Cerenis™ THERAPEUTICS

CEREN
LISTED
EURONEXT

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Cerenis Overview

Listed: ENXTPA (Euronext Paris)
Ticker: CEREN
Located: Balma, Midi-Pyrénées, France
Market Cap[1]: $40.1 MM
Went Public: March 25, 2015

Key Investors:

- Bpifrance Investissement
- Sofinnova Partners
- HealthCap
- TVM Capital GmbH
- Alta Partners
- Montaigne Capital

Board of Directors:

- Richard Pasternak, M.D. (Chairman)
- Jean-Louis Dasseux, Ph.D., M.B.A. (Director)
- Christian Chavy (Director)
- Laura A. Coruzzi, Ph.D., J.D. (Director)
- Michael H. Davidson (Director)
- Karen Noël (Director)
- Barbara Yanni, J.D, M.A., B.A. (Director)
- Olivier Martinez, Ph.D., M.B.A. (Observer)

Jean-Louis DASSEUX, PhD, MBA
Founder and CEO

- More than 30 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 85 patent families relating to HDL, the treatment of cardiovascular diseases and targeted delivery of active agents in oncology
- Two products currently in phase III clinical trials (Bempedoic acid at Esperion Therapeutics and CER-001 at Cerenis Therapeutics)
- Esperion Therapeutics sold to Pfizer for $1.3 Billion in 2004

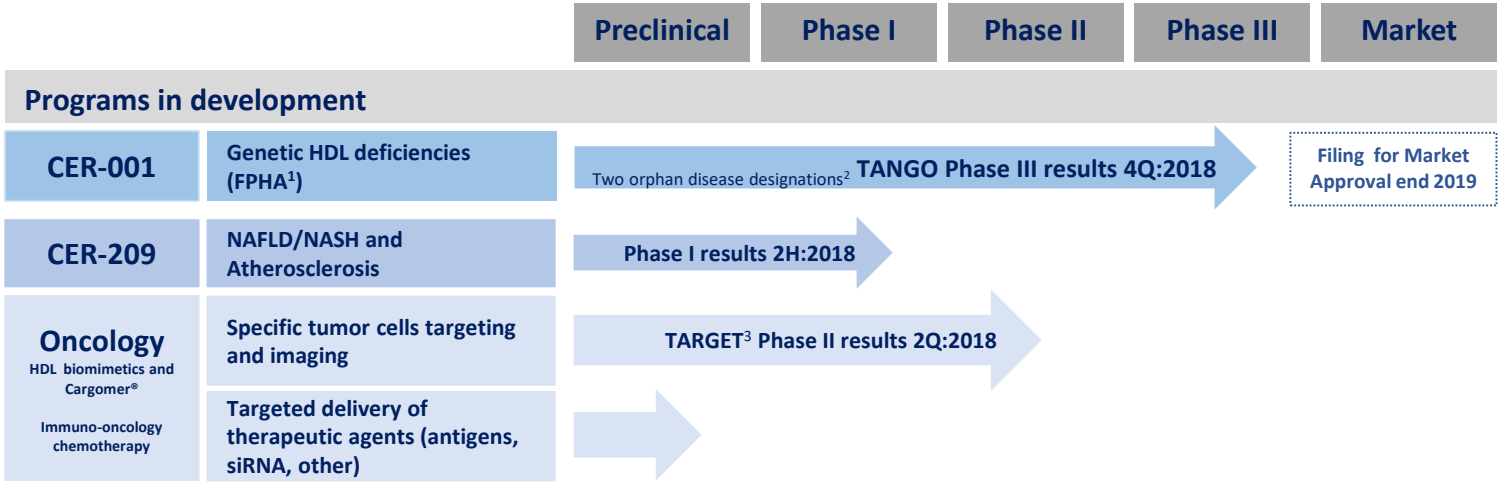
Cyrille TUPIN, CPA
CFO

- 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

Cerenis Highlights

- **Late Stage Program in Orphan Cardiovascular Diseases**
  - CER-001 is an HDL mimetic in Phase III trials for genetic HDL deficiencies
  - Results expected in 4Q:2018
- **Targeted HDL drug delivery platform with potential in oncology indications**
  - Preliminary Phase II results recently reported in esophageal cancer patients demonstrated clinically meaningful targeting of esophageal tumor tissue by labeled CER-001
- **Phase I program in NAFLD/NASH – CER-209, a first-in-class P2Y13r agonist has the potential to address both hepatic steatosis and atherosclerosis**
  - Data expected in 2H:18
- **Strong and experienced Management Team and seasoned Scientific Advisory Board**
  - CEO Jean-Louis Dasseux is a leading expert in lipid metabolism, atherosclerosis and cardiovascular diseases and brings over 30 years of experience in the pharmaceutical industry; integral member of the Esperion team; Esperion was sold to Pfizer in 2004 for $1.3 billion
  - CFO Cyrille Tupin has helped Cerenis raise over $200 million in three financing rounds at Cerenis and completed IPO raising $60 million
  - Scientific Advisory Board composed of five key members
- **Several near term catalysts**
  - Phase 3 results in lead program CER-001 expected in 4Q:18
  - Phase 1 CER-209 data
  - further HDL drug delivery data expected in 2H:18

