Cerenis™
THERAPEUTICS

The HDL Company

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An experienced management

Jean-Louis DASSEUX, PhD, MBA

Founder and CEO

- More than 25 years of experience in the pharmaceutical industry (Pfizer, Esperion Therapeutics, Fournier Laboratories)
- A leading world expert in lipid metabolism, atherosclerosis and cardiovascular diseases
- Inventor of more than 60 patent families relating to HDL and the treatment of cardiovascular diseases

Cyrille TUPIN, CPA

CFO

- Audit Director at Sygnatures, the largest private auditing and consulting company in Toulouse, France
- More than 7 years at PWC working on high-profile business transactions

Value proposition: why invest in CERENIS?

CER-001: major potential in the treatment of patients post-ACS

1. A therapy targeting the 2/3 of patients who are poorly served with available medical treatments
2. Advanced and promising clinical developments currently in Phase II (CARAT)
3. Compelling to big pharma (e.g., OMTHERA $443 m; Esperion $1.3 bn; KOS $3.7 bn)[1]
4. A manufacturing process validated on an industrial level with proven clinical safety and tolerability

In the short term: CER-001, a drug for treating orphan diseases

1. A potential of value creation in the short term, currently in Phase III (TANGO)
2. A major unmet medical need
3. Application for marketing approval before 2018

CER-209: major potential in the treatment of patients with atherosclerosis and NAFLD/NASH

1. A significant unmet medical need
2. CER-209, a highly specific P2Y13 receptor agonist promoting lipid elimination
3. Launch of a phase 1 study with CER-209 in NASH/NAFLD in Q1 2017

A LISTED COMPANY WITH SUBSTANTIAL POTENTIAL IN HDL THERAPY

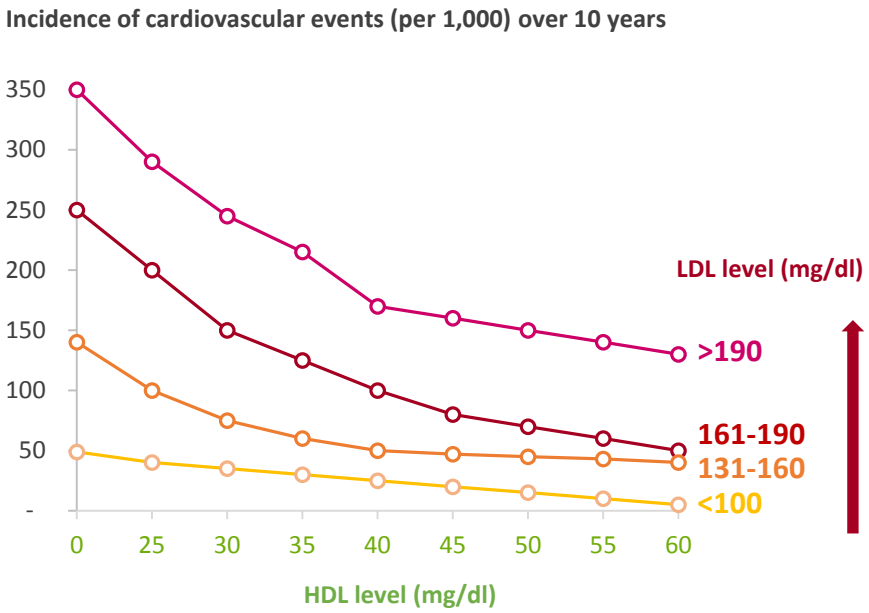
1. *Press releases,*
OMTHERA: http://www.astrazeneca.com/Media/Press-releases/Article/20130528-omthera
Esperion: http://www.bloomberg.com/apps/news?pid=newsarchive&sid=apU2qcYCmkO4&refer=us
KOS: http://www.bloomberg.com/apps/news?pid=newsarchive&sid=af_8tglk4fHE

HDL therapy: one of the most promising treatments for removing cholesterol

Fundamental role of HDL in removing cholesterol

- **At each LDL level, it is the HDL level** that determines the cardiovascular risk
- **An HDL therapy that increases the number of HDL particles** is one of the best approaches for treating atherosclerosis
- **No HDL medical treatment** that can treat or eliminate atherosclerosis is yet available

A major epidemiological study on HDL [1]



CERENIS IS THE COMPANY THAT OFFERS ONE OF THE MOST COMPREHENSIVE INNOVATIVE HDL SOLUTIONS FOR TREATING ATHEROSCLEROSIS

1. PROCAM:
7,152 men aged 35 to 65
406 coronary events over 10 years

Cardiovascular disease:
Still an unmet medical need after more than 30 years of existing therapy

Leading cause of death in the world

- **1 out of 3 deaths worldwide (source: WHO)**
- **The disease category with the greatest health expenditure:**
  - **$107 bn in the United States, in 2010**
  - **$110 bn in Europe, in 2009**

A primary cause: atherosclerosis

- **Atherosclerosis: accumulation of cholesterol plaque in the arteries**

Only 1/3 of cardiovascular patents receive benefit from the best current treatments

ONLY ONE REAL SOLUTION: ELIMINATE CHOLESTEROL PLAQUE WITH CERENIS

10 years of R&D to achieve one of the world's most advanced HDL solutions

2005: creation of Cerenis → 2015 | 2016 | 2017 | 2018

Product	Indications	Preclinical	Clinical
CER-001 (HDL mimetic)	Post-Acute Coronary Syndrome (ACS)	POC [2] ★ Preclinical development	Phase I → 1st Phase II → 2nd Phase II
	HDL genetic defects (FPHA [1])	Preclinical development	POC [2] ★ Phase I → Orphan disease designation ★ Phase II → Request for EU marketing approval ★ AMM Phase III
CER-209 (P2Y13 receptor agonist)	NAFLD/NASH/ Atherosclerosis	POC [2] ★ Preclinical development	Start of Phase 1 in Q1 2017

Development financed through four capital increases

- €25 m in 2005
- €42 m in 2006
- €50 m in 2010
- IPO: €53.4 m in 2015

Investors

SOFINNOVA PARTNERS, AltaPartners, IRDI, bpifrance, HealthCap, Daiwa, TVM | Capital, iXO PRIVATE EQUITY, OrbiMed Healthcare Fund Management, CEREN LISTED EURONEXT

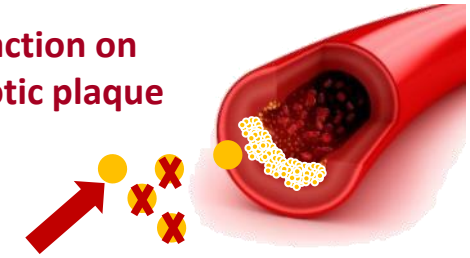
3 TARGETED INDICATIONS: ACS, FPHA AND NAFLD/NASH/ATHEROSCLEROSIS

1. *Familial Primary Hypoalphalipoproteinemia*
2. *Proof of Concept*

HDL therapy: one of the most promising treatments for removing cholesterol

LDL APPROACH: reduces bad cholesterol

No direct action on atherosclerotic plaque



AVAILABLE DRUGS:
Statins: inhibit cholesterol synthesis
Resins and Inhibitors: limit intestinal absorption of cholesterol
Fibrates: reduce the level of triglycerides containing LDL cholesterol

Indirect long-term effect with no direct action on plaque: only 1/3 of patients get benefit

HDL APPROACH: reduces plaque

Reduces atherosclerotic plaque

NO DRUGS YET AVAILABLE:
CER-001: Cerenis HDL mimetic candidate that reduces atherosclerotic plaque

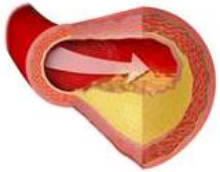
Rapid direct effect: reduction in atherosclerotic plaque

LDL DRUGS HAVE A LIMITED EFFICACY ON PLAQUE REDUCTION

Tremendous market opportunity for HDL-focused therapies

Cardiovascular disease

2 main indications



Acute Coronary Syndrome

2.8 million patients (US + EU)

- **1/3 of patients receive benefit**
  - Stent
  - LDL therapies
- **2/3 of patients do not receive benefit** → **No existing HDL treatment**

HDL genetic defect (FPHA)

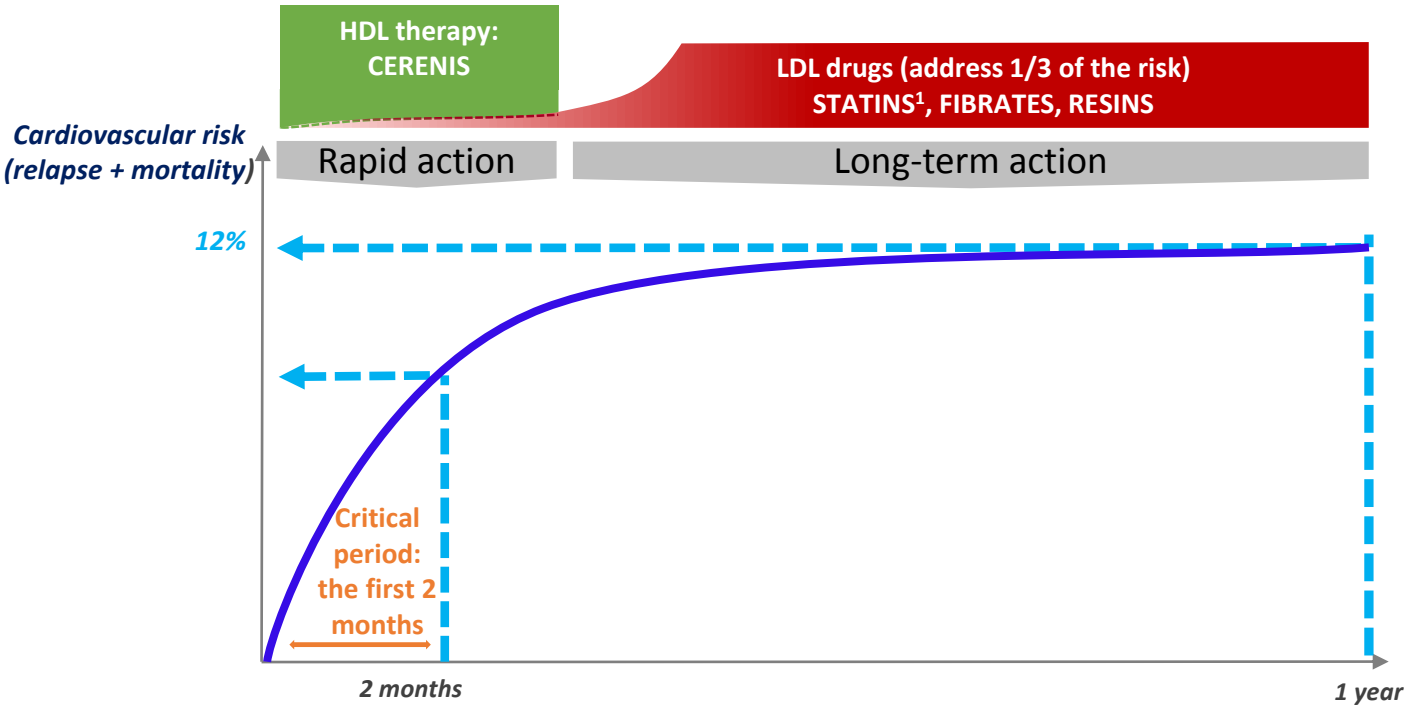
100,000 – 150,000 patients (US + EU)

→ **No existing HDL treatment**

Cerenis™ THERAPEUTICS

NO HDL DRUG IS CURRENTLY AVAILABLE FOR ALMOST 3 MILLION PATIENTS

HDL therapy is the only solution for post-ACS



- 12% [2] of patients relapse during the 12 months following an ACS, 2/3 of them during the first 2 months
- 19-26% [3] of patients over age 45 die during the 12 months that follow a cardiovascular event
- ACS hospitalization costs: $20,000 - $60,000 per patient per event

HDL THERAPY IS THE ONLY SOLUTION ADDRESSING THE CRITICAL 2-MONTH POST-ACS PERIOD

1. *Vale N. et al Cochrane Database of Systematic Reviews 2014, Issue 9.*
2. *PLATO clinical study, AstraZeneca*
3. *Source: AHS*

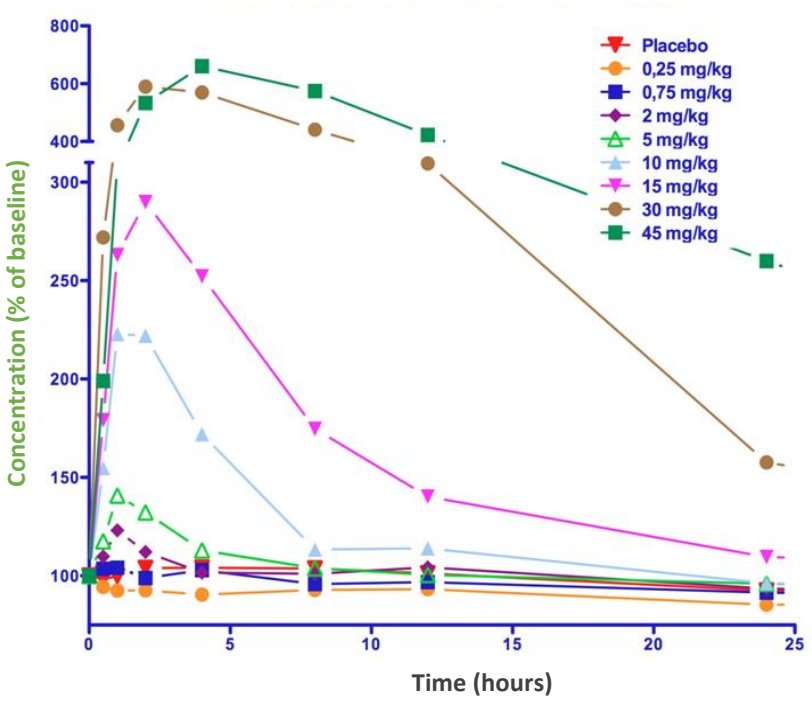
Safety proven in Phase I

Phase I showed:

Mobilization of HDL cholesterol

- Increase in HDL cholesterol: +700% for 45 mg/kg dose
- Mobilization observed beginning with the 2 mg/kg dose
- No patient safety issues

Concentration of HDL cholesterol following the infusion of CER-001



A PROVEN SAFETY PROFILE AT ALL DOSES

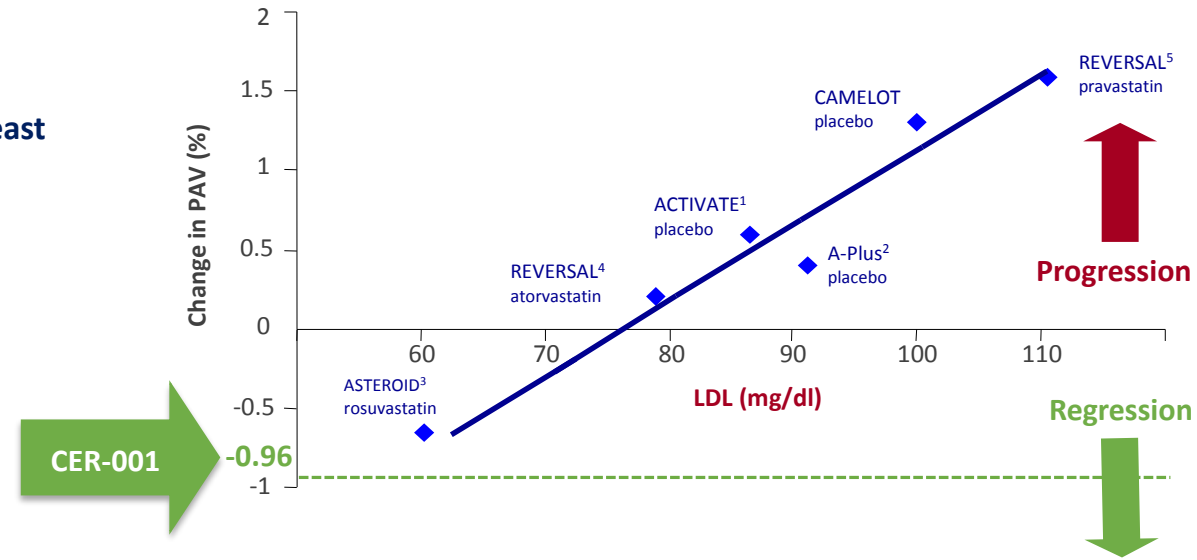
Compelling clinical results: proof of efficacy in Phase II

CHI SQUARE: Phase II post-ACS study

Effects on plaque

- **Significant regression in the volume of atherosclerosis plaque, substantially better than existing treatments**
- **Rapid action in just 2 months vs. at least 2 years for other treatments**

Change in the percentage atherosclerosis volume (PAV)



An independent analysis (SAHMRI) showed:

- **A significant reduction in atherosclerotic plaque compared with the placebo**

CER-001 IS THE MOST EFFICIENT OF ALL TREATMENTS

1 *Nissen S and al. N Engl J Med 2006;354:1253-1263.* ***2*** *Tardif J and al. Circulation 2004;110:3372-3377.*
3 *Nissen S and al. JAMA 2006;295 (13):1556-1565* ***4*** *Nissen S and al. JAMA 2004;292: 2217–2225.*
5 *Nissen S and al. JAMA 2004; 291:1071–1080*

Compelling clinical results: identification of the optimal dose for treatment

Conclusions of CHI-SQUARE, the 1st Phase II study:

- Cholesterol mobilization by CER-001 at every dose level
- Demonstrated patient safety profile
- Primary endpoint (reduction in plaque at 12 mg/kg dose vs. placebo) not achieved
- Reduction in the total volume of atherosclerosis vs. baseline was statistically significant at 3 mg/kg

An independent analysis (SAHMRI) confirmed the optimal dose[2] :

Change in the percentage atherosclerosis volume (PAV)

Patients with PAV ≥30 at baseline

Parameter	Placebo (n=69)	3 mg/kg (n=58)		6 mg/kg (n=78)		12 mg/kg (n=66)
PAV	-0.259	**-0.963**		-0.619		+0.177
P value		**0.038** [1]		0.287		0.587

- Too high a concentration of HDL induces a down-regulation of ABCA1 transporter, which is necessary for cholesterol efflux. The 12 mg/kg dose caused such a down-regulation whereas 3 mg/kg did not resulting in the highest efficacy
- The optimal dose enabling a maximization of the plaque regression vs. placebo: 3 mg/kg
- Next study: number of infusions

THE OPTIMAL DOSE HAS BEEN IDENTIFIED
THE OPTIMAL NUMBER OF INFUSIONS STILL NEEDS TO BE DETERMINED

1. *Statistically significant result*
2. *Greater regression of coronary atherosclerosis with the pre-beta high-density lipoprotein mimetic CER-001 in patients with more extensive plaque burden American Heart Association sessions 2015, S. Nicholls et al.*

Validation of the optimal dose

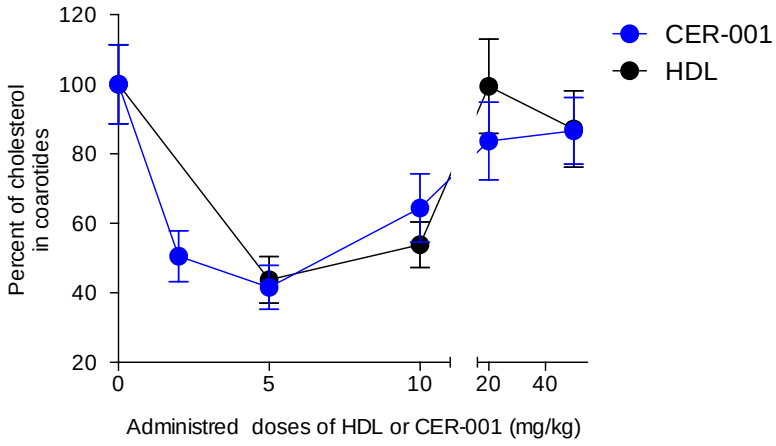
The publication highlights CER-001 preclinical positive results:

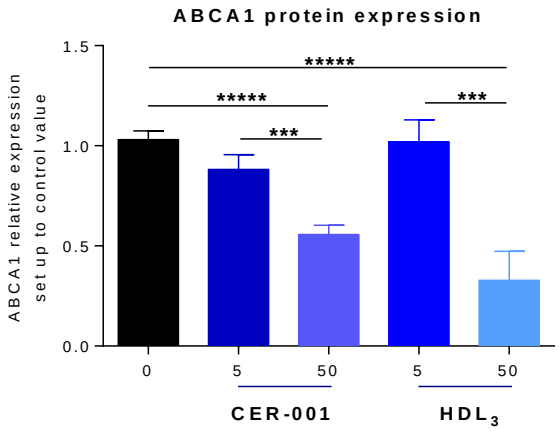
- **CER-001 mimics native HDL**
- **Ability of CER-001 to inhibit the formation of atherosclerotic plaque with better efficacy at lower doses**

Dose-response mechanism follows a U-shaped curve

- **At high dose see strong down-regulation of the ABCA1 transporter, the cellular gatekeeper for eliminating excess tissue cholesterol**
- **Confirmation of the optimal 3mg/kg dose of the Phase II CARAT clinical trial in the post-ACS indication**

Decrease percentage of an atherosclerotic plaque within carotids [1]





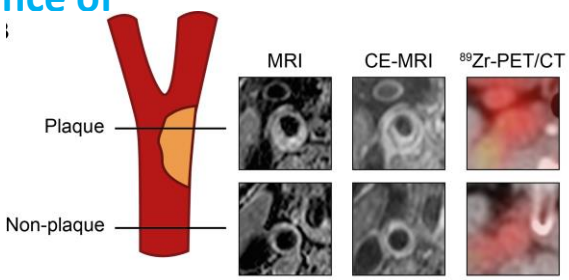
CONFIRMATION OF OPTIMAL DESIGN FOR CARAT AND TANGO STUDIES

1 *PLOS ONE: Tardy et al.* September 3, 2015, DOI: 10.1371/journal.pone.0137584

CER-001 targets plaque: LOCATION clinical study

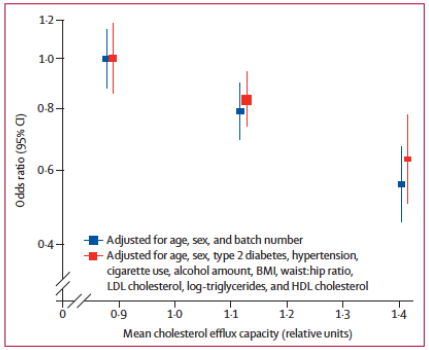
The LOCATION study provides the first evidence of

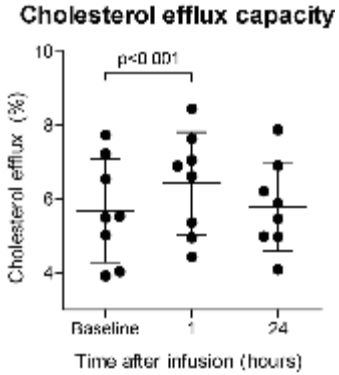
- **CER-001's ability to:**
  - **Penetrate atherosclerotic plaques**
  - **Preferentially target atherosclerotic plaques**
- **CER-001's capacity to increase cholesterol efflux**



Increased cholesterol efflux capacity is a predictive marker of a reduction in cardiovascular-related morbidity and mortality :

Association between cardiovascular risk and cholesterol efflux capacity*





** Source : Lancet Diabetes Endocrinol 2015, Danish Saleheen, Robert Scott, Sundas Javad, Wei Zhao, Amrith Rodrigues, Antonino Picataggi, Daniya Lukmanova, Megan L Mucksavage, Robert Luben, Jeff ery Billheimer, John J P Kastelein, S Matthijs Boekholdt, Kay-Tee Khaw, Nick Wareham, Daniel J Rader*

** Source: 17th SYMPOSIUM INTERNATIONAL DE L'ATHEROSCLEROSE (IAS), 23 au 26 mai 2015 à Amsterdam, Erik Stroes et al., Academic Medical Center of Amsterdam, The Netherlands*

THE LOCATION CLINICAL STUDY SUPPORTS CER-001'S PROOF OF CONCEPT

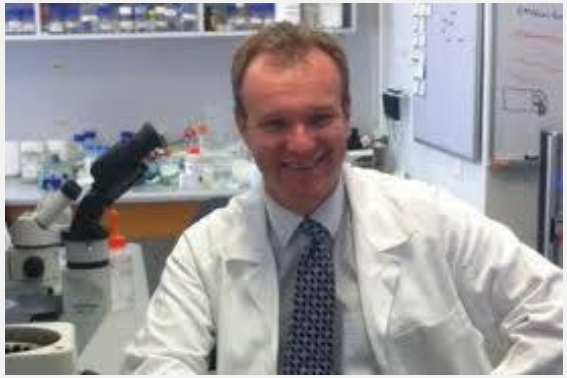
CER-001: the future benchmark in HDL mimetic

A prestigious steering committee for the CARAT trial

- Dr. John Kastelein
- Dr. Béla Merkely
- Dr. Stephen Nicholls, **Principal Investigator**
- Dr. Steven Nissen
- Dr. Kausik Ray
- Dr. Gregory Schwartz
- Dr. Stephen Worthley

"I'm particularly enthusiastic about collaborating with Cerenis Therapeutics for the future Phase II CARAT clinical study of CER-001. On the basis of our convincing analyses of the Phase II CHI-SQUARE study highlighting the efficacy of the optimal 3mg/kg dose, I'm highly confident regarding the potential success of this important clinical step to establish CER-001 as the market benchmark in HDL mimetic."

Professor Stephen Nicholls

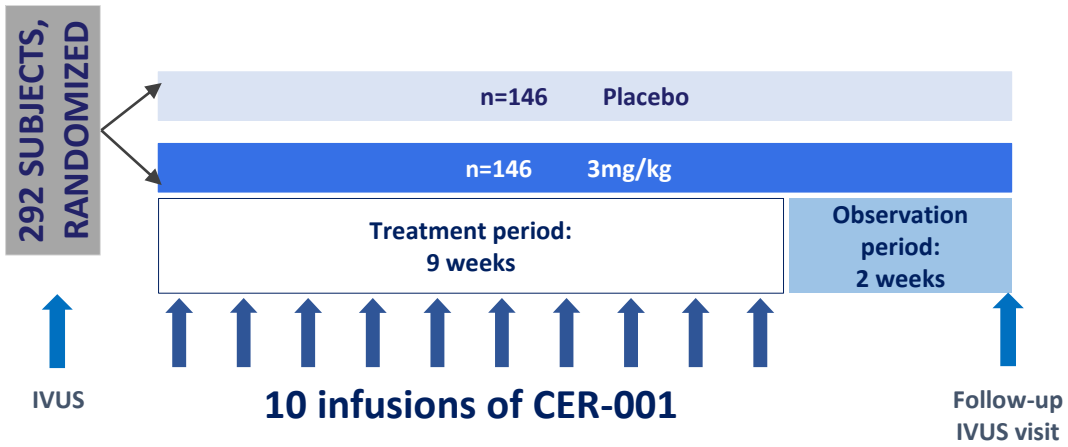


Last Patient Dosed in CARAT Phase II Study with CER-001 in Post-Acute Coronary Syndrome Patients

