TANDEM Topline Results

November 20, 2024

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TANDEM

Results overview

- TANDEM successfully met all co-primary endpoints with statistical significance:
  - FDC vs. placebo
  - FDC vs. ezetimibe
  - FDC vs. obicetrapib monotherapy, and
  - Obicetrapib vs. placebo

- Continued support for potential synergistic benefit of the combination, highlighting potential benefit beyond convenience

- Safety results consistent with our prior studies

- Growth of ezetimibe and non-statin therapies believed to support significant opportunity for the FDC, if approved

- Data supports global regulatory filings of the fixed-dose combination

Note: FDC = fixed-dose combination

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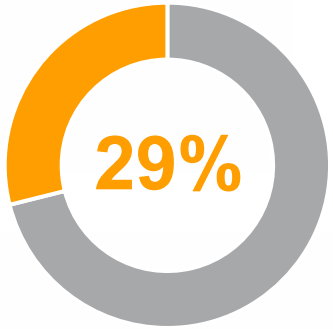
Majority of ASCVD/HeFH Patients have not Demonstrated Achievement of LDL-C Targets

Primary prevention HeFH patients with an LDL-C target <100 mg/dL (2011-2017)[1]

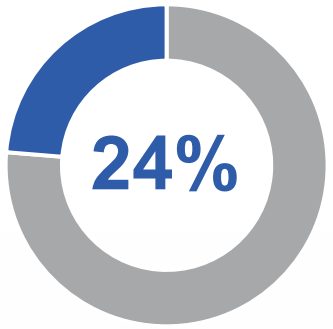
LDL-C < 100 mg/dL



<1/3 achieved LDL-C <100 mg/dL

ASCVD patients with an LDL-C target of LDL<70 or <55 mg/dL (2017-2018)[2]

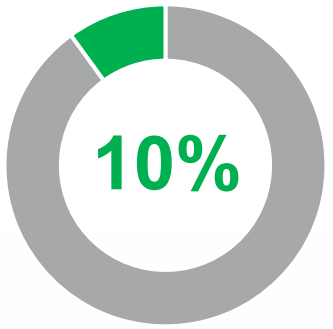
LDL-C < 70 mg/dL



<1/4 achieved LDL-C <70 mg/dL

Very high risk ASCVD patients with an LDL-C target <55 mg/dL (2020-2021)[3]

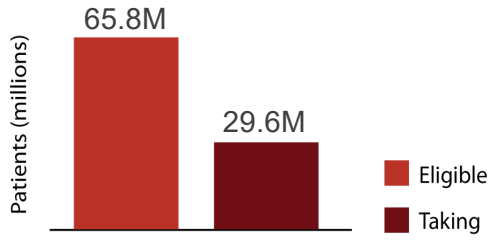
LDL-C < 55 mg/dL



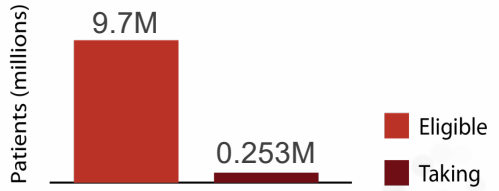
10% achieved LDL-C <55 mg/dL

Despite availability of treatments continue to see minimal uptake, especially adjunct to statins[4]

Statin Utilization



PCSK9i Utilization



ASCVD=atherosclerotic cardiovascular disease; HeFH=heterozygous familial hypercholesterolemia; LDL-C=low-density lipoprotein-cholesterol.

1. Schreuder MM, et al. LDL cholesterol targets rarely achieved in familial hypercholesterolemia patients: A sex and gender-specific analysis. Atherosclerosis. 2023 2. Gao Y, Shah LM, Ding J, Martin SS. US trends in cholesterol screening, lipid levels, and lipid-lowering medication use in US adults, 1999 to 2018. J Am Heart Assoc. 2023;12(3):e028205; 3. Katzmann JL, et al. Simulation study on LDL cholesterol target attainment, treatment costs, and ASCVD events with bempedoic acid in patients at high and very-high cardiovascular risk. PLoS One. 2022;17(10):e0276898; 4. J Am Heart Assoc 2022;11:3026075; doi: 10.1161/JAHA.122.026075

