

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **February 7, 2017**

GEMPHIRE THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-37809
(Commission
File No.)

47-2389984
(IRS Employer
Identification No.)

**17199 N. Laurel Park Drive, Suite 401
Livonia, Michigan 48152**
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: **(248) 681-9815**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

Gemphire Therapeutics Inc. (the "Company") will conduct an analyst and investor event and present a Company and clinical update on February 7, 2017.

A copy of the slides which accompanied the presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference. The presentation slides will also be available immediately prior to and for 90 days following the presentation on the Investors and Media page of Gemphire's website at <http://ir.gemphire.com>.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit</u>	<u>Description</u>
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99.1	Slides Presented at Analyst and Investor Event
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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GEMPHIRE THERAPEUTICS INC.

Dated: February 7, 2017

By: /s/ Jeffrey S. Mathiesen
Jeffrey S. Mathiesen
Chief Financial Officer

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EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Slides Presented at Analyst and Investor Event.

4



*Advancing a class
on top of statins*

February 2017



This presentation includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Except for statements of historical fact, any information contained in this presentation may be a forward-looking statement that reflects the Company's current views about future events and are subject to risks, uncertainties, assumptions and changes in circumstances that may cause events or the Company's actual activities or results to differ significantly from those expressed in any forward-looking statement. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "could", "would", "should", "plan", "predict", "potential", "project", "expect," "estimate," "anticipate," "intend," "goal," "strategy," "believe," and similar expressions and variations thereof. Forward-looking statements may include statements regarding the Company's business strategy, market size, potential growth opportunities, capital requirements and use of proceeds, clinical development activities, the timing and results of clinical trials, regulatory submissions, potential regulatory approval and commercialization of the product candidate. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, the Company cannot guarantee future events, results, actions, levels of activity, performance or achievements. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under the heading "Risk Factors" in our filings with the SEC. These forward-looking statements speak only as of the date of this presentation and the Company undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date hereof.

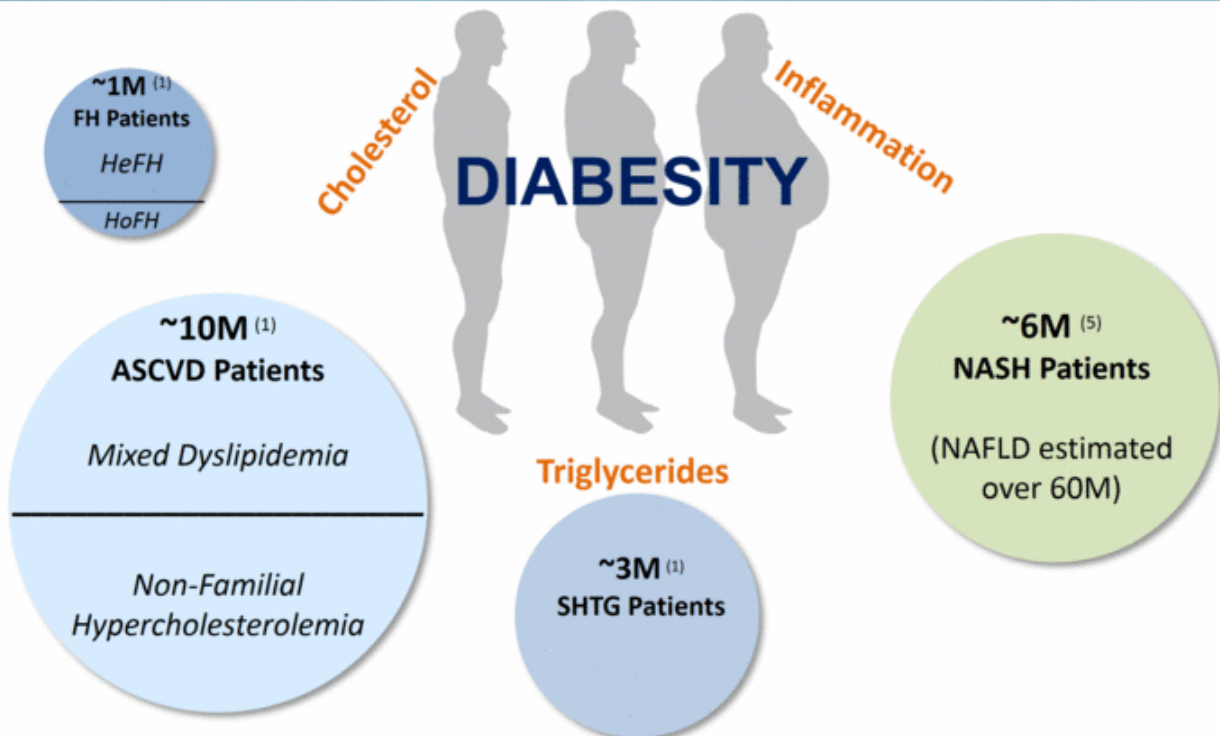
This presentation also contains estimates and other statistical data made by independent parties and by us relating to market shares and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