Cerenis Pipeline



1. *Familial Primary Hypo Alphalipoproteinemia*
2. *ApoA-I and ABCA1 deficiencies*
3. *The TARGET study is a single-center observational trial directed by Drs. Erik Stroes and Hanneke Van Laarhoven from the Amsterdam Medical Center enrolling adult subjects with a pathologically proven diagnosis of primary esophageal carcinoma in situ*

THREE TARGET INDICATIONS WITH HIGH UNMET MEDICAL NEED: FPHA, NAFLD/NASH/ATHEROSCLEROSIS AND ONCOLOGY

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CER-001: a drug for treating orphan diseases

CER-001 – Phase III program for treating orphan diseases

A drug for treating orphan diseases

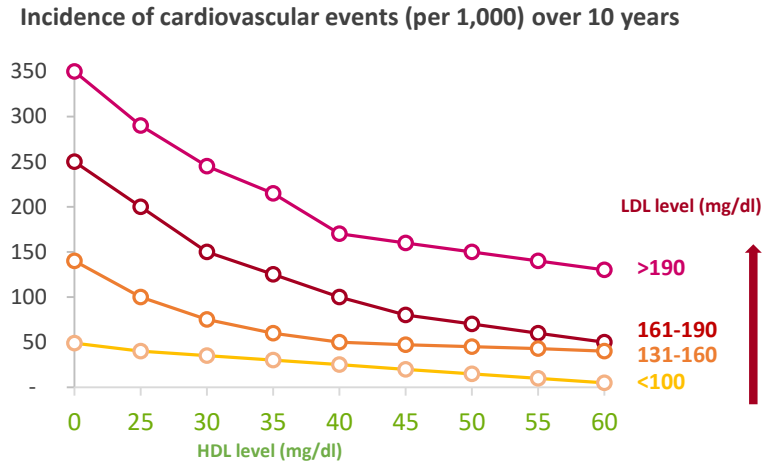
1. HDL deficiency, a major unmet medical need
2. Two orphan designations for apoA-I and ABCA deficiency
3. Results of the phase III study (TANGO) are expected by 4Q2018
4. A manufacturing process validated on an industrial level

HDL therapy: potential 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]



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

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

The key advantage of HDL therapy for FPHA

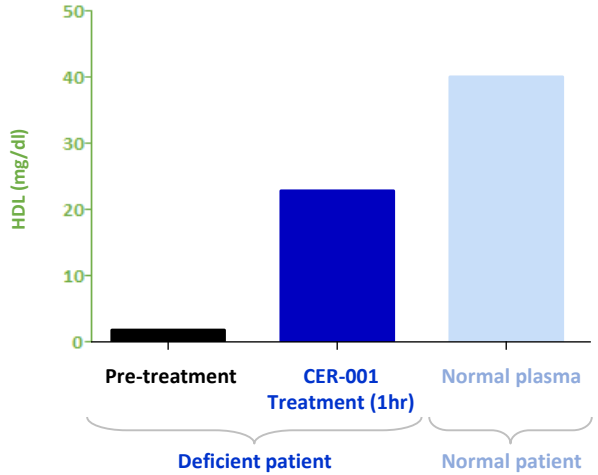
FPHA: genetic defect affecting HDL synthesis

- CERENIS' solution restores the blood's ability to mobilize cholesterol into HDL to facilitate its elimination

2 orphan drug designations obtained from the EMA

- HDL deficiency (no apoA-I synthesis)
- Tangier disease (absence of ABCA1)

Mobilization of HDL cholesterol in the blood[1]



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

1. *Company: SAMBA study*

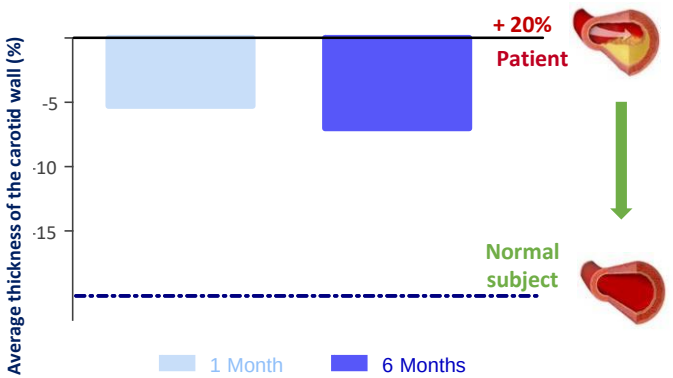
Confirmed proof of concept in HDL deficient patients

The Phase II study showed:

Reduction of the vascular wall thickness

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

Efficacy on carotid atherosclerosis[1]



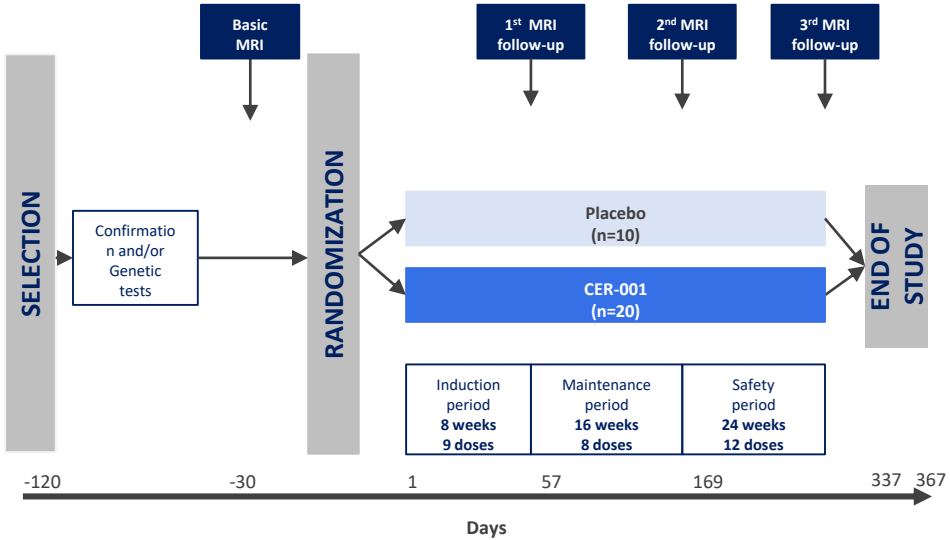
IN THE BODY, CER-001 BEHAVES JUST LIKE A NATURAL HDL PARTICLE

1. *J Lipid Res. 2015 Jan 5. ePub*

TANGO: a phase III in FPHA (HDL deficiencies)

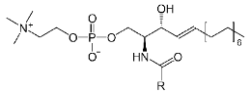
The TANGO study should show:

- A reduction in coronary plaque in the carotid



THE TARGET OBJECTIVE IS TO OBTAIN MARKETING APPROVAL IN IDENTIFIED GENETIC DEFECTS (APOA-I AND ABCA1 DEFICIENCIES)

Cerenis holds the proprietary manufacturing process for natural recombinant human apoA-I and HDL particles

1 PRODUCTION	2 OPTIMIZATION	3 ASSEMBLY	4 LOADING
			
Secretion of the **apoA-I protein via a mammalian cell**	Synthesis of suitable phospholipids	Assembled via a natural process	Active drug encapsulated in HDL particle
✓ **Purity**	✓ **Stability**	✓ **Scalability**	✓ **Integration**

- **Manufacturing costs that will lead to substantial savings at scale-up**
- **An economically-viable HDL manufacturing process**

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CARGOMERS® AND HDL MIMETICS

CERENIS' PROPRIETARY TARGETED HDL DRUG DELIVERY

CERENIS Targeted HDL Drug Delivery Platform

Expanding its HDL strategy into immuno-oncology and chemotherapeutic drug delivery

1. First HDL nanoparticle delivery platform to be initially dedicated to the oncology market

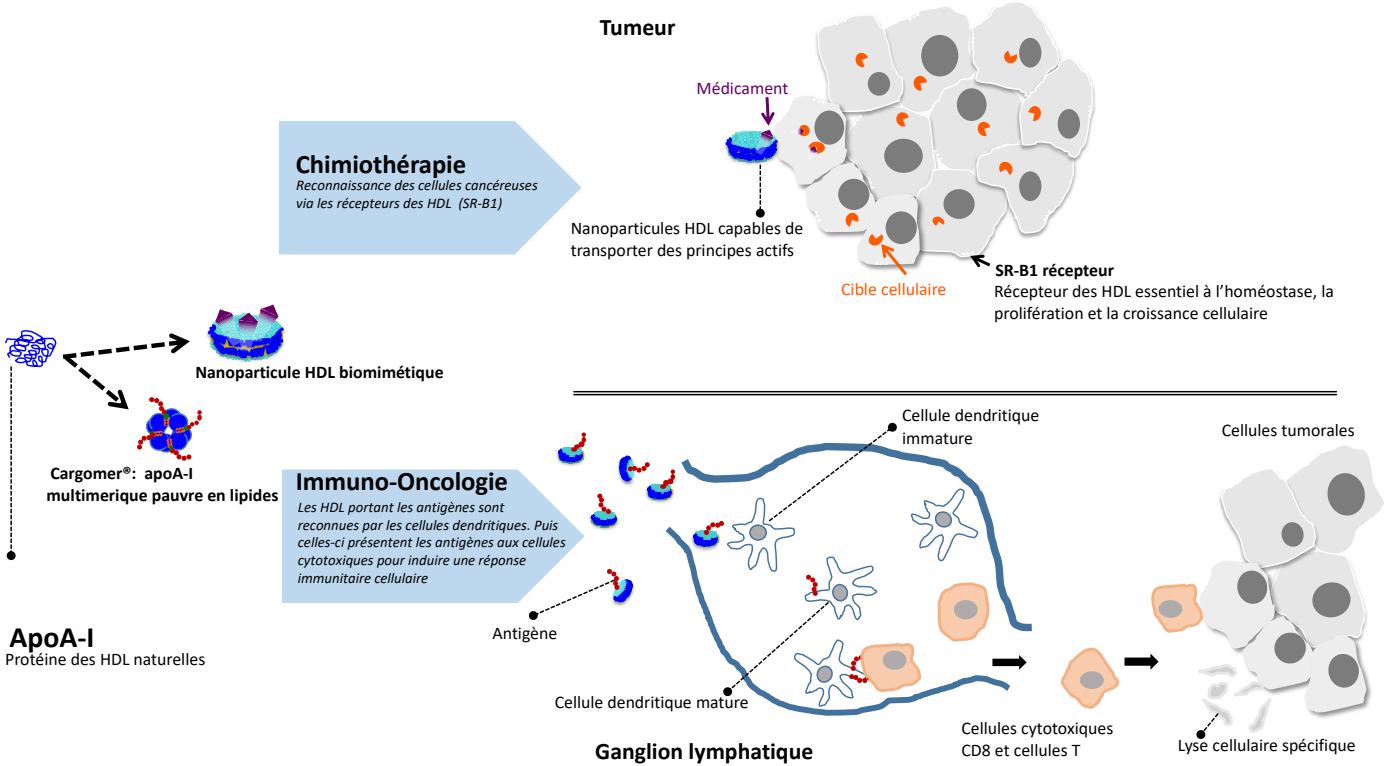
2. Immuno-oncology is one of the most promising cancer treatment technology in a market valued at $100 billion by 2020[(1)]

