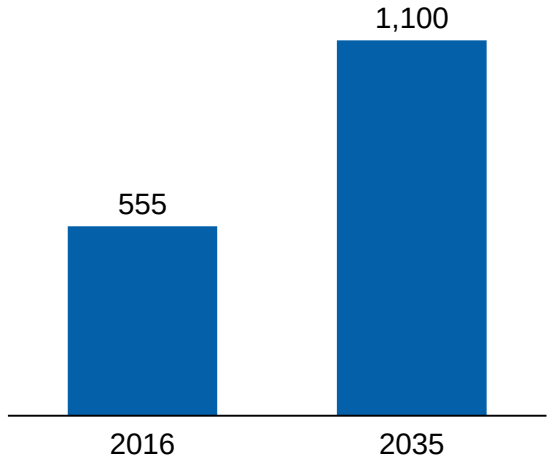
CVD accounts for more deaths than any other disease[1]

% of deaths



US CVD costs to surpass 1 trillion p.a. by 2035[2]

USD billion



30m patients with ASCVD in US[5]

900k lives lost to CVD annually in the US[3]

After years of decline, number of lives lost is rising again[4]

14% of health expenditure due to CVD, more than any major diagnostic group[6]

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. Includes direct and indirect costs. Source: AHA/ ASA Cardiovascular Disease: A costly burden for America. Projections through 2035. 3. Ahmad FB, Anderson RN. The leading causes of death in the US for 2020. JAMA. 2021;325(18):1829-1830. 4. Virani SS, et al. Heart Disease and Stroke Statistics—2021 Update: A Report From the American Heart Association. Circulation. 2021;143(8): e254–e743. Accessed July 17,2021. 5. Wong ND et al. J Clin Lipidol. 2016;10(5):1109-1118. 6. Virani SS et al. Circulation. 2020;141(9):e139-e596. Note: The effect of Leqvio® on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 and VICTORION-2P trials.

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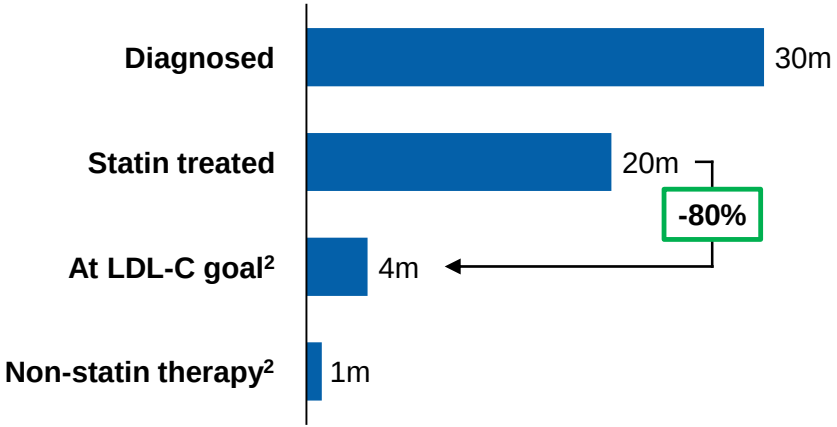
In the US, Leqvio® is positioned to meet the needs of 80% of statin-treated ASCVD patients currently not at LDL-C goal

US ASCVD patient population[1]



Leqvio® is uniquely positioned to address unmet needs in ASCVD

A1 Adherence

Effective and sustained[4] LDL-C reduction with **two doses per year**[3], generally well-tolerated[1]

A2 Access

Medical benefit coverage for majority of patients at launch

A3 Affordability

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

ASCVD – Atherosclerotic Cardiovascular Disease. LDL-C – Low Density Lipoprotein Cholesterol. 1. Ray KK, et al. N Engl J Med. 2020;382(16):1507-1519. 2. Non-statin lipid lowering therapies include ezetimibe and PCSK9i mAbs. 3. After an initial dose, again at 3 months, and again every six months thereafter. 4. Across the 6-month dosing interval.