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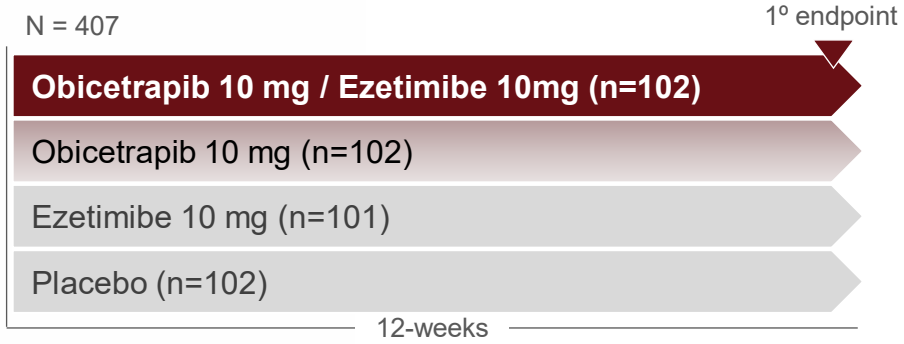
Study Design and Baseline Characteristics

A Placebo-Controlled, Double-Blind, Randomized, Phase 3 Study to Evaluate the Effect of Obicetrapib 10 mg and Ezetimibe 10 mg Fixed Dose Combination Daily on Top of Maximally Tolerated Lipid-Modifying Therapy in Participants With Heterozygous Familial Hypercholesterolemia (HeFH) and/or Atherosclerotic Cardiovascular Disease (ASCVD) or Multiple ASCVD Risk Factors

Study Design



Key Inclusion Criteria

- ASCVD
- ASCVD risk equivalents
- LDL-C≥ 70 mg/dL
- Maximally tolerated lipid lowering therapy

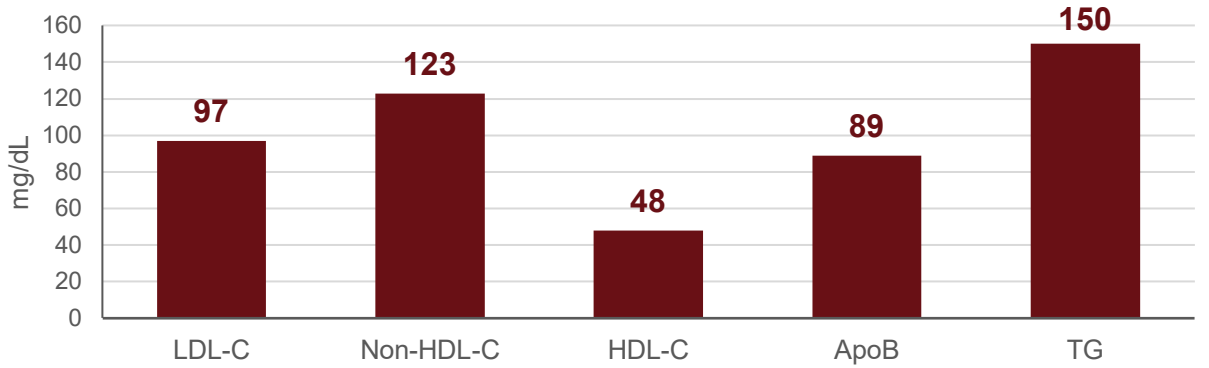
Key Exclusion Criteria

- Uncontrolled severe hypertension
- Diagnosis of homozygous FH

Endpoints

- Percent change from baseline in LDL-C compared to placebo
- Co-Primary Endpoints
  - FDC vs. Placebo
  - FDC vs. Eze
  - FDC vs. Obi
  - Obi vs. Placebo

Baseline Lipids (total study population)



Demographics

- Female 44%
- White 83%
- BMI 32 kg/m^3

Baseline Lipid Modifying Therapy

- High intensity statin: 71%

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Additional baseline details of all randomized patients

	Placebo (n=102)	Ezetimibe (n=101)	Obicetrapib (n=102)	Obicetrapib and Ezetimibe (n=102)
Mean Age (years)	66.1	67.6	66.7	67.3
Sex (F) n (%)	51 (50.0%)	45 (44.6%)	33 (32.4%)	48 (47.1%)
Race n (%)				
White	84 (82.4%)	82 (81.2%)	85 (83.3%)	86 (84.3%)
African American	17 (16.7%)	13 (12.9%)	15 (14.7%)	14 (13.7%)
Height, cm (mean)	169.9	171.2	169.8	168.8
Weight, kg (mean)	91.7	92.0	92.0	93.6
BMI (mean)	31.7	31.1	31.7	32.8
High intensity statin	75 (73.5%)	71 (70.3%)	66 (64.7%)	75 (73.5%)

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Obicetrapib/ezetimibe FDC observed to lower LDL-C approx. 50%

	Ezetimibe (n=101)	Obicetrapib (n=102)	Obicetrapib and Ezetimibe (n=102)
Day 84 – from placebo			
Mean %	-23.3	-35.5	**-52.2**
Median %	-22.6	-37.2	**-54.0**
LS mean %	-20.7	-31.9	**-48.6**
Comparison to pbo	-	(p<0.0001)	**(p<0.0001)**
Comparison to eze 10 mg	-	-	**(p<0.0001)**
Comparison to obi 10 mg	-	-	**(p=0.0007)**

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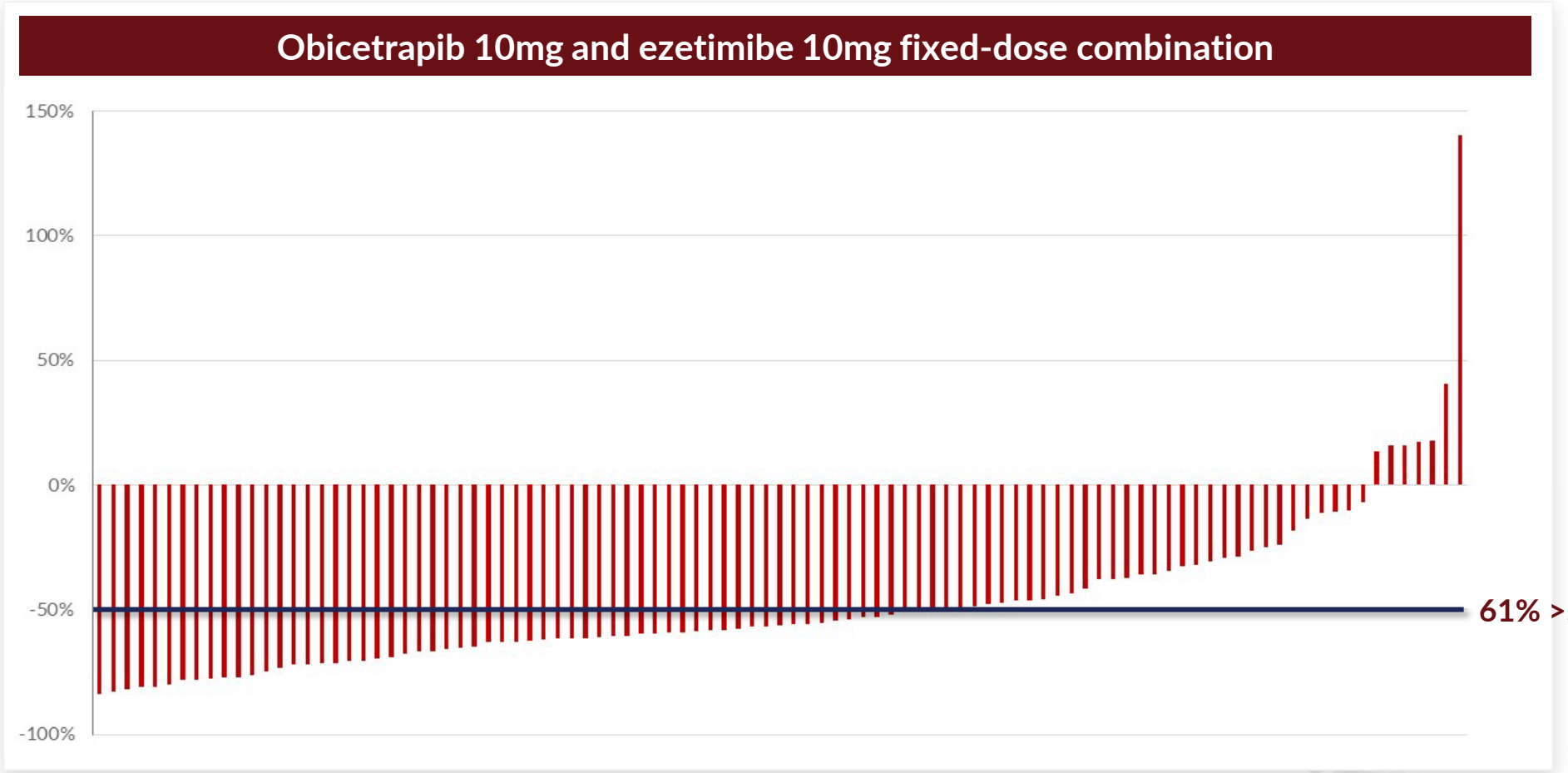
Over 60% of individuals on the FDC saw a more than 50% decrease in LDL-C



Note: each line represents a single patient in the fixed-dose combination arm

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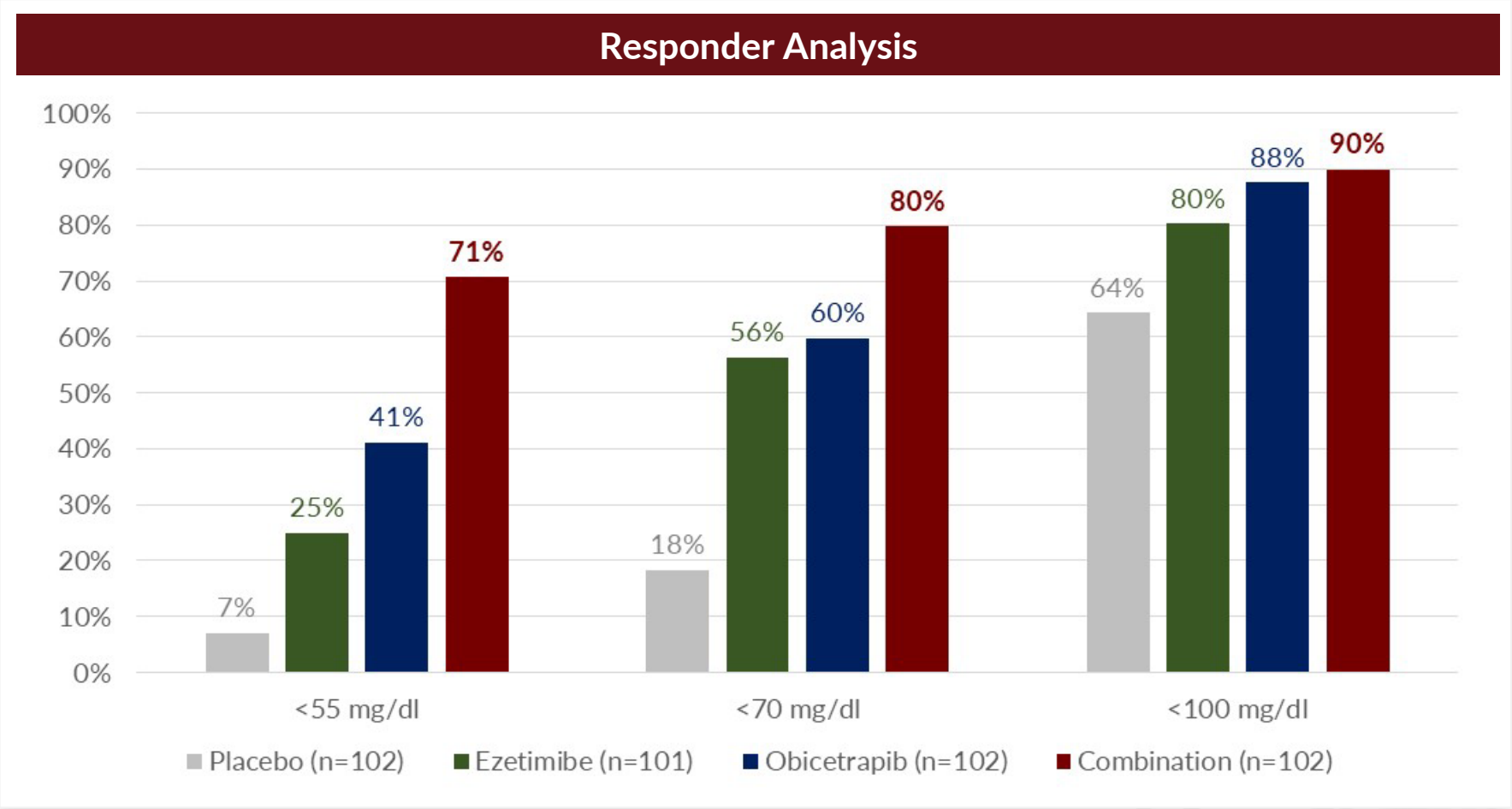
Over 70% of patients on the FDC achieved less than <55 mg/dL



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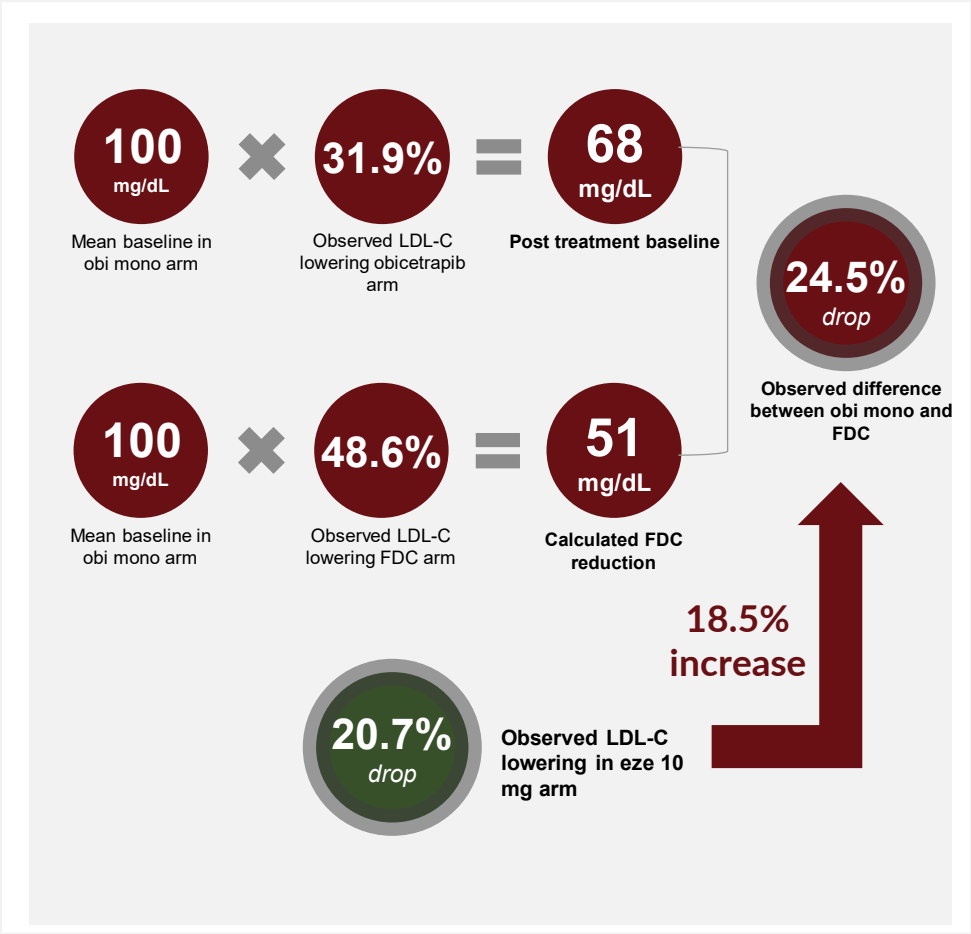
Continued support for potential synergistic effects in combination



18.5% projected greater reduction in LDL-C in the combination than in the ezetimibe monotherapy arm

- Ezetimibe monotherapy showed a 20.7% placebo adjusted reduction in LDL-C
- However, the observed LDL-C reduction between the obicetrapib monotherapy arm and the FDC arm was 24.5%, which we believe was driven by the effect of adding ezetimibe to the FDC
- We therefore project 18.5% greater LDL-C reduction by ezetimibe when combined with obicetrapib in the FDC (24.5% vs 20.7%) than what would be expected with ezetimibe monotherapy alone

Note: based on LS mean percent reductions. The calculations above are hypothetical calculations based on the LDL-C reduction observed in the relevant treatment groups in our TANDEM trial.