3. TARGET : Phase II clinical study, primary objective met: First ever performed clinical study demonstrating labeled HDL nanoparticles tumor uptake in esophageal cancer patients

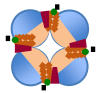
4. CERENIS is positioned to utilize HDL related particles to selectively target a wide variety of tissues

[(1)]: Hexa Research. (2016). Immuno-oncology market, by type [mAb (naked, conjugate), cancer vaccines, immune checkpoint inhibitors (PD-1, PD-L1, CTLA-4]), by application (lung, melanoma, leukemia, lymphoma): Global forecast to 2022.

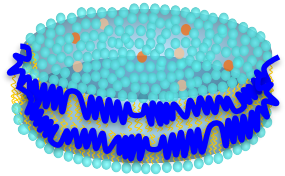
HDL particles are perfect delivery vehicles able to selectively bring cell killing agents to cancer cells



ApoA-I with its flexible structure, is a key asset to accomodate different drug loads and target different tissues



Cargomer®: multimeric apoA-1
(2-6nm)

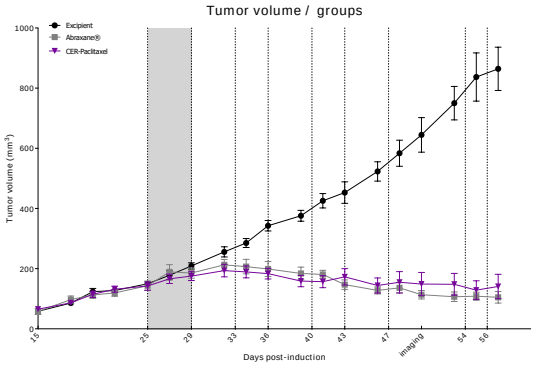


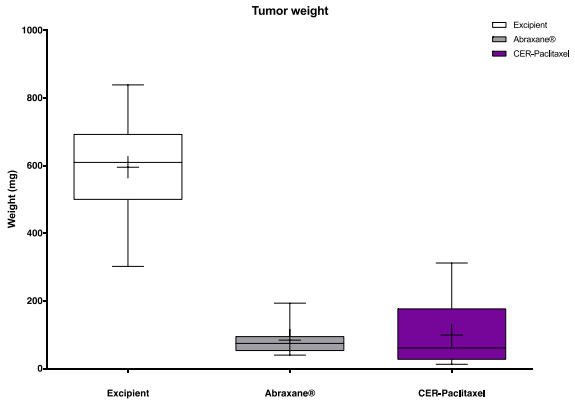
Discoidal HDL
(7-9nm)

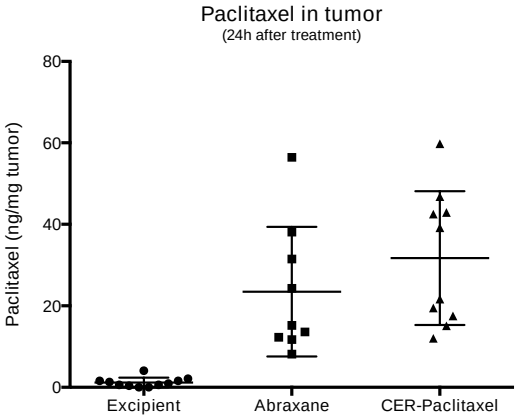
- The ability of monomeric apoA-I to form multimeric structures, offers the opportunity to have a carrier with adaptive capacity and a different pace of release as number of subunits increase.
- The small size of monomeric or multimeric apoA-I allows to penetrate the blood brain barrier as well as the lymph compartment.
- Cerenis delivery vehicles take advantage of the wide distribution of HDL/apoA-I receptors (SR-B1 / ABCA1/ABCG1) in tissues.

CERENIS HDL PLATFORM: A « ONE STOP » DRUG DELIVERY PARTNER

Recombinant human apoA-I Pre beta HDL demonstrates excellent targeted Paclitaxel delivery in xenograft murine model of human breast cancer