Leqvio®
clinical data and label

David Soergel, MD
Head of Global Drug Development
Cardiology, Renal, Metabolism

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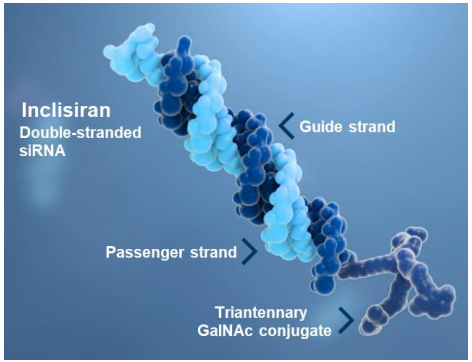
Leqvio® provides an innovative and differentiated approach to lowering LDL-C in ACSVD patients

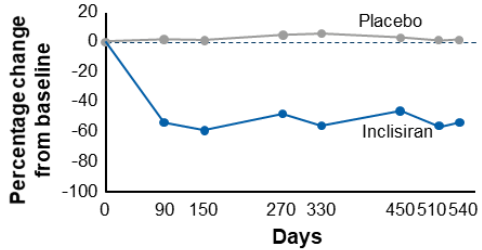
First and only siRNA LDL cholesterol lowering treatment[4,5]



Effective and sustained[3] LDL-C reduction[1]

ORION-10

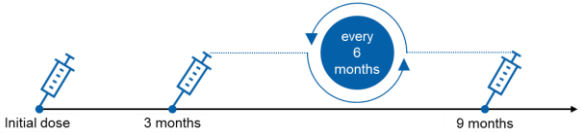
Percentage change in LDL



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 scheme[3]



May integrate seamlessly into a patient's health care routine

LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease siRNA – small interfering Ribonucleic Acid 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. Khvorova A, et al. N Engl J Med. 2017;376:4-7 5. Fitzgerald K, et al. N Engl J Med. 2017;376:41-51.

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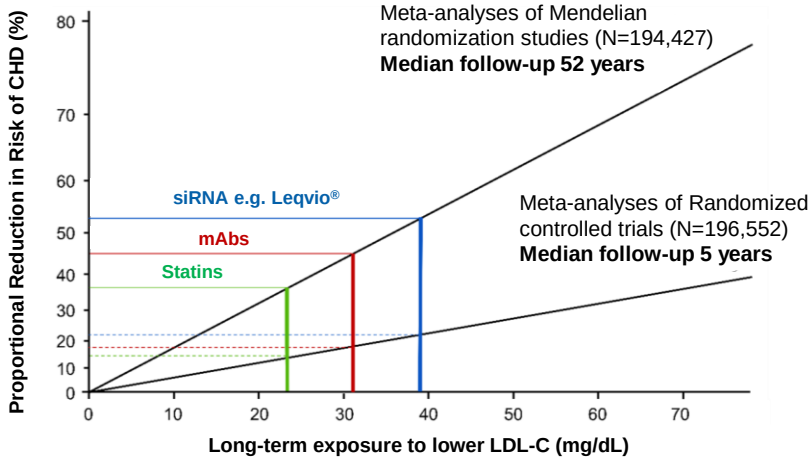
50 years of evidence demonstrate that effective and sustained LDL-C reduction improves cardiovascular outcomes*[1,2]

Log-linear association per unit change in LDL-C and the risk of cardiovascular disease[5]



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 year[3]

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. * Note: The effect of Leqvio® on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 and VICTORION-2P trials.

Guidelines recognize evidence of link between lower LDL-C and improved outcomes[3]

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 (2021)[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. Visseren FLJ et al. Eur Heart J. 2021; Sep 7; 42(34):3227-3337. 3. The effect of Leqvio® on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 trial.

Leqvio® delivers effective and sustained[3] LDL-C reduction of up to 52%[1,2] with twice-yearly[4] HCP-administered dosing

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

	% Change in LDL-C from baseline		Difference between groups (in mean percentage change)
	Leqvio®	Placebo	
ORION-10[5]	-51	1	**-52%** *(p < 0.0001)*
ORION-11[5,6]	-46[6]	4[6]	**-51%**[6] *(p < 0.0001)*
ORION-9[5]	-40	8	**-48%** *(p < 0.0001)*

LDL-C – Low Density Lipoprotein Cholesterol. ASCVD – Atherosclerotic Cardiovascular Disease. HCP – Healthcare Professional SoC – standard of care 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 HypercholesterolemiaFrederick 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. 4. After an initial dose, again at 3 months, and again every six months thereafter. As a strong complement to a maximally tolerated statin 5. Leqvio® prescribing information East Hanover, NJ. Novartis: 2021 6. ASCVD subjects only; ASCVD-Risk Equivalents excluded from analysis

Leqvio® has a well tolerated safety profile

No significant safety or tolerability concerns identified with the long-term* administration of Leqvio®[1,2]

	ORION-9 (n=481)[1]				ORION-10 (n=1,559)[2]				ORION-11 (n=1,615)[2]			
	Leqvio® n=241		Placebo n=240		Leqvio® n=781		Placebo n=778		Leqvio® n=811		Placebo n=804	
Safety population	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%

- Most common adverse events with similar frequency in Leqvio® and placebo groups
- Adverse events associated with Leqvio® were all mild or moderate in severity, transient and resolved without sequelae
- Common adverse reactions (≥ 3%) include injection site reaction, arthralgia, urinary tract infection, diarrhea, bronchitis, pain in extremity, and dyspnea

CV – Cardiovascular TEAE – Treatment Emergent Adverse Event * Over 18 months. 1. Inclisiran for the Treatment of Heterozygous Familial HypercholesterolemiaFrederick 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 CholesterolKausik 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.

Large integrated program to establish Leqvio® as part of the standard of care in ASCVD management

Lipid lowering	Outcomes	Healthcare system partnerships	Implementation science and RWE
Registration trials	**Secondary Prevention**	**NHS collaboration**	**Initiation of treatment**
ORION-3 (Ph2 extension) ORION-5 (Ph3 HoFH) ORION-8 (Ph3 extension)	ORION-4 (Oxford) VICTORION-2-PREVENT	VICTORION-SPIRIT (UK)	VICTORION-INITIATE (US)
Geographic expansion	**Primary Prevention**		**Post-ACS**
ORION-14 (China) ORION-18 (China) ORION-15 (Japan)	ORION-17 (Oxford)		VICTORION-INCEPTION (US)
Diverse patient populations			
ORION-13 (V-YOUTH) ORION-16 (V-YOUTH)			

>75,000 patients in >50 countries; Program expansion underway

ASCVD – Atherosclerotic Cardiovascular Disease. RWE – Real World Evidence

Leqvio® is now approved in the US with a label that contains no contraindications, warnings/precautions, or drug interactions

Indication statement[1]

Leqvio® is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (**ASCVD), who require additional lowering of low-density lipoprotein cholesterol (LDL-C).**

Limitations of use: The effect of Leqvio® on cardiovascular morbidity and mortality has not been determined.

16m addressable ASCVD patients not at LDL-C goal

Dosage and administration[1]

The recommended dosage of Leqvio®, in combination with maximally tolerated statin therapy, is 284 mg administered as a **single subcutaneous injection** initially, again at 3 months, and then **every 6 months**; Leqvio® should be **administered by a healthcare professional.**

May seamlessly integrate into a patient's health care routine

Medical benefit coverage expected

HeFH – Heterozygous Familial Hypercholesterolemia ASCVD – Atherosclerotic Cardiovascular Disease. LDL-C – Low Density Lipoprotein Choletsterol 1. Leqvio® prescribing information East Hanover, NJ. Novartis: 2021

US market and launch readiness

Victor Bulto
Head of Novartis Pharma US

Despite the availability of lipid-lowering therapy, significant unmet need remains in ASCVD

Clinical unmet need

80% of statin-treated ASCVD patients currently not at LDL-C goal[1]

Non-clinical unmet need

A1 Adherence

Real-world challenges to adherence compromise outcomes[2]

A2 Access

Considerable access hurdles for current treatments

A3 Affordability

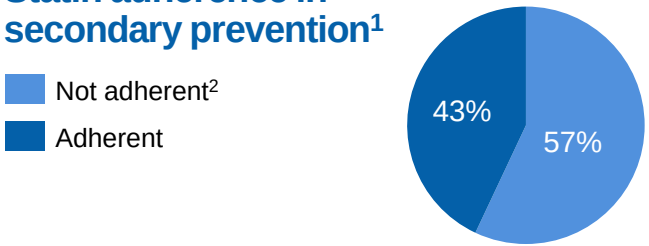
Patient out-of-pocket costs can be a barrier to access

ASCVD – Atherosclerotic Cardiovascular Disease LDL-C – Low Density Lipoprotein Choletsterol 1. Wong ND. Journal of Clinical Lipidology. 2016;10(5):1109–1118 2. The effect of Leqvio® on cardiovascular morbidity and mortality is currently being studied in the ongoing Phase III ORION-4 and VICTORION-2P trials.

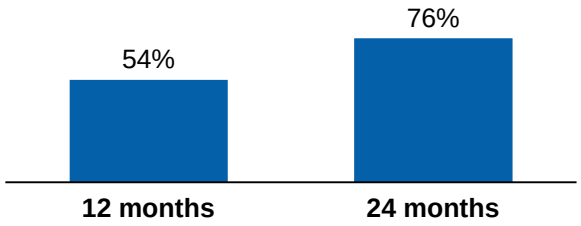
A1

Adherence – real-world challenges compromise outcomes[4]

Statin adherence in secondary prevention[1]

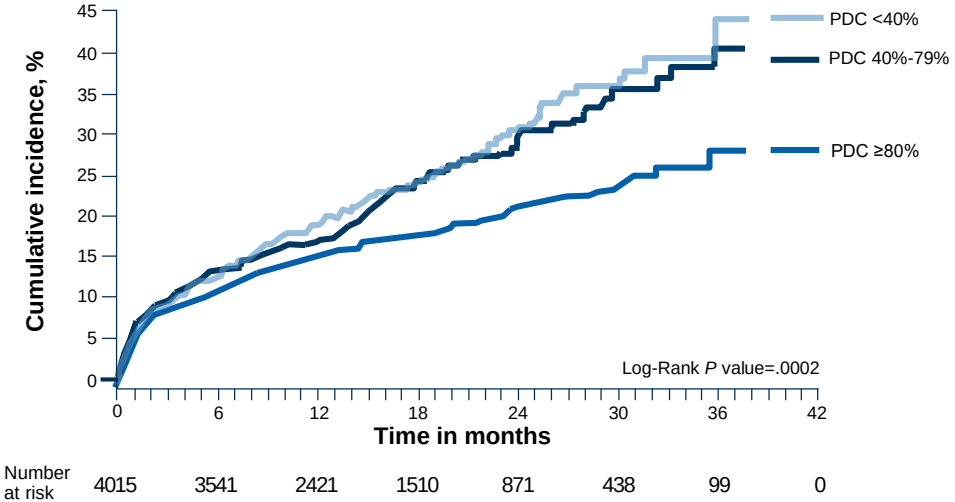


Non-adherent PCSK9i patient share[3]



Sustained lipid lowering reduces CV risk[1]

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 and VICTORION-2P trials.

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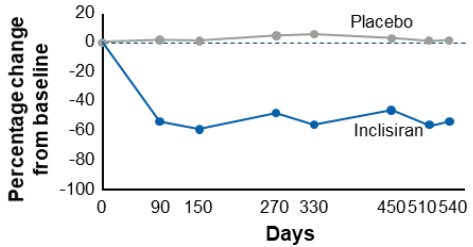
A1

Adherence – Leqvio® has the potential to address adherence challenges

Effective and sustained[3] LDL-C reduction[1]

ORION-10

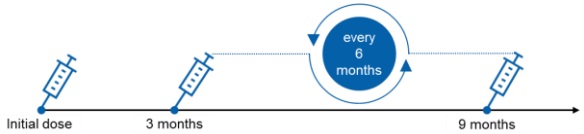
Percentage change in LDL cholesterol



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 scheme[3]



May integrate seamlessly into a patient's health care routine

HCP administered

No patient education on administration required

LDL-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.

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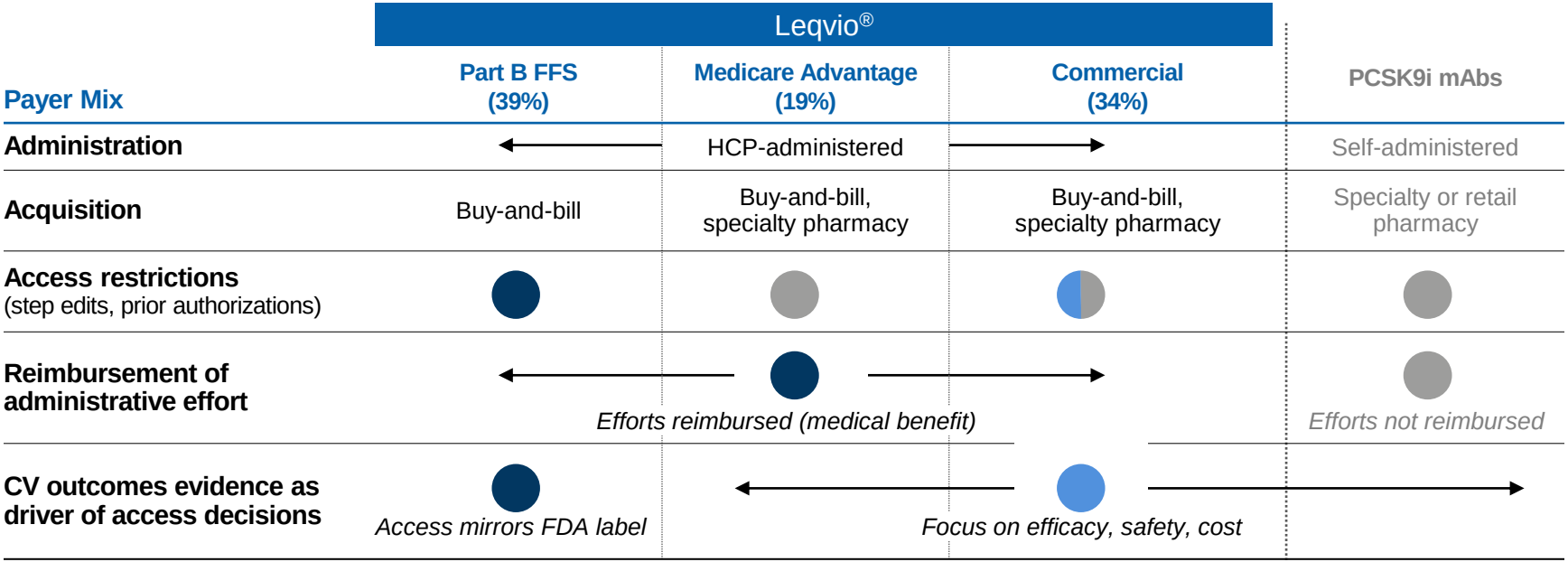
A2

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



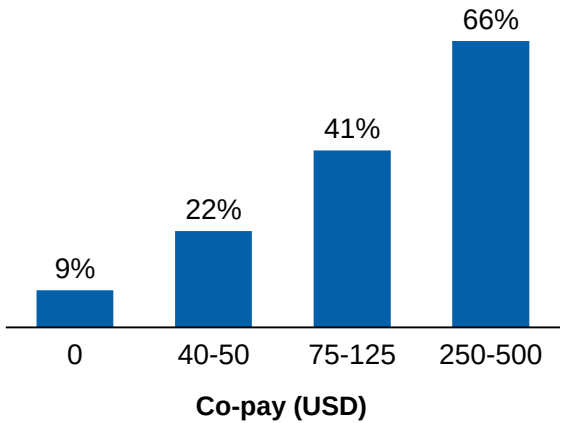
More favorable — Less favorable

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

A3

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

PCSK9i abandonment rate by OOP cost[1]



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
Commercial	34%	Eligible patients pay as little as 0 USD
Medicare Advantage	19%	Varies; 0-20% co-insurance
Other (Medicaid, federal)	8%	<10 USD

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

PCSK9i - Proprotein convertase subtilisin/kexin type 9 inhibitor OOP – Out Of Pocket 1. LAAD; IQVIA US Market Access Strategy Consulting.

The price of Leqvio® reflects its value as an innovative, LDL-lowering treatment that uniquely addresses key unmet needs in ASCVD

Clinical benefits of Leqvio®

Efficacy

Leqvio® provides effective and sustained LDL-C reduction up to 52% vs. placebo[1,2]

Safety

Leqvio® offers a demonstrated safety profile, generally well tolerated across different patient populations

Non-clinical benefits of Leqvio®

Adherence

Effective and sustained LDL-C reduction with two HCP-administered doses per year[3]

Access

Medical benefit coverage for majority of patients at launch

Affordability

2/3 of patients pay as little as $0 co-pay at launch

$3,250	Price per dose (WAC)
x2	Doses per year[3]
$6,500	Annualized price

- Value-based
- Cost-effective

LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease HCP – Healthcare Professional WAC – Wholesale Acquisition Cost 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. After an initial dose, again at 3 months, and again every six months thereafter. As a strong complement to a maximally tolerated statin

Leqvio® go-to-market model: systems engagement, complemented by broad HCP education with CRM sales team

	Systems of care	HCPs
Targets customers	▪ ~200 prioritized systems ▪ 45% currently prioritize ASCVD[2]	▪ Representing ~60% of NBRx volume[1]
Engagement approach	▪ Cross-functional teams engaged with key systems stakeholders ▪ Aim to ensure protocols in place to identify and manage ASCVD patients not at goal	▪ Leveraging strong commercial CRM footprint ▪ Highlighting unmet need and raise importance of LDL-C
Leqvio® pathway	▪ May leverage existing buy-and-bill infrastructure or refer to an alternative injection center	▪ May administer in-office or refer to alternative injection center

ASCVD – Atherosclerotic Cardiovascular Disease HCP – Healthcare Professional CV – Cardiovascular CRM – Cardiovascular, Renal, Metabolic LDL-C – Low Density Lipoprotein Cholesterol 1. Data on file. 2. Data on file

Flexibility, support and optionality will ensure seamless customer experience and timely access to Leqvio®

Flexibility
of acquisition and administration

Robust network of >1,100 AICs

- ✓ ~75% of target HCPs have an AIC within 25 miles
- ✓ AIC locator tool available to providers and patients

Support
with initial acquisition and reimbursement complexity

Largest access and reimbursement field team in the industry

- ✓ Establishing buy-and-bill infrastructure
- ✓ Understanding coding and reimbursement
- ✓ Navigating PA and medical exception process

Optionality
to address heterogenous customer needs

Dedicated case managers

- ✓ Benefit verification and coverage support
- ✓ Co-pay assistance
- ✓ Billing and coding support

Dedicated social workers

- ✓ Patient care program
- ✓ Adherence support

Leqvio® access and reimbursement website[1]

AIC – Alternative injection center HCP – Healthcare Professional PA – Prior Authorization 1. Leqvio-access.com

Expect modest initial ramp as we lay the foundation for multi-blockbuster potential

H1 2022 – laying foundation

- High interest from early adopters
- Independent HCPs ready for buy-and-bill
- AICs responding to demand
- Temporary J-code
- Coverage to label for FFS Medicare

H2 2022 – getting to scale

- Permanent J-code available
- Buy-and-bill capabilities established
- System P&T committee review complete
- Finalization of commercial & Medicare Advantage payer coverage policies

Lead indicators

# of health systems/ facilities adopting Leqvio®	# of systems with repeat orders	# of AIC facilities administering Leqvio®	Intent to prescribe

HCP – Healthcare Professional AIC – Alternative Injection Center P&T – Pharmacy and Therapeutics FFS – Fee For Service

Confident in successful US launch

- Effective and sustained LDL-C reduction[1] with twice a year maintenance dose administered by HCP
- Broad label covering 16m US ASCVD patients not at LDL-C goal
- Go-to-market model designed to overcome clinical barriers and address access, adherence and affordability
- Sales, reimbursement and medical teams with deep experience in the US cardiovascular market
- Robust network of AICs to provide acquisition and administration flexibility
- Value-based price per dose (USD 3,250)
- Comprehensive patient and HCP support programs available at launch to ensure timely access
- Product available from specialty distributors in early January

LDL-C – Low Density Lipoprotein Cholesterol ASCVD – Atherosclerotic Cardiovascular Disease AIC – Alternative Injection Center HCP – Healthcare Professional 1. Across the 6-month dosing interval.

Q&A

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Thank you

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