The CARAT study should show:

- A significant reduction in the percentage atherosclerosis volume vs. placebo
- The superior efficacy of an increase in the number of doses

Study led by the South Australian Health and Medical Research Institute Limited (SAHMRI)



IDENTIFICATION OF THE OPTIMAL TREATMENT AND ENROLLMENT OF PATIENTS WITH SUBSTANTIAL ATHEROSCLEROSIS PLAQUE

The key advantage of HDL therapy for FPHA

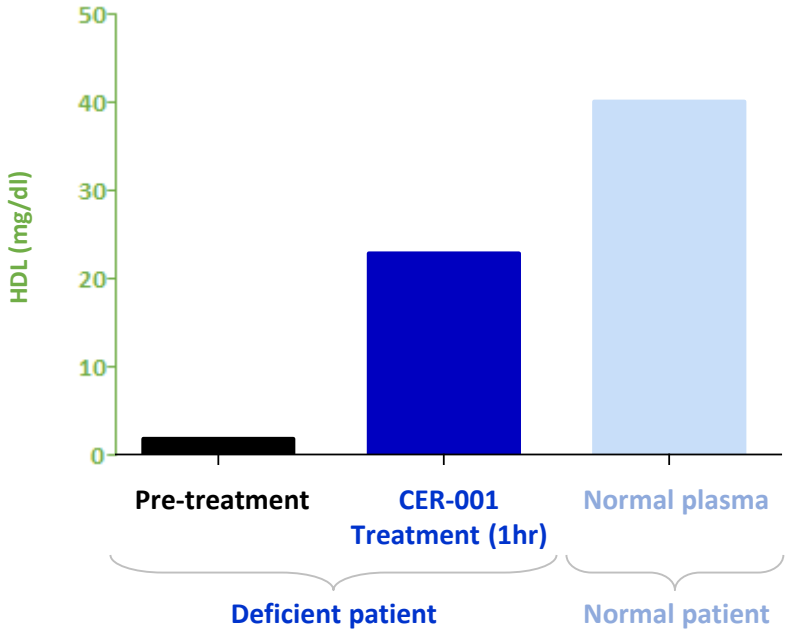
FPHA: a rare syndrome of severe HDL deficiency

- Caused by mutations in the genes responsible for HDL synthesis/maturation
- Characterized by accelerated atherosclerosis

CER-001 treatment

- CERENIS' solution restores the blood's ability to mobilize cholesterol into HDL to facilitate its elimination
- Two Orphan Drug designations obtained
  - HDL deficiency (no apoA-I synthesis)
  - Tangier disease (absence of ABCA1)

Mobilization of HDL cholesterol in the blood[1]



CERENIS: A THERAPEUTIC SOLUTION TO MEET THE UNMET FPHA MEDICAL NEED

1. *Company: SAMBA study*

Confirmed universal proof of concept amongst those deficient in HDL

The Phase II SAMBA study:

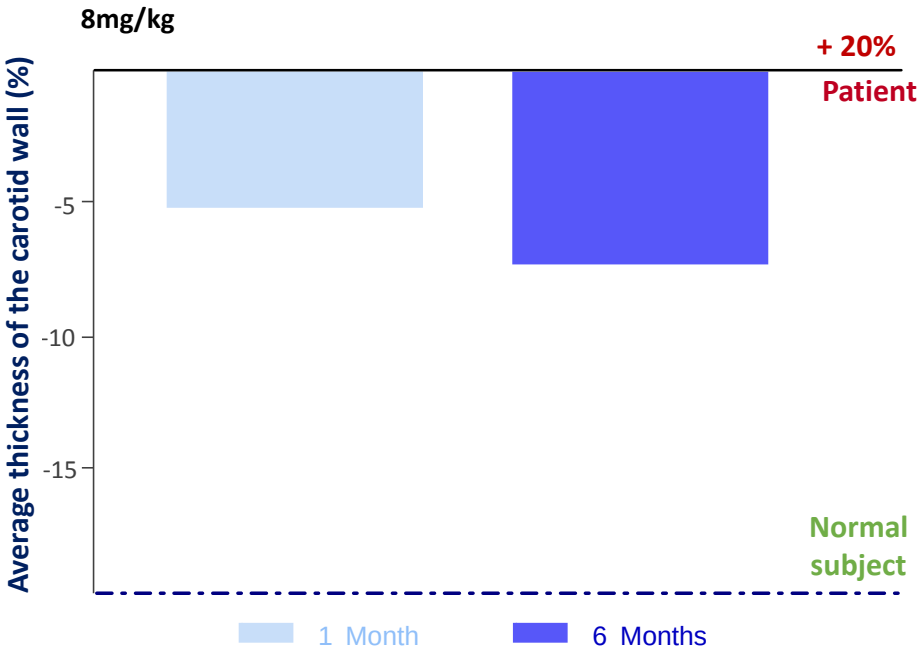
Evaluated the efficacy of CER-001

- 7 FPHA patients in an open-label, single-arm, active-treatment study for a one-month treatment of 9 doses
- Assessed the reconstitution of the endogenous reverse lipid transport pathway

Showed reduction of the vascular wall thickness

- Behaves like a natural HDL
- Eliminates cholesterol
- Reduces plaque

Efficacy on carotid atherosclerosis[1]