- **A Phase 2 clinical CV/NASH biotech company** with first-in-class oral, once-daily gemcabene licensed from Pfizer
 - Safety and efficacy validated based on comprehensive data from 895 subjects across 18 trials (11 Phase 1 and 7 Phase 2) and over 30 preclinical toxicology studies
- **\$30M IPO at \$10/share in August 2016 (NASDAQ:GEMP) with 'blue-chip' biotech investors**
 - Cormorant, Adage, Excel Venture Mgt, Capital Midwest, Pfizer, and Management/Directors
 - Analyst coverage from Jefferies, RBC, Canaccord Genuity, Laidlaw, and LifeSci Capital
- **Large, unmet global market opportunity** despite new therapies
 - Gemcabene differentiated MOA (cholesterol, triglycerides, & inflammation) in cardiovascular disease with upside potential for the treatment of NASH (e.g., recent POC data, AZURE-1 Phase 2 planned)
- **Significant clinical catalysts expected in 2017**
 - Data readouts expected in 3 Phase 2b trials COBALT-1, ROYAL-1, INDIGO-1 in dyslipidemic patients
- **Established regulatory approval pathway with surrogate lipid (LDL-C or TG) endpoints** for the selected patient populations
- **Leadership team with track record** developing/commercializing/partnering multiple CV and orphan drugs based in Michigan (the origins of best selling drug Lipitor)
- **Valuation at ~\$100M (as of 2/3/17), GEMP CV and NASH peer group** may include MDCO, ESPR, AMRN, MDGL, ICPT, CNAT, TBRA (acquired by Allergan), ENTA, and GNFT
- **Cash \$28.4M (9/30/16)**, no debt, funding for trials through EoP2 meetings in 1H 2018

Related Multiple Large Markets of Dyslipidemia and NASH

An Estimated 20 Million US Patients Addressable by Gemcabene



Dyslipidemia Market (\$26B)

All Statins ~\$6.1B⁽²⁾⁽³⁾, Ezetimibe ~\$2.7B⁽²⁾⁽³⁾, Bile Acid Sequestrants ~\$0.7B⁽²⁾, PCSK9s ~\$0.5B⁽⁴⁾, Fibrates ~\$1.0B⁽²⁾, Niacin ~\$1.0B⁽²⁾, Rx Fish Oil ~\$1.2B⁽²⁾

NASH Market (\$35B+ by 2025)⁽⁶⁾

- 1) Company estimate based on DRG Market Data, NHANES and FH Foundation.
- 2) Estimated revenues for U.S. dyslipidemia market sales in 2013.
- 3) Includes revenues when used as a standalone therapy and as a fixed-dose combination therapy.
- 4) Projected revenues for U.S. sales in 2016.
- 5) The National Institute of Diabetes and Digestive and Kidney Diseases, 2016
- 6) Estimated peak global market for NASH treatments, Deutsche Bank 2014

