# Evaluation of real-world treatment outcomes among women 50 years of age and older who were treated with statin + ezetimibe or statin monotherapy in France and Spain

Paula Chu, PhD¹, Amy Zhao, MB², Ryan Irvine, MS³, James Li, MS, MA³, Gordon Goodall, PhD¹

<sup>1</sup>Organon International, Lucerne, Switzerland; <sup>2</sup>Net2Source Inc., Somerset, New Jersey; <sup>3</sup>Organon & Co., Jersey City, New Jersey

## BACKGROUND

- Statins have demonstrated efficacy in reducing major cardiovascular events<sup>1</sup>
- However, individuals undergoing statin therapy alone may not consistently achieve the desired reduction in low-density lipoprotein-cholesterol (LDL-C), which could leave them at continued risk<sup>2</sup>
- In such scenarios, increasing the statin dosage or introducing adjunctive nonstatin lipid-lowering agents such as ezetimibe is often prescribed, aligning with clinical best practices<sup>2</sup>
- Despite this, empirical real-world evidence (RWE) on the clinical advantages of including an add-on therapy remains scarce, especially among women ≥50 years of age
- These data may yield valuable insights into the effectiveness of the treatment approach within this demographic

# STUDY AIM, DESIGN AND OUTCOMES

- This retrospective study (2017–2020) assessed the
  - Goal attainment, the goals evaluated were the intensified/ additional goals in the 2021 European Society for Cardiology (ESC) guidelines on cardiovascular disease prevention in clinical practice,<sup>2</sup> and
  - Percentage (%) change in LDL-C among women ≥50 years of age receiving combination therapy vs. those receiving statin monotherapy in France and Spain
- Data were obtained from primary care electronic medical records in France and Spain through The Health Intervention Network (THIN) database
- Patients had a 12-month baseline period before the initial treatment date with a follow-up period of at least 12 months, a minimum of 4 weeks of continuous treatment with the prescribed lipid-lowering therapy, and LDL-C tests within prespecified windows
- To mitigate potential confounding effects, propensity score matching was performed; the treatment groups were matched by age group (categorized as 50–69 and ≥70 years), cardiovascular disease (CVD) risk (high or very high risk per 2021 ESC guidelines), and statin intensity (low, moderate, high)
- The covariates in the multiple regression analyses for goal attainment and % change in LDL-C and goal attainment included treatment group, age group, CVD risk, statin intensity, and baseline LDL-C value
- Analyses were performed separately for each country

# REFERENCES

- 1. Cholesterol Treatment Trialists' Collaboration. Lancet. 2019;393:407-415.
- 2. Visseren et al. Eur Heart J. 2021;42:3227-3337.

## DISCLOSURES & FUNDING STATEMENT

- P Chu, R Irvine, J Li, G Goodall: Organon employees and stock/shareholders
- A Zhao: Employee of Net2Source Inc (under contract with Organon)
- This study was funded by Organon & Co.
- Medical writing support was funded by Organon and provided by Cathryn M. Carter (Organon, Jersey City, NJ, USA) and Shridevi Venkataramani (PhD, Tata Consultancy Services, India)

## RESULTS

## FRANCE

- 370 French patients were included in the analyses after propensity score matching (n=185 each in mono- and combination therapy)
- 54.6% of patients were ≥70 years old, 51.4% had high CVD risk, and 77.8% received moderate intensity statin therapy in both the groups
- 7.0% in monotherapy and 12.4% in combination therapy achieved their treatment goal
- LDL-C goal attainment was more likely with combination- vs. monotherapy (odds ratio [OR]: 2.07, 95% confidence interval [CI]: 1.00–4.29)
- Baseline LDL-C was significantly associated with goal attainment
- Combination therapy had significantly higher mean % change from baseline (15.2% vs. 8.5%, p=0.029)

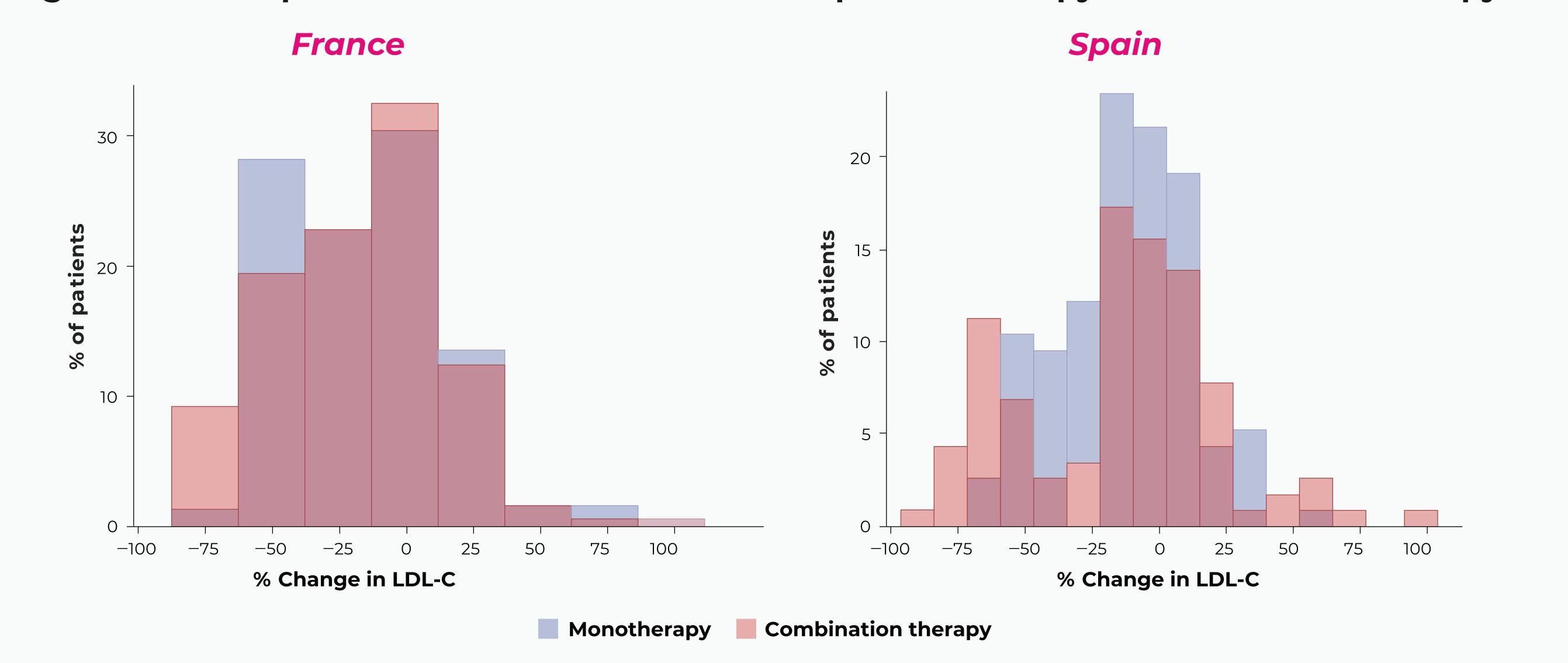
# Patients who achieved their LDL-C goal Mean % change in LDL-C from baseline Mean % change in LDL-C from baseline 15.2 15.2 Monotherapy Combination therapy

# Propensity score matching among patients in France

	Before matching			After matching	
Baseline characteristics	Monotherapy (n=1,983)	Combination therapy (n=185)	p value	Monotherapy (n=185)	Combination therapy (n=185)
Age at index date, n (%)			0.224		
50–69 years	993 (50.1)	84 (45.4)		84 (45.4)	84 (45.4)
≥70 years	990 (49.9)	101 (54.6)		101 (54.6)	101 (54.6)
Cardiovascular disease risk, n (%)			0.054		
Very high	820 (41.4)	90 (48.7)		90 (48.7)	90 (48.7)
High	1163 (58.7)	95 (51.4)		95 (51.4)	95 (51.4)
Statin intensity, n (%)			<0.001		
Moderate	1366 (68.9)	144 (77.8)		144 (77.8)	144 (77.8)
High	192 (9.7)	36 (19.5)		36 (19.5)	36 (19.5)

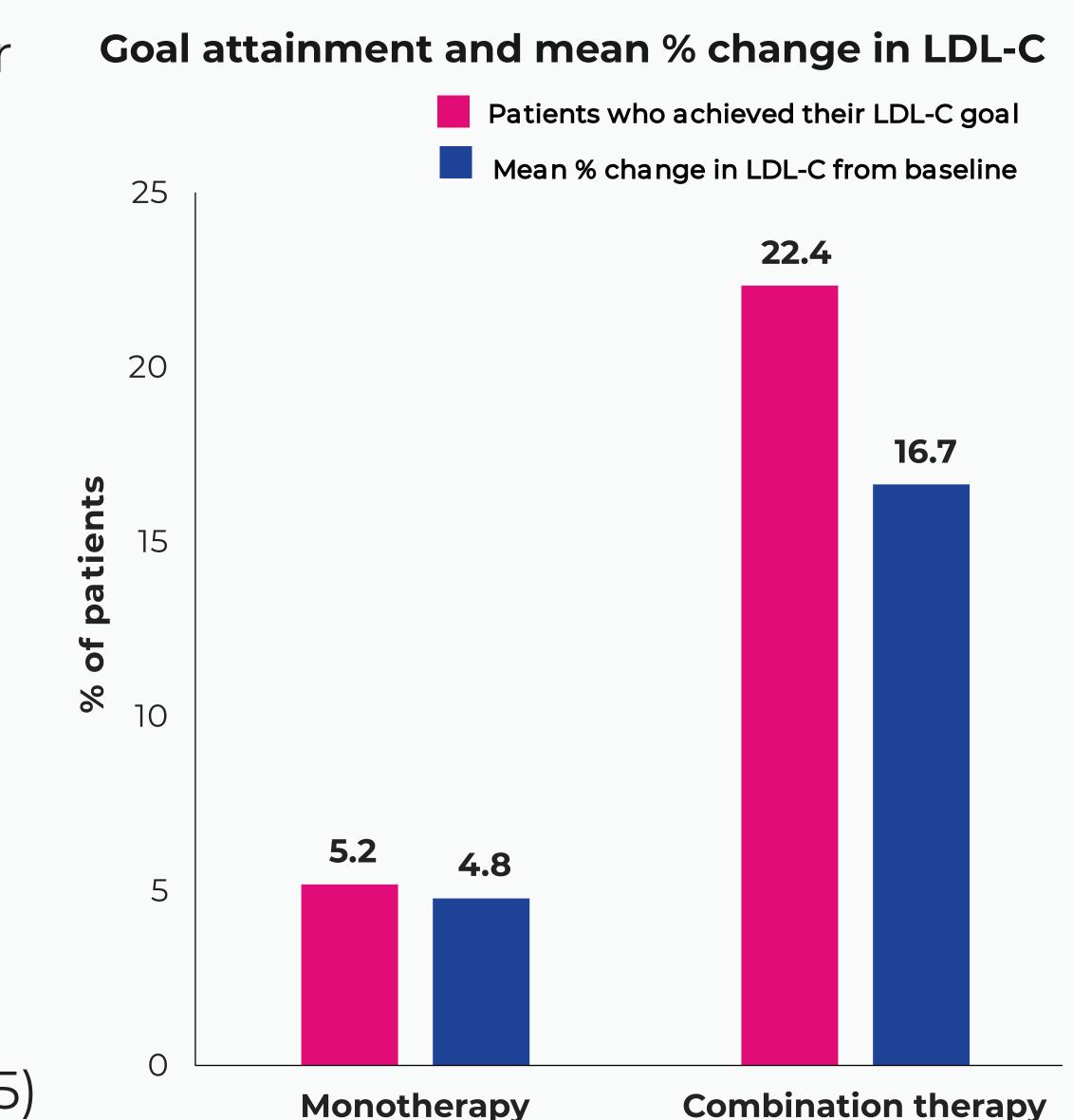
The percentages do not add up to 100 since some patients were on low intensity statins

# Change of LDL-C in patients from baseline to follow-up: monotherapy vs. combination therapy



### SPAIN

- 232 Spanish patients were included in the analyses after propensity score matching (n=116 each in mono- and combination therapy)
- 56.9% of patients were ≥70 years old, 54.3% had high CVD risk, and 74.1% received moderate intensity statin therapy in both the groups
- 5.2% in monotherapy and 22.4% in combination therapy achieved their treatment goal
- LDL-C goal attainment was more likely with combination- vs. monotherapy (OR: 8.54, 95% CI: 3.08–23.66)
- Baseline LDL-C was significantly associated with goal attainment
- Combination therapy had significantly higher mean % change from baseline in LDL-C (16.7% vs. 4.8%, p=0.0005)



## Propensity score matching among patients in Spain

	Before matching			After matching	
Baseline characteristics	Monotherapy (n=3,128)	Combination therapy (n=116)	p value	Monotherapy (n=116)	Combination therapy (n=116)
Age at index date, n (%)			0.489		
50–69 years	1248 (39.9)	50 (43.1)		50 (43.1)	50 (43.1)
≥70 years	1880 (60.1)	66 (56.9)		66 (56.9)	66 (56.9)
Cardiovascular disease risk, n (%)			<0.001		
Very high	885 (28.3)	53 (45.7)		53 (45.7)	53 (45.7)
High	2243 (71.7)	63 (54.3)		63 (54.3)	63 (54.3)
Statin intensity, n (%)			<0.001		
Moderate	2221 (71.0)	86 (74.1)		86 (74.1)	86 (74.1)
High	382 (12.2)	30 (25.9)		30 (25.9)	30 (25.9)

The percentages do not add up to 100 since some patients were on low intensity statins

# CONCLUSIONS

- This RWE evidence study revealed that women aged ≥50 years who received combination therapy were more likely to attain LDL-C goal targets when compared with statin monotherapy
- Furthermore, this cohort experienced a substantial reduction in LDL-C levels during the follow-up period when compared with matched cohorts receiving statin monotherapy
- While combination therapy improved LDL-C levels, this study highlights the need for proactive lipid management to achieve the known cardiovascular benefits and ensure compliance, given the low overall goal attainment
- The study also emphasizes the significance of RWE in delineating actual outcomes versus what is achieved in controlled clinical trials