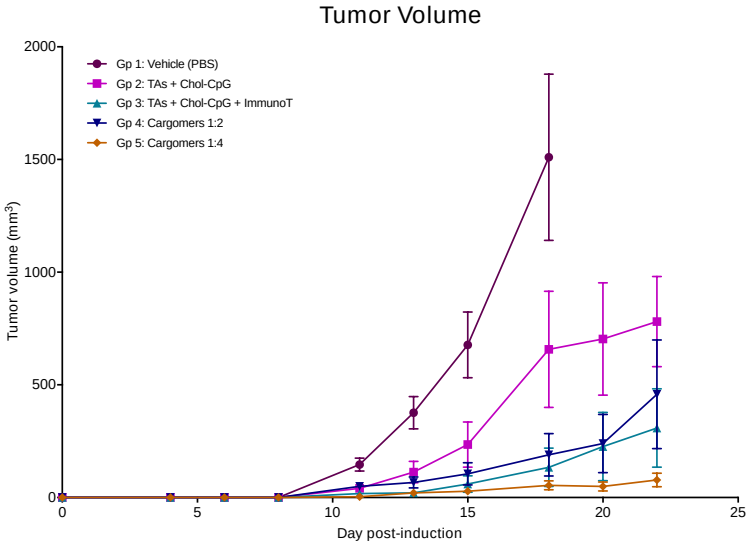


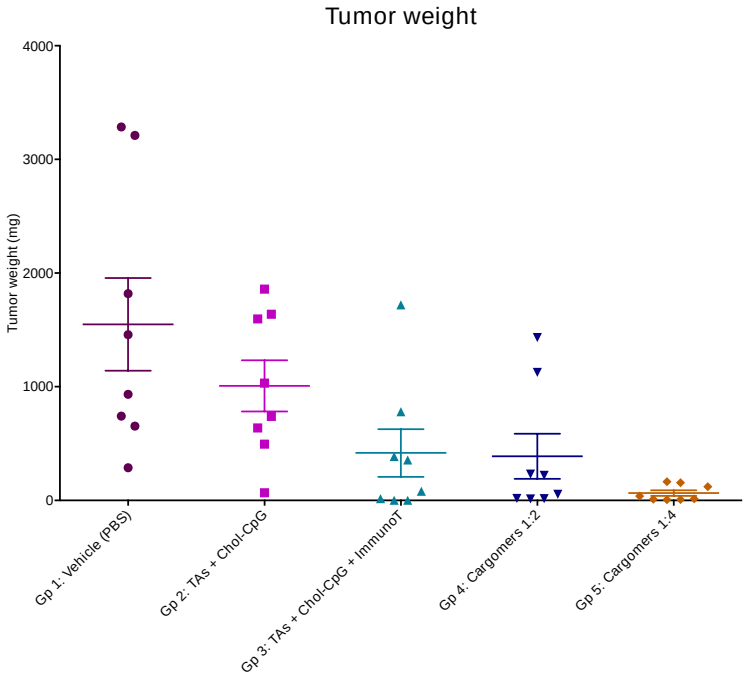


HDL NANOPARTICLES TRAPPING OF CHEMOTHERAPEUTIC AGENTS PROVIDES:

- **ENHANCED STABILITY.**
- **TARGETED DELIVERY FOR BETTER EFFICACY**
- **BETTER TOLERABILITY**

Immuno-oncology: effects of cargomer® (apoA-I multimer) on melanoma





CARGOMER® INDUCE AN IMMUNE RESPONSE PREVENTING TUMOR GROWTH.
CARGOMER® 1:4 IS THE MOST POTENT AND DOES NOT REQUIRE CHECK POINT INHIBITION.

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HDL particles have strong advantages over existing drug delivery technologies

	HDL particles
Safety and efficacy ✓	Natural structure stabilized by apolipoproteins, particularly apolipoprotein A-I (apo A-I) and uniquely capable of delivery of biologically active molecules to tissues and circulating cell in humans.
Biocompatibility ✓	Once the load is delivered, the remaining apoA-I is rapidly and safely integrated in the natural lipoprotein metabolism pathways leading to no accumulation of empty carrier.
Strong ability to target specific cells ✓	HDL particles are recognized by the SR-B1 receptor expressed on cancer cells' surface. The receptor-mediated uptake of the payload, enable delivery of the drug carried in the core of the HDL particle.
Adaptive structure ✓	ApoA-I is flexibly and adaptive, from lipid-poor apoA-I, to discoidal and large spherical particles, allowing different types and quantities of drug payloads for different applications in cancer chemotherapy and antigen carrying immuno-oncologic applications.
Proprietary manufacturing process ✓	Cerenis owns the right to an exclusive, validated, and scalable manufacturing process to produce apoA-I, apoA-I peptides and HDL on an industrial scale.
Indications ✓	Cerenis extensive and broad IP covers composition of matter and methods of use (indications).

HDL PARTICLES ARE NATURE'S UNIVERSAL TARGETING DELIVERY SYSTEMS TO TISSUES AND CIRCULATING CELLS

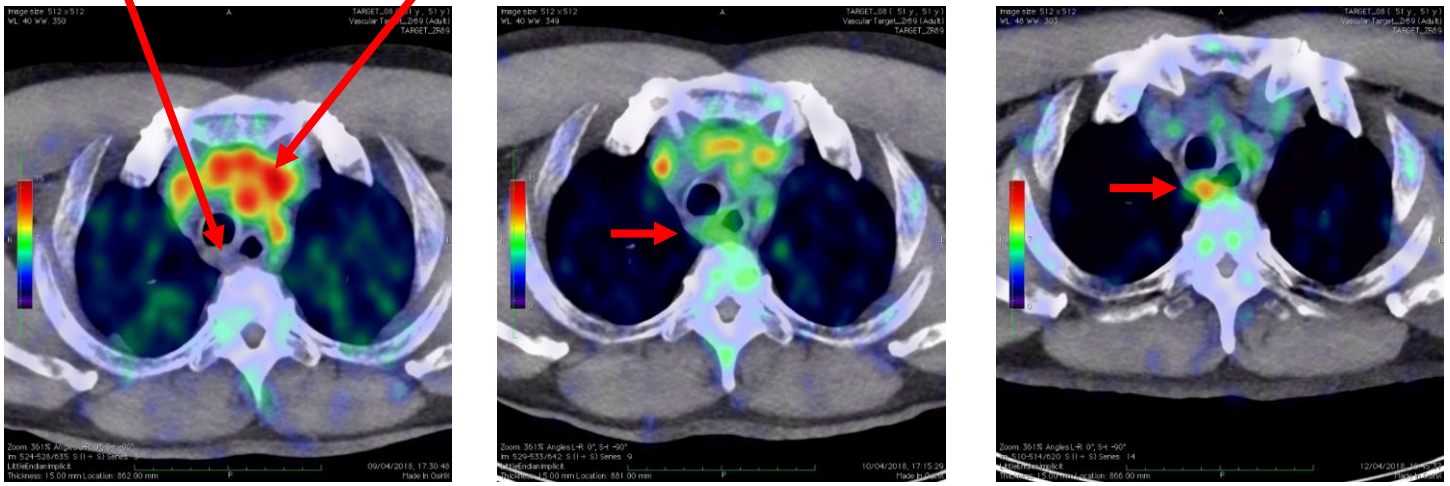
TARGET, Phase II study in cancer patients validated HDL nanoparticles for targeted drug delivery

July 2018

- **Primary objective met:** First ever performed clinical study demonstrating labeled HDL nanoparticles tumor uptake in esophageal cancer patients
- **Sustained tumor labeling** supports future use of HDL mimetics to improve effective delivery of therapeutic agents
- **Encouraging preliminary results observed in patients with esophageal cancer**, often refractory to standard therapy

TARGET WILL SUPPORT THE OPPORTUNITY TO TREAT CANCER PATIENTS USING HDL NANOPARTICLES AS A SPECIFIC DRUG DELIVERY PLATFORM FOR IMMUNO-ONCOLOGY

TARGET: Example of focal accumulation



T=1H

T=24H

T=72H

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CER-209: Major Potential in the Treatment of Patients with NAFLD/NASH and Atherosclerosis

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NAFLD/NASH and Atherosclerosis

- Non-alcoholic fatty liver disease (NAFLD) has become one of the most frequent chronic liver diseases in the Western society and its prevalence is likely to rise even further.
- Pathogenesis of **NAFLD results from disturbed lipid homeostasis and excessive accumulation of lipids in the liver**. NAFLD often develops in the context of the metabolic syndrome (MetS) and is strongly associated with obesity, insulin resistance (IR), type 2 diabetes mellitus (T2DM), and dyslipidemia. Nonalcoholic steatohepatitis (NASH), a more advanced form of the disease, is characterized by steatosis, inflammatory changes, and hepatocyte cell ballooning associated with varying degrees of liver fibrosis
- According to the American Liver Foundation, **NASH is one of the leading causes of cirrhosis in adults in the United-States**.
- **25% of adults having NASH will develop a cirrhosis**. There currently are **no approved therapies** for these diseases.
- In addition, epidemiological studies demonstrate that the cardiovascular risk is increased in patients with hepatic steatosis and that the **cardiovascular diseases associated are the leading causes of death in patients with liver steatosis**[1].

1. *J Franque S. M. et al. Journal of Hepatology, 2016, vol. 65, 425-443*
   World J Gastroenterol 2015 June 14; 21(22): 6820-6834

CER-209, a potential breakthrough treatment for Nonalcoholic Steatohepatitis (NASH) and Atherosclerosis

Unique HDL therapy enables to address NAFLD/NASH and Atherosclerosis

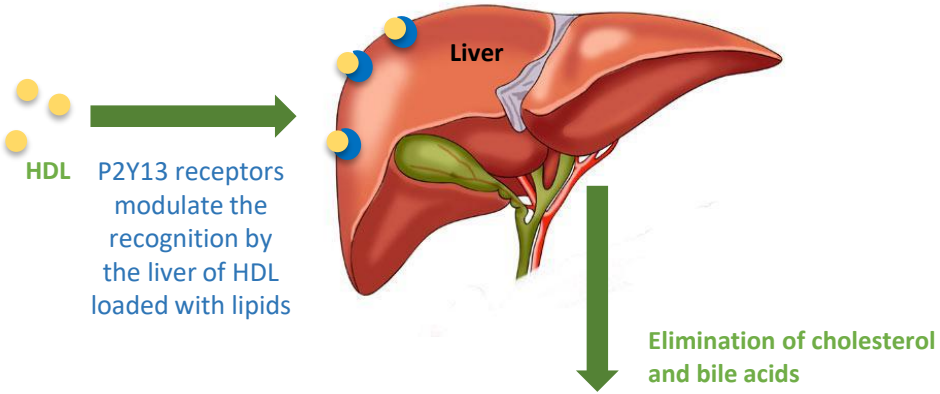
- **CER-209 is the first in class drug candidate of oral P2Y13 receptor agonists**. CER-209, a new-patented molecule coming from Cerenis' research, has the potential to play an innovative role **by addressing both hepatic steatosis and atherosclerosis.**
- **CER-209's major activity in NASH and NAFLD treatment lies in its ability to promote HDL recognition and lipid elimination by the liver**, through the activation of natural metabolic pathways mediated by the P2Y13 receptor[1].
- **Since atherosclerosis is frequently observed in patients with NASH**, these patients have high cardiovascular risk. Thus, an agent that lowers that risk in addition to treating steatohepatitis and liver inflammation is of considerable value.
- Current NAFLD/NASH treatments based on lipid lowering drugs attempt to reduce LDL cholesterol **but they can increase liver enzymes.**

1. *Fabre ACC et al., Hepatology 2010;52:1477–1483*
Serhan N. et al., Biochim. Biophys Acta 2013;1831:719–725.
Goffinet M. et al., PLoS ONE 2014;9:e95807.

CER-209, A FIRST-IN-CLASS POTENTIAL THERAPEUTIC SOLUTION TO ADDRESS BOTH NASH AND ATHEROSCLEROSIS

CER-209 increases HDL recognition by the liver by stimulating the activity of HDL receptors

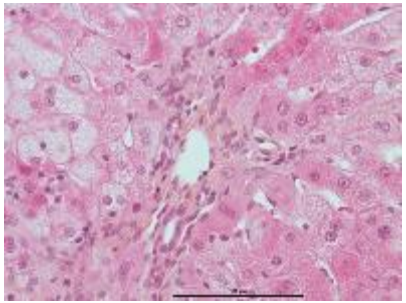
- **A new mechanism of action** which involves the last steps of the RLT pathway
- **Agonist activity of CER-209 on the liver P2Y13 receptors facilitates elimination of mature HDL particles loaded with lipids**, through better HDL liver recognition and increased bile secretion
- CER-209 treatment leads to higher fecal excretion of triglycerides, cholesterol and bile acids.



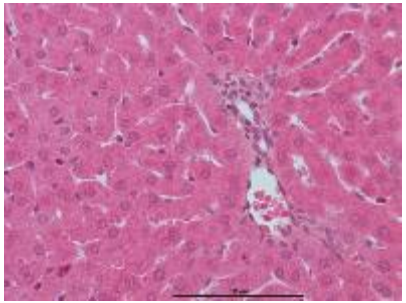
CER-209, A NEW MECHANISM OF ACTION

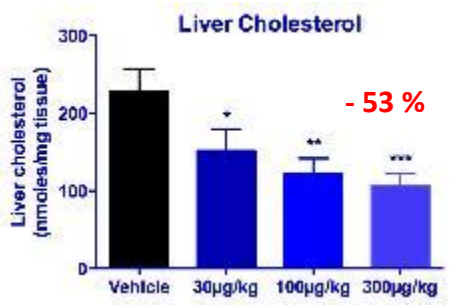
CER-209: Promotes regression of liver steatosis (NASH)
(preclinical model)

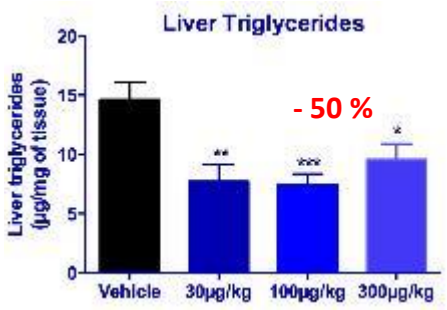
Vehicle

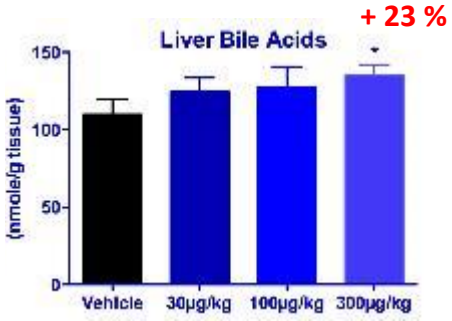


CER-209 @ 300 µg/kg







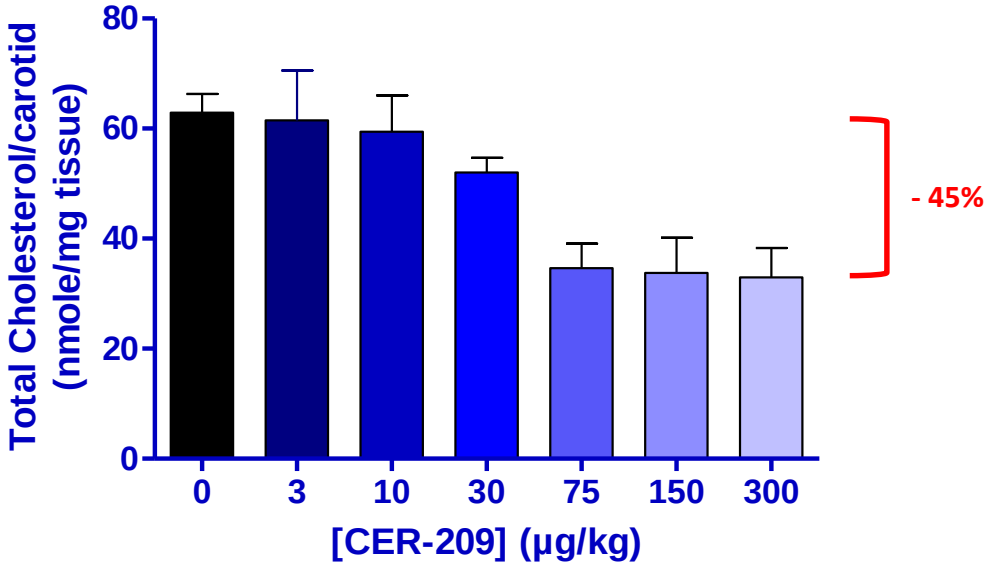


Cerenis US Patent 8,349,833 (2013); *Goffinet M. et al (2014) PLOS One*

**p < 0.05, **p < 0.01, ***p < 0.001.*

CER-209 also inhibits carotid atherosclerotic plaque progression

(APOE$^{-/-}$ preclinical model, Flow cessation model, 15 days of treatement)



CER-209: phase I clinical trial is ongoing

Single Dose Tolerance study (SDT) completed

- No drug related safety nor tolerance issues identified
- The pharmacokinetics observations support CER-209 once daily oral dosing

Multiple Dose Tolerance study (MDT) in subjects with a high risk of NAFLD/NASH underway

- Randomized, double blind and placebo controlled trial
- Daily doses of 10, 30, and 60 mg of CER-209 will be given for 28 days
- Primary objective is safety and tolerability. Pharmacokinetic and pharmacodynamics endpoints will also be studied

Seasoned scientific experts and strategic pharmaceutical industry veterans join Cerenis' scientific advisory board in oncology

MAY 2018

Creation of its Scientific Advisory Board in Oncology (SAB-Oncology) with five key appointments

- **Briggs Morrison, MD**: Chairman of Cerenis' SAB Oncology – CEO of Syndax Pharmaceuticals. Former Head of Global Medicines Development and Chief Medical Officer at Astra Zeneca. Former Head of Clinical Development at Pfizer.
- **Mark Frohlich, MD**: Former Executive V.P. of Portfolio Strategy at Juno Therapeutics. Former EVP of R&D and Chief Medical Officer of Dendreon Corporation
- **Aurélien Marabelle, MD, PhD**: Clinical Director of the Cancer Immunotherapy Program at Gustave Roussy Cancer Center
- **Robert Schneider, PhD**: Albert Sabin Professor of Molecular Pathogenesis, Professor of Radiation Oncology. Associate Director of the NYU Cancer Institute, Director of Translational Cancer Research, and Co-director of the Breast Cancer Research Program at NYU School of Medicine.
- **Robert Spiegel, MD**: Principal of Spiegel Consulting LLC and an Assistant Professor of Medicine at Weill Cornell Medical College Former Sr. V.P. for worldwide Clinical Research and Chief Medical Officer at Schering-Plough

Briggs Morrison, commented: *"… Targeted drug delivery has always been a "holy grail" in Oncology and Cerenis may be at the point where such a challenge can be overcome…"*

VALIDATION OF CERENIS' STRATEGIC EXPANSION IN TARGETED HDL DRUG DELIVERY THROUGH PROMISING PROPRIETARY PLATFORM

A Solid IP Covering Composition of Matter and Methods of Use

16 patent families protecting compounds, indications and manufacturing/diagnostic methods

PRODUCT	INDICATION	MANUFACTURING/DIAGNOSTIC
Family 1: CER-001, charged lipoproteins and their uses		**Family 2:** Manufacturing methods for reconstituted HDL particles and highly-homogenous resulting populations of HDL particles
	Family 10: Treatment of FPHA	
Families 12: Apomer®		
	Family 4: Treatment of Dyslipidemias	**Family 3:** Companion diagnostics and dosage of CER-001
Family 6: HDL mimetic peptides (CER-522)		
Family 7: P2Y13 receptor agonists (CER-209)		**Family 5:** Synthetic sphingomyelin synthesis / production methods
Family 11: Cargomer®		
Families 14 – 15 – 16: Drug delivery HDL vectors		**Family 9:** Carrier particles for administering drugs
	Family 13: Imaging by labeled HDL	
Family 8: PPAR agonists (CER-002)		

Cerenis at the 2018 HDL Workshop (adjacent to ATVB|PVD Scientific Sessions)

MAY 2018

Jean-Louis Dasseux, founder and CEO of CERENIS Therapeutics, presented at the 2018 HDL Workshop adjacent to the Vascular Discovery Scientific Sessions

- Presentation of CERENIS Therapeutics' strategy in targeted HDL drug delivery applied to oncology and its clinical experience in HDL development to create a unique targeted HDL drug delivery platform
- Title of the presentation: "*ApoA-I and HDL, Nature's Universal Targeting Delivery Systems*"
- Date of the presentation: Wednesday May 9 , 2018 in San Francisco, California

DELIVERY BY HDL PARTICLES ALLOWS TO TARGET SPECIFICALLY TUMORS USING IMMUNOTHERAPY AND/OR CHEMOTHERAPEUTICS

CERENIS program highlights

CER-001: major potential in the treatment of patients with HDL deficiencies due to genetic defects

1. A potential for value creation in the short term (TANGO Phase III results **4Q2018)**
2. Two orphan drug designations granted
3. Application for marketing approval in 2019
4. A strong patent estate and a manufacturing process validated on an industrial level

HDL Targeted Drug Delivery: Immuno-Oncology and Chemotherapy

1. Preliminary Phase II results demonstrate clinically meaningful targeting of esophageal tumor tissue labeled by CER-001
2. An innovative proprietary technology leveraging the natural properties of HDL to specifically target and deliver active pharmaceutical ingredients

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

1. A potential of value creation in the short term (Phase I results **4Q2018)**
2. CER-209, a highly specific P2Y13 receptor agonist promoting lipid elimination covered by a strong IP

LISTED COMPANY WITH SUBSTANTIAL POTENTIAL IN LIPID METABOLISM AND ONCOLOGY


Cerenis™
THERAPEUTICS