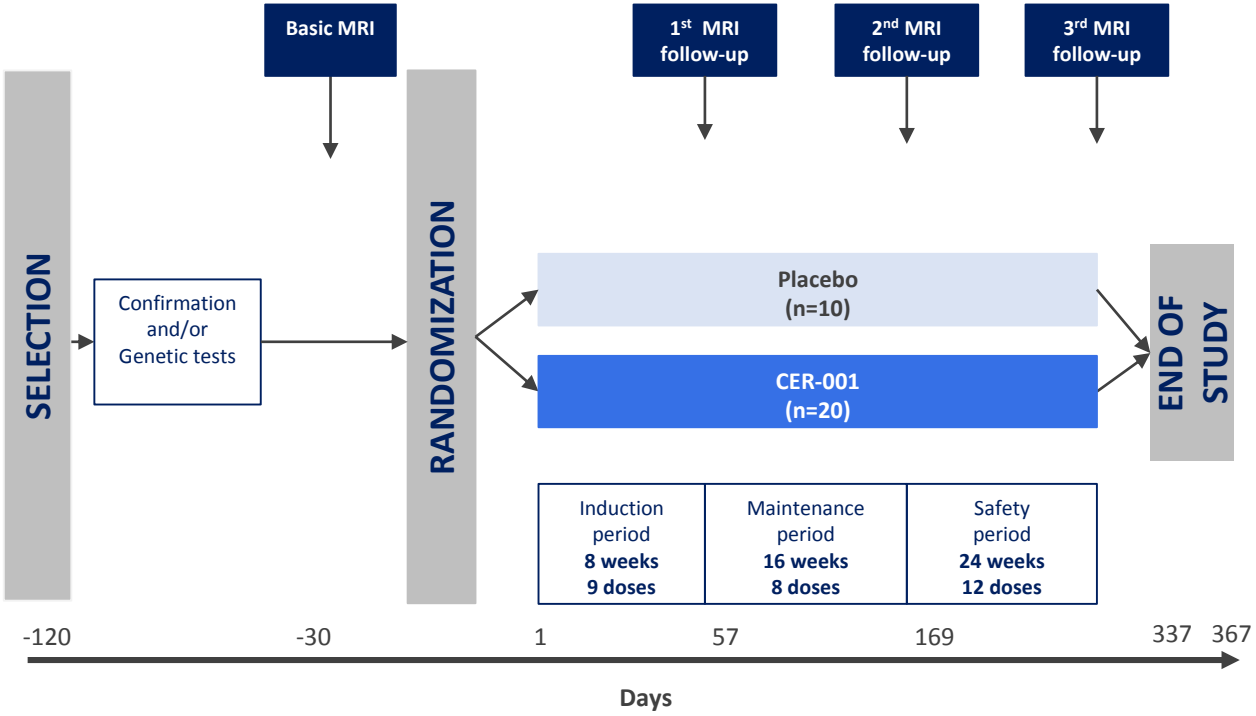
IN THE BODY, CER-001 RESULTED IN A STATISTICALLY SIGNIFICANT REDUCTION OF PLAQUE IN THE CAROTID ARTERY VESSEL WALL

1. J Lipid Res. 2015 Jan 5. ePub

Phase III TANGO (FPHA)

The TANGO study should show:

- A reduction in coronary plaque in the carotid and aorta
- Enrollment began in December 2015



THE TARGET OBJECTIVE IS TO OBTAIN MARKETING APPROVAL IN THE TWO IDENTIFIED GENETIC DEFECTS (APOA-I DEFICIENCY / TANGIER DISEASE)

A safe and industrializable natural mimetic solution

	CERENIS	The Medicines Company	CSL
Product specificity	Only mimetic with the biological properties of natural HDL	Mutant protein produced in an *E. coli* bacteria	Protein extracted from plasma
Composition of the nanoparticle	Natural HDL mimetic	Mutant form	Multiple forms of A-I apolipoprotein

				Competitive advantage of CER-001
Purity	✓✓✓	✓	✗	Homogenous particle population
Mobilization of cholesterol / Efficacy	✓✓✓	✓	✓	Lower required dosage
Side effects/Toxicity	✓✓✓	✗	✗	No identified toxicity
Intellectual property	✓✓✓	✗	✗	Protection of the active principle blocking any reproduction of the nanoparticle
Composition	✓✓✓	✓	✓	Only charged-complex natural HDL mimetic
Manufacturing process	✓✓✓	✓	✓	Only 3 purification steps

CER-209, the unique first-in-class therapeutic solution to address both NASH and atherosclerosis

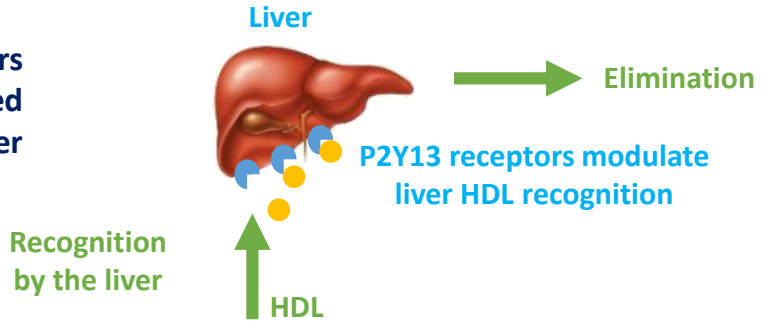
HDL therapy enables to address atherosclerosis and NAFLD/NASH

- Atherosclerosis is frequently observed in patients with NASH, thus presenting high cardiovascular risk, in addition to steatohepatitis and liver inflammation
- Current treatments based on lipid-lowering drugs attempt to reduce LDL cholesterol but they often increase liver enzymes, thereby limiting the benefits for treating NASH patients
- Other treatments currently under development for NASH, such as targeting the nuclear receptor PPAR as well as FXR agents, may face problems associated with their multiple effects

CER-209 increases HDL elimination by the liver…

- A new mechanism of action that involves the last steps of the RLT pathway
- Agonist activity of CER-209 on the liver P2Y13 receptors facilitates elimination of mature HDL particles loaded with lipids such as cholesterol, through better HDL liver recognition and increased bile secretion

…by stimulating the activity of HDL receptors



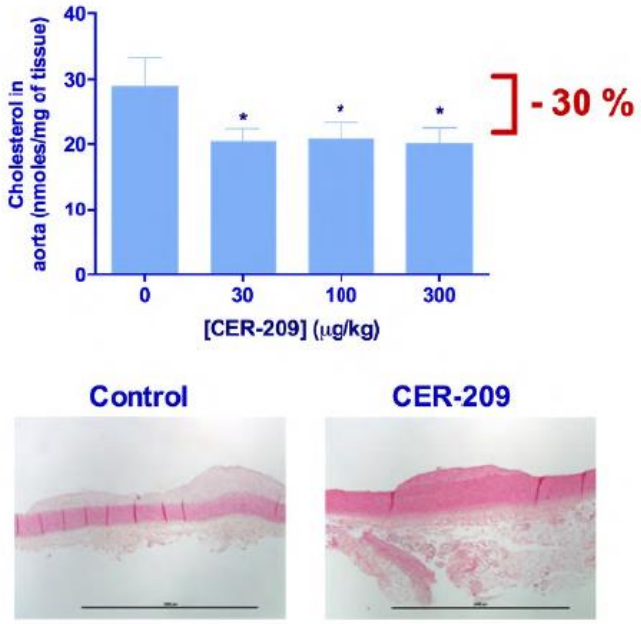
FDA IND APPROVAL TO BEGIN PHASE 1 STUDY WITH CER-209 IN NAFLD AND NASH IN Q1 2017

STUDY DESIGN NEARING COMPLETION

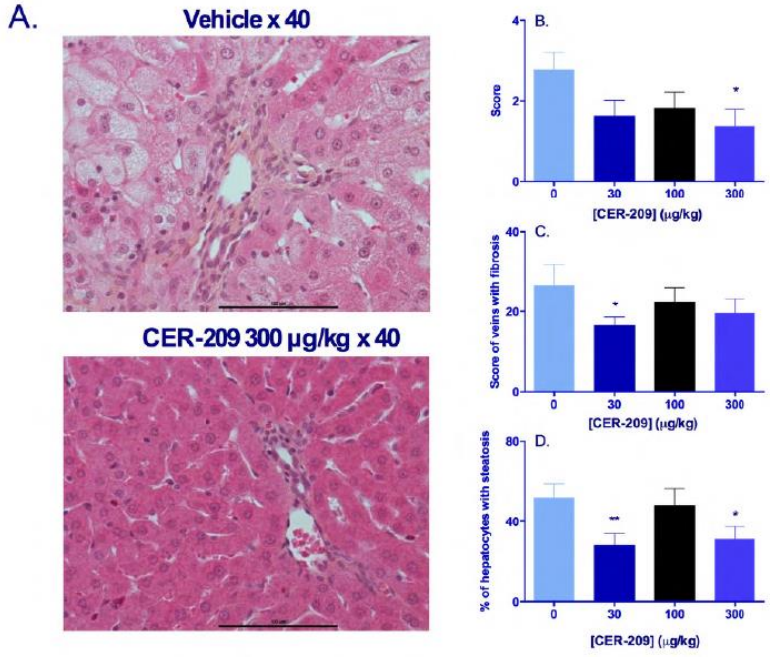
Experimental positive results for CER-209 presented at the 25th Conference of the APASL *(ASIAN PACIFIC ASSOCIATION FOR THE STUDY OF THE LIVER)*

CER-209, an agonist of the P2Y13, decreases both atherosclerosis and liver steatosis

Plaque regression after treatment with CER-209*



Regression of liver steatosis after high-cholesterol diet and treatment with CER-209*



CER-209 HAS A STRONG POTENTIAL FOR THE TREATMENT OF NASH AND NAFLD

** P2Y13 receptor agonist CER-209 decreases both atherosclerosis and liver steatosis in vivo: Rudi Baron, Marine Goffinet, Nadia Boubekeur, Claudine Tardy, Guy Cholez, Daniela C. Oniciu, Narendra D. Lalwani, Jean-Louis H. Dasseux and Ronald Barbaras*

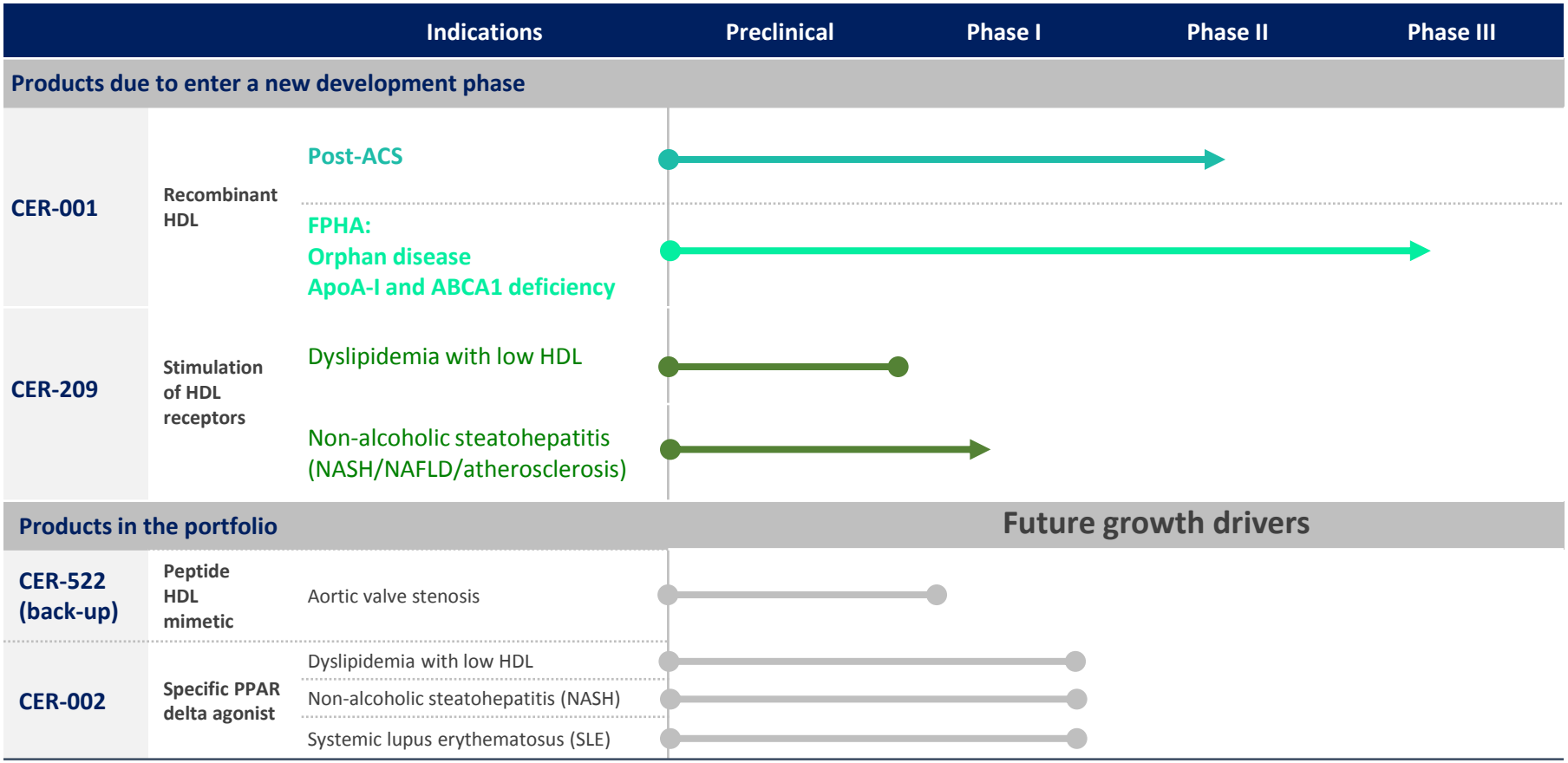
A well-protected platform and technology

- **9 patent families protecting the products, indications and manufacturing / diagnostic methods**

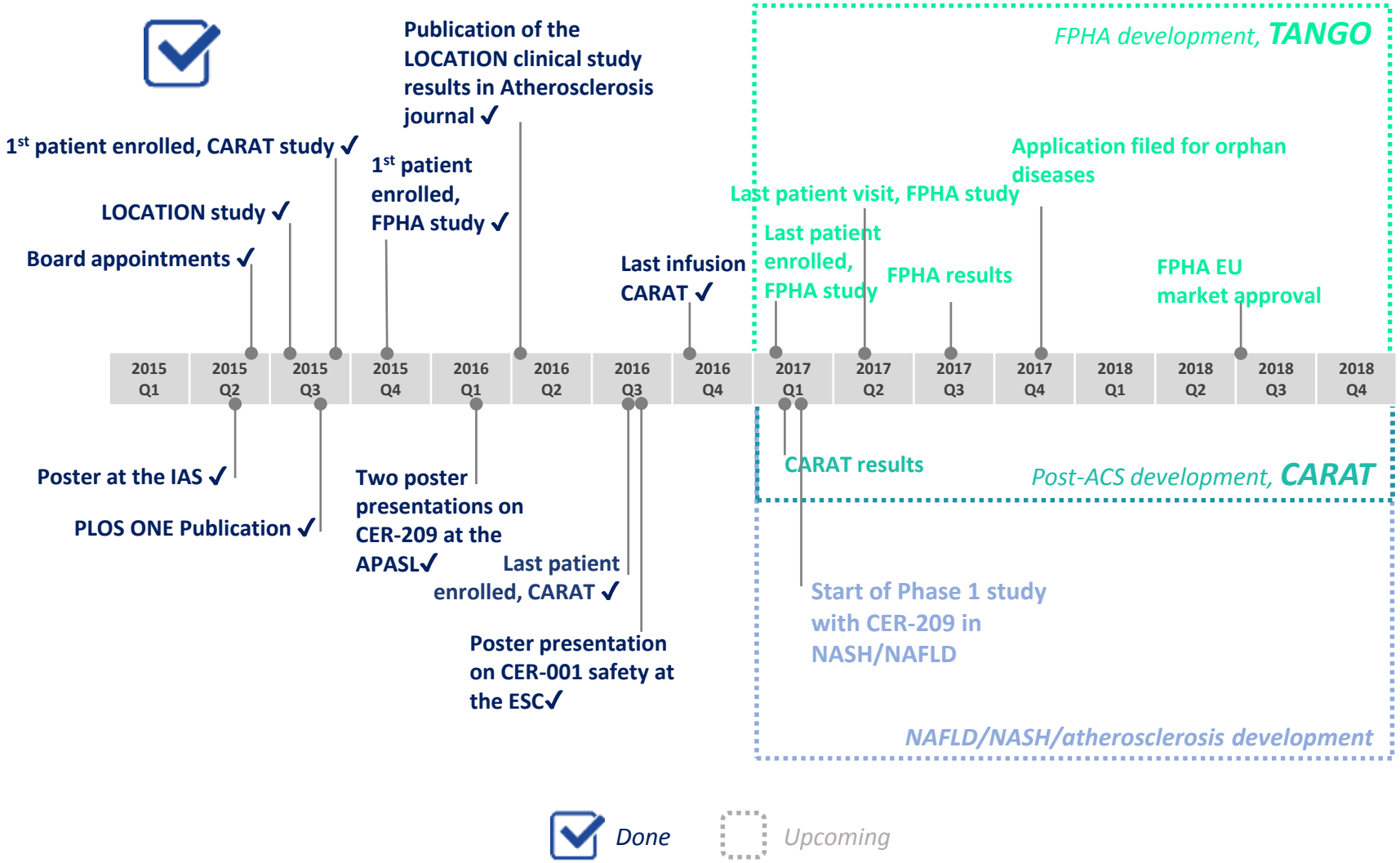
PRODUCT	INDICATION	MANUFACTURING/DIAGNOSTIC
Family 1: Formulation of CER-001 and its use		**Family 2:** Manufacturing methods for reconstituted HDL particles and highly-homogenous resulting populations of HDL particles
Family 6: HDL mimetic peptide including CER-522	**Family 4:** Treatment of dyslipidemias	**Family 3:** Companion diagnostics and dosage of CER-001
Family 7: P2Y13 receptor agonists (CER-209)		**Family 5:** Synthetic sphingomyelin synthesis / production methods
Family 8: PPAR agonists (CER-002)		**Family 9:** Carrier particles for administering drugs

NO COMPETITOR CAN REPRODUCE THE CHARGED NANOPARTICLE, EVEN PARTIALLY

A structured and diversified portfolio



Solid near- and medium-term news flow



WEALTH CREATION PERSPECTIVE IN BOTH THE NEAR AND MEDIUM TERM

Simplified balance sheet and income statement

Consolidated accounts (IFRS)

BALANCE SHEET	31/12/2015	30/06/2016
€ thousands		
ASSETS		
Total non-current assets	446	340
Total current assets	45,661	37,152
Total assets	**46,107**	**37,492**
LIABILITIES		
Total shareholders' equity	33,198	22,359
Total non-current liabilities	7,120	7,082
Total current liabilities	5,790	8,051
Total liabilities	**46,107**	**37,492**

- **Gross cash position of:**
  - **€7.8 m on December 31, 2014**
  - **€43.0 m on December 31, 2015**
  - **€37.2 m on June 30, 2016**
  - **€28.7 m on September 30, 2016**
- **Of which €6.6 m is linked to Bpifrance (OSEO) advance payment**
- **Of which €6.8 m is trade payables**

INCOME STATEMENT	31/06/2015	30/06/2016
€ thousands		
Operational income	0	0
Marketing and Admin. costs	(1,064)	(3,828)
R&D costs	(5,239)	(10,213)
Operating profit / loss	**(6,303)**	**(14,041)**
Financial profit / loss	**(760)**	**(626)**
Net profit / loss	**(7,062)**	**(14,662)**

- **Enrollment of clinical studies: CARAT, TANGO and LOCATION**
- **Affected by non-cash elements:**
  -IFRS treatment of the BPI repayable advances

**** Unaudited***

Simplified cash flow table

CASH FLOW TABLE	30/06/2015	30/06/2016
€ thousands		
Cash flow from operations	(6,079)	(11,018)
Cash flow from investments	(25)	(2)
Cash flow from financing	48,924	940
Change in cash position	**42,820**	**10,079**
Cash position at start of period	7,843	42,951
Currency effect	(3)	0
Cash position at end of period	**50,660**	**32,872**

- **March 2015 IPO**
- **Cash position as of June 30, 2016**

**** Unaudited***

Value proposition: why invest in CERENIS?

CER-001: major potential in the treatment of patients post-ACS

1. A therapy targeting the 2/3 of patients who are poorly served with available medical treatments
2. Advanced and promising clinical developments currently in Phase II (CARAT)
3. Compelling to big pharma (e.g., OMTHERA $443 m; Esperion $1.3 bn; KOS $3.7 bn)[1]
4. A manufacturing process validated on an industrial level with proven clinical safety and tolerability

In the short term: CER-001, a drug for treating orphan diseases

1. A potential of value creation in the short term, currently in Phase III (TANGO)
2. A major unmet medical need
3. Application for marketing approval before 2018

CER-209: major potential in the treatment of patients with atherosclerosis and NAFLD/NASH

1. A significant unmet medical need
2. CER-209, a highly specific P2Y13 receptor agonist promoting lipid elimination
3. Launch of a phase 1 study with CER-209 in NASH/NAFLD in Q1 2017

A LISTED COMPANY WITH SUBSTANTIAL POTENTIAL IN HDL THERAPY

1. *Press releases,*
OMTHERA: http://www.astrazeneca.com/Media/Press-releases/Article/20130528-omthera
Esperion: http://www.bloomberg.com/apps/news?pid=newsarchive&sid=apU2qcYCmkO4&refer=us
KOS: http://www.bloomberg.com/apps/news?pid=newsarchive&sid=af_8tglk4fHE