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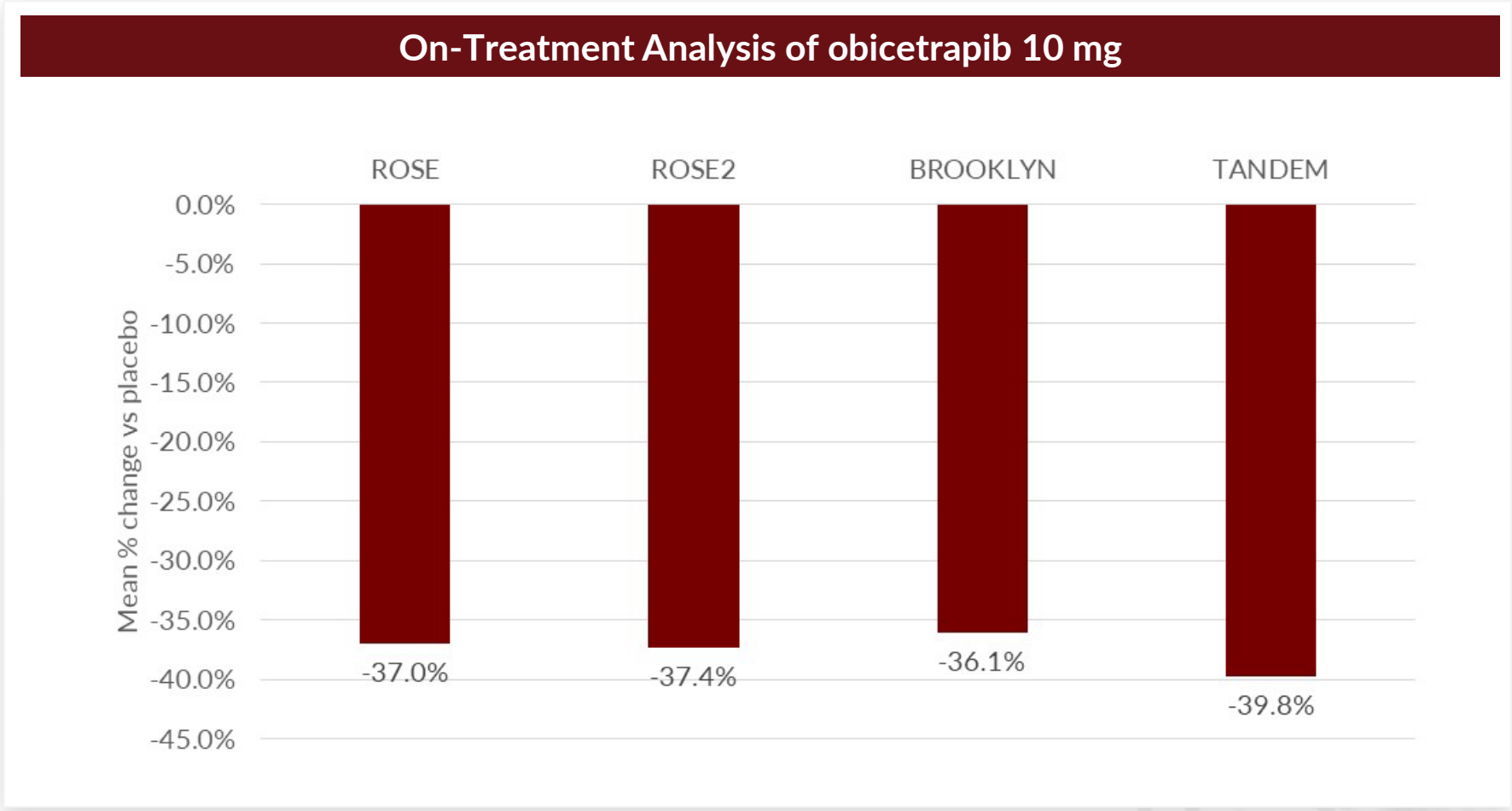
Observed On-treatment LDL-C reduction for ROSE, ROSE2, BROOKLYN & TANDEM



Note: ROSE at week 8, ROSE2, BROOKLYN, and TANDEM as of week 12.

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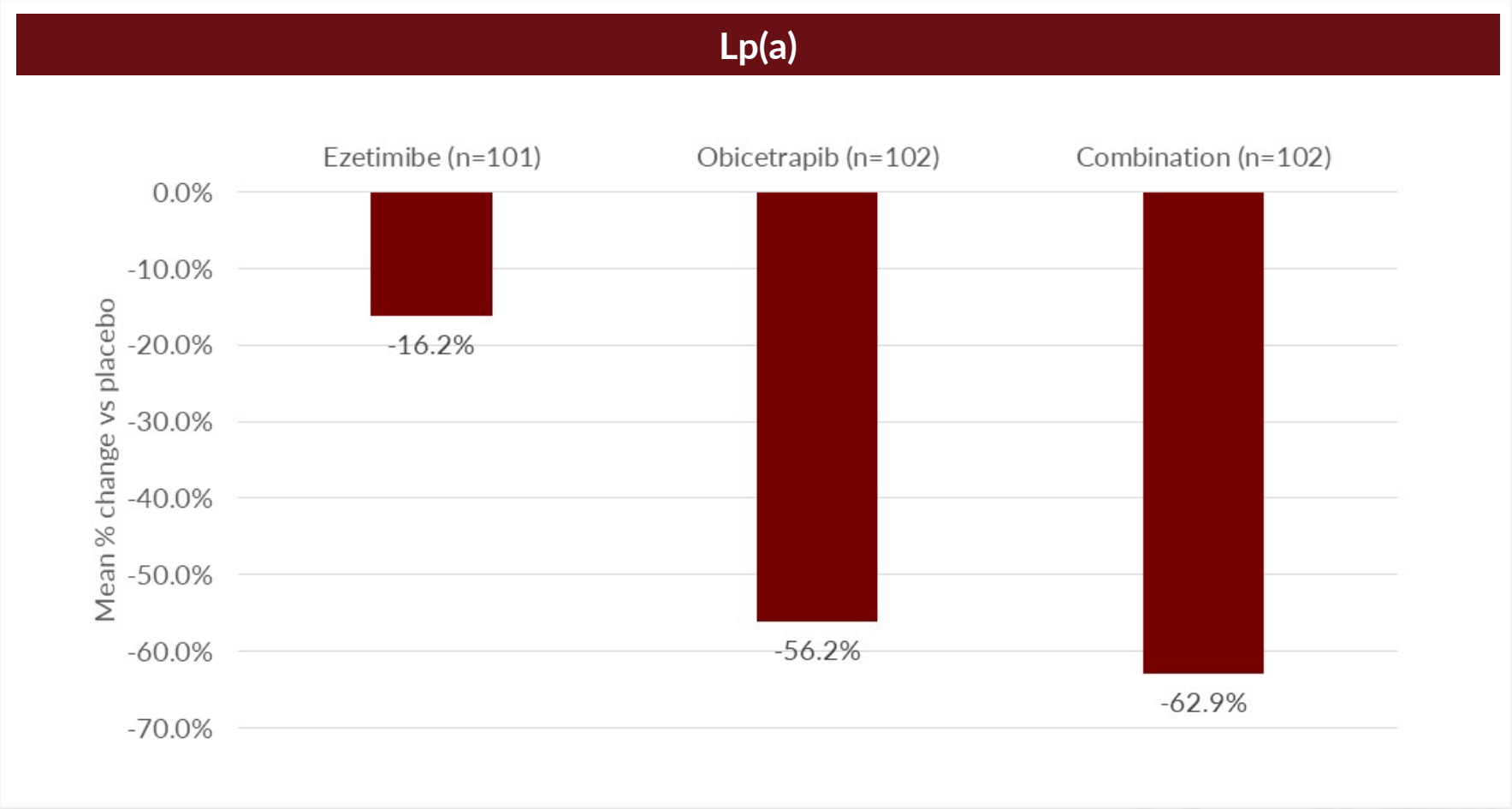
Observed Lp(a) reduction in TANDEM



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Safety results consistent with our prior studies

	Placebo (n=102)	Ezetimibe (n=101)	Obicetrapib (n=102)	Obicetrapib / Ezetimibe (n=102)
Any study drug-related TEAEs	4 (3.9%)	3 (3.0%)	7 (6.9%)	3 (2.9%)
Any study drug-related TEAEs leading to discontinuation of study drug	2 (2.0%)	1 (1.0%)	6 (5.9%)	1 (1.0%)
Any study drug related TESAEs	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Note: treatment emergent adverse events (“TEAEs”) and study drug-related treatment emergent serious adverse events (“TESAEs”)

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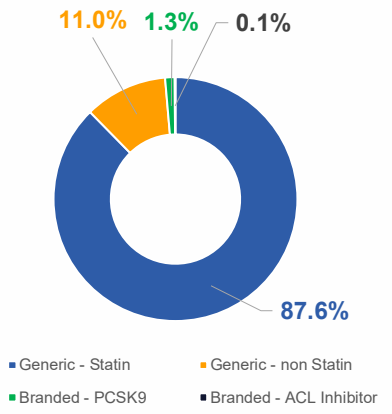
Lipid Lowering Therapy (LLT) Market is a Growing Opportunity

1



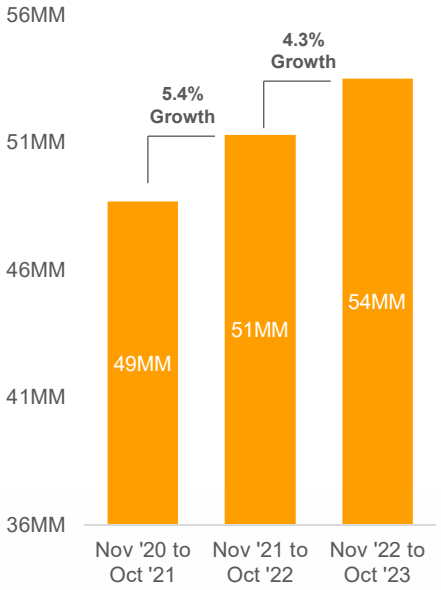
256M

Prescriptions written in past 12 months.[1]

Over 250 MM Rx's annually

2

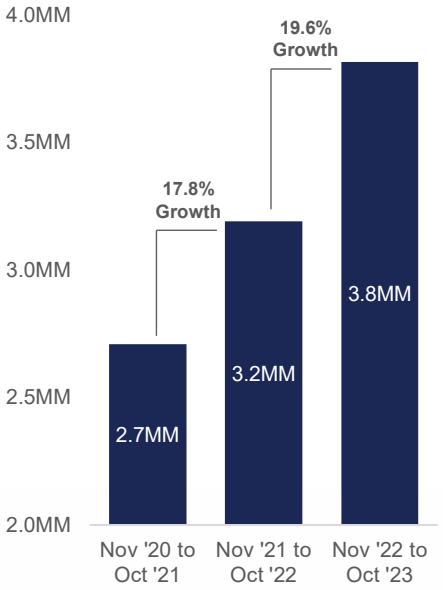
Patients on Lipid lowering Therapy[2]



Market growing at over 4% over the last 2 years

3

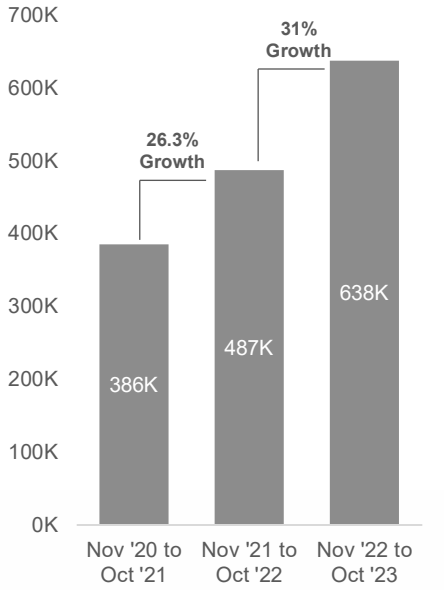
Patients on Non-statin[3] Treatment



Non-statin market growing at high double digits

4

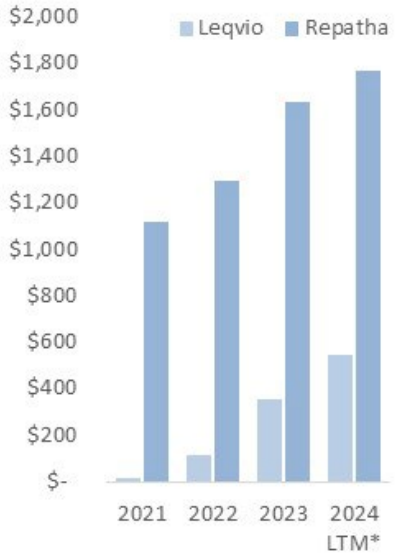
Patients on Branded[4] Treatment



Branded market growing even faster

5

Branded sales driving market opportunity ($ millions)



PCSK9 sales accelerating post launch miscalculations

Recent guideline and label changes driving renewed acceleration

2022: ACC **updated guidelines**[5] to target LDL-C <55 mg/dl in high-risk patients in line with ESC/EAS

2024: FDA highlights need to **reduce access restrictions** for LLTs. Labels updated from "on top of maximally tolerated statins" to "treatment of primary hyperlipidemia" for some LLTs[6]

1. Source: IQVIA XPT - Data Period – 12 months of TRx from Dec '22 to Nov '23 Source: IQVIA LAAD data from Nov '20 to Oct '23 2. All Lipid Lowering therapies: Statins, Ezetimibe and combinations; PCSK9 and BPA 3. Non-Statins : Ezetimibe and combinations; PCSK9 and BPA 4. Branded: PCSK9 and BPA 5. Lloyd-Jones DM, et al. J Am Coll Cardiol. 2022;80(14):1366-1418 6. Leqvio (inclisiran). Prescribing information. Novartis; 2023.; Nexletol (bempedoic acid). Prescribing information. Esperion Therapeutics Inc; 2023. Note: LTM=last 12 months ending 2Q24

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Conclusions

- TANDEM successfully hit all co-primary endpoints, observed to lower LDL-C by approximately 50%, including:
  - A greater than 60% reduction in more that 50% of patients,
  - More than 70% of patients achieved LDL-C below 55 mg/dL
- 18.5% synergy projected with combination, highlighting potential benefit above simple convenience
- ~20% ezetimibe and overall market growth believed to support significant market opportunities for obicetrapib and FDC, if approved
- Data support global filing of the fixed-dose combination
- Other biomarkers consistent with our prior studies
- Additional data to be presented at an upcoming medical conference

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