A NOVEL, COST-EFFECTIVE, ONCE-DAILY ORAL THERAPY

Efficacy

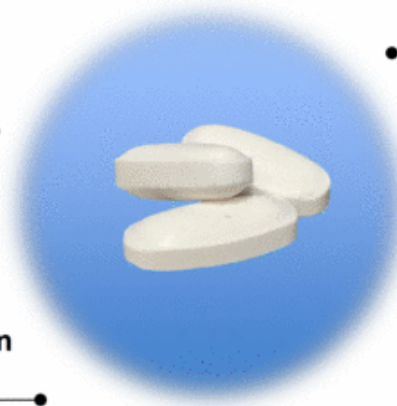
Safety

Significant Lipid-Lowering

LDL-C	~30%	↓
TG	~40%	↓
hsCRP	~40%	↓

Additive Effect in Combination w/ Statins Lowered

LDL-C	~30%	↓
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No Drug-Drug Interactions

- High dose atorvastatin
- High dose simvastatin
- Digoxin

Promising Safety and Tolerability

- No myalgia as monotherapy
- No liver toxicities
- No significant effect on kidney function
- No QTc prolongation
- No clinically meaningful change in blood pressure
- No food effect

Note: Percentages (Mean and Median - LDL-C, Median - hsCRP, TG) have been demonstrated across multiple clinical studies. A decrease in CRP (an earlier clinical assay) correlates with a decrease in hsCRP (the current CV risk assay).

Gemcabene Development Program Overview

895 Subjects Treated with Gemcabene Across 18 Clinical Trials



	Patient Population:	Trial:	Doses:	Duration:
Phase 2	Hypercholesterolemia	1027-018 <i>n</i> =66 (GEM=42)	300, 900 mg (add-on various low, moderate and high intensity statins)	8 wks
		A4141001 <i>n</i> =277 (GEM=208)	300, 600, 900 mg (concurrent 10, 40, 80 mg atorvastatin)	8 wks
	Low HDL-C and Normal or Elevated TG	1027-004 <i>n</i> =161 (GEM=129)	150, 300, 600, 900 mg	12 wks
	Healthy Obese Non-Diabetic	1027-014 <i>n</i> =53 (GEM=26)	900 mg	4 wks
	Hypertension	1027-012 <i>n</i> =102 (GEM=43)	900 mg (arm with quinapril 20 mg)	12 wks
		1027-015 <i>n</i> =23 (GEM=23)	900 mg	4 wks
Osteoarthritis	A4141004 <i>n</i> =404 (GEM=242)	150, 450, 900 mg (arm with rofecoxib 25 mg)	4 wks	
Phase 1	Completed 11 Phase I Trials in Healthy Volunteers	1027-008 <i>n</i> =20 (GEM=20)	900 mg (DDI Study with 80 mg simvastatin)	15 days
		A4141002 <i>n</i> =20 (GEM=20)	300, 900 mg (DDI Study with 80 mg atorvastatin)	22 days
		1027-001, -002, -003, -009, -010, -011; A4141003, -005, -006 <i>n</i> =163 (GEM=142)	25 to 1,500 mg	Single and Multiple Dose Studies; Up to 4 wks
Preclinical	<ul style="list-style-type: none"> ✓ Completed over 30 nonclinical GLP toxicology studies, including: <ul style="list-style-type: none"> ✓ 26-week study in rats and monkeys; 52-week study in monkeys □ Ongoing two year carcinogenicity studies in mice and rats 			

Gemcabene Pipeline and Clinical Plans

Multiple Clinical Catalysts in 2017



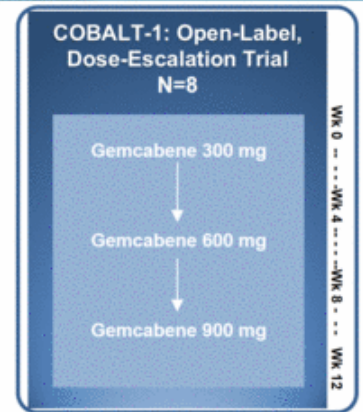
Indication	Phase 1	Phase 2a	Phase 2b	Phase 3	NDA	Anticipated Milestones
Homozygous Familial Hypercholesterolemia (HoFH)						COBALT-1 Phase 2b trial (n=8) ongoing and interