

Dyslipidaemia: KOL Insight

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Abstracts

Effective but expensive: will PCSK9 inhibitors find widespread use in cardiology?

PCSK9 inhibitors could be game changers for dyslipidaemia patients. But high cost and long-term safety questions have relegated them to third-line use. Can they move up the treatment algorithm? If so, how will they compete with other recently-approved, and pipeline drugs?

Find out in FirstWord's new report, KOL Insight: Dyslipidaemia. Request sample pages now.

Covering 9 recently marketed drugs, and 6 currently in clinical trials, the report reveals candid insights about the dyslipidaemia landscape from 12 key opinion leaders (KOLs) in North America and Europe.

You'll learn whether competition from Pfizer's pipeline PCSK9 inhibitor, bococizumab can push down prices, how outcomes trials will influence PCSK9 inhibitor use, and which of the myriad pipeline drugs—mainly gene/antisense therapies and small molecules aimed at niche patient populations—are likely to succeed.

Expert insight into the dyslipidaemia treatment landscape

The report covers 9 marketed dyslipidaemia drugs and 6 pipeline therapies currently in Phase III trials:

Recently Marketed Drugs

Praluent (alirocumab; Regeneron/Sanofi): Are Praluent and Repatha well differentiated? Can one brand gain a competitive advantage?



Repatha (evolocumab; Amgen): Do KOLs expect cardiovascular outcome studies to clarify Repatha's position in the treatment algorithm?

Statin FDC combinations

Cholib (simvastatin/fenofibrate; AbbVie): What are the key differences between Cholib's and Liptruzet's target patient populations?

Liptruzet (atorvastatin/ ezetimibe; Merck & Co.): Do KOLs prefer statin/ezetimibe combinations like Liptruzet or fenofibrate combinations like Cholib?

Omega-3 fish oils

Vascepa (icosapent ethyl; Amarin): Do minor differences between Vascepa and Epanova translate into clinical benefits for either brand?

Epanova (omega-3 carboxylic acids; AstraZeneca): What are the key factors limiting prescriptions of branded Omega-3s like Epanova?

Gene therapy/antisense oligonucleotide

Glybera (alipogene tiparvovec; uniQure): Is Glybera's high cost justified? Do KOLs expect it to come down?

Kynamro (mipomersen; Sanofi): What factors will determine whether Kynamro reaches the European market?

MTP inhibitors

Juxtapid/Lojuxta (lomitapide; Aegerion Pharmaceuticals): What key advantage do MTP inhibitors offer over other dyslipidaemia drugs?

Pipeline Drugs

PCSK9 inhibitors

Bococizumab (Pfizer): How do KOLs expect bococizumab to compete with current PCKS9 inhibitors?



Antisense oligonucleotide

Volanesorsen (Ionis Pharmaceuticals): Are KOLs more optimistic about volanesorsen than previous antisense treatments?

Small molecule therapies

K877 (PPAR-alpha agonist; Kowa Pharmaceutical): What will determine whether K877 gains a foothold in the US and EU markets?

Anacetrapib (CETP inhibitor; Merck & Co.): Will anacetrapib fare better than other CETP inhibitors? How will clinical trial design affect its prospects?

Pradigastat (DGAT-1 inhibitor; Novartis): Why do some KOLs suspect that Novartis has ended the clinical programme for pradigastat?

Apabetalone/RVX-208 (BET protein inhibitor; Resverlogix): If approved, apabetalone is likely to be used in combination with other therapies. Which ones?

Top Takeaways

PCSK9 inhibitors are a true breakthrough: The first one in years. But KOLs question whether they'll see broader use. Find out what will determine their place in the treatment algorithm.

Promising outlook for gene and antisense therapies: KOLs are upbeat about the long-term prospects for gene- and antisense therapy. Does their optimism extend to current options?

Scepticism about small molecules: To date, pipeline small molecule therapies haven't fully won KOLs over. Will they find a place in the treatment algorithm?

Tough times for Omega-3s: Availability of over-the-counter (OTC) products isn't the only factor limiting uptake of Omega-3s. Find out what else is preventing more widespread use.



Reimbursement is challenging: The high cost of some new dyslipidaemia treatments has raised questions about whether these drugs are worth it, and whether payers are likely to reimburse.

Safety is a key concern: Concerns about side effects and long-term safety hang over several newer dyslipidaemia drugs. Find out what they are and how KOLs expect them to influence use.

Trial design is critical: Some companies are developing new generations of drugs that have fared poorly in the past. Can careful clinical trial design help them show more positive results?

Themes Explored

Uncertainty about the treatment algorithm: How will the dyslipidaemia treatment algorithm change? It's too early to tell. KOLs don't have the information they need to determine where most newly-approved and pipeline drugs will ultimately be positioned.

Potential for niche and combination treatments: Despite lukewarm feelings about some of the newer dyslipidaemia drugs, KOLs aren't ruling out the possibility that they'll be positioned as niche treatments for rare conditions, or used in combination therapies.

Future of statins: Nearly three decades in, statin use is still going strong. That's unlikely to change soon, as new treatment options focus on use with statins, or target statin-intolerant patients.

A report based on expert knowledge

We interviewed 12 KOLs from North America and Europe between 02/12/2015 and 08/01/2016.

North American KOLs

Peter Howard Jones, MD, FACP, FNLA. Director, Associate Professor, Methodist Diabetes & Metabolism Institute and Baylor College of Medicine, Houston, TX.

Sergio Fazio, M.D., Ph.D. Director, Professor, The Knight Cardiovascular



Institute of OHSU, Portland, Oregon.

Khurram Nasir, M.D., MPH. Research Director, Center for Prevention and Wellness Director, High-risk Cardiovascular Disease Clinic Baptist Health South Florida.

Nihar R. Desai, MD, MPH. Assistant Professor of Medicine & Investigator, Center for Outcomes Research and Evaluation, Yale School of Medicine. New Haven, CT.

James Underberg, MD. Clinical Assistant Professor of Medicine, NYU Medical School, New York.

Paul Hopkins, MD, MSPH. Professor of Internal Medicine, University of Utah School of Medicine. Salt Lake City, UT.

European KOLs

Philippe Moulin, MD, Ph.D. Consultant Physician & Professor, University Claude Bernard, Lyon, France.

Leopoldo Pérez de Isla. Associate Professor, Servicio de Cardiología, Hospital Clínico San Carlos, Madrid, Spain.

Anthony S. Wierzbicki, BA (MA), BMBCh, DPhil, FRCP, DM (Oxon). Consultant Physician & Professor, Guy's and St Thomas' NHS Foundation Trust, King's College London, UK

Alberico Catapano, Ph.D. Professor of Pharmacology at the University of Milano, Italy.

German KOL (Anonymous). Professor of cardiology at a leading university hospital in Germany.

German KOL (Anonymous). Professor of internal medicine at a leading university in Germany.



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Contents

- **1. EXECUTIVE SUMMARY**
- 2. RESEARCH OBJECTIVES

3. RESEARCH FOCUS

3.1. Dyslipidaemia treatment

4. MARKETED THERAPIES

4.1. Overview

5. PCSK9 PROTEIN INHIBITORS

- 5.1. Recently marketed drugs
 - 5.1.1. Praluent (alirocumab; Regeneron, Sanofi)
 - 5.1.2. Repatha (evolocumab; Amgen)

6. STATIN FDC COMBINATIONS

- 6.1. Overview
- 6.2. Recently marketed drugs
 - 6.2.1. Cholib/Zolip (fenofibrate/simvastatin; AbbVie)
 - 6.2.2. Liptruzet (atorvastatin/ezetimibe; Merck & Co.)

7. OMEGA-3 FISH OILS

- 7.1. Overview
- 7.2. Recently marketed drugs
 - 7.2.1. Epanova (omega-3 carboxylic acids; AstraZeneca)
 - 7.2.2. Vascepa (ethyl eicosapentaenoic acid; Amarin)

8. GENE THERAPY/ ANTISENSE OLIGONUCLEOTIDE

- 8.1. Overview
- 8.2. Recently marketed drugs
 - 8.2.2. Glybera (alipogene tiparvovec; uniQure)



8.2.3. Kynamro (mipomersen; Sanofi)

9. MTP INHIBITORS

- 9.1. Overview
- 9.2. Recently marketed drugs
- 9.2.2. Juxtapid/Lojuxta (Iomitapide; Aegerion Pharmaceuticals)

10. PIPELINE THERAPIES

10.1. Overview

11. PPAR-ALPHA AGONISTS

- 11.1. Overview
- 11.2. K877 (Kowa Pharmaceutical)

12. PCSK9 INHIBITORS

- 12.1. Overview
- 12.2. Bococizumab (Pfizer)

13. CETP INHIBITORS

- 13.1. Overview
- 13.2. Anacetrapib (Merck & Co.)

14. DGAT-1 INHIBITORS

- 14.1. Overview
- 14.2. Pradigastat (Novartis)

15. APOLIPOPROTEIN C-III (APOC-III) INHIBITOR

- 15.1. Overview
- 15.2. Volanesorsen (Ionis Pharmaceuticals)

16. BET PROTEIN INHIBITOR



16.1. Overview

16.2. Apabetalone/RVX-208 (Resverlogix)

17. CONCLUSION

17.1. Current and future treatment algorithm

18. APPENDIX

18.1. KOL biographies18.1.2. KOLs from North America18.1.3. KOLs from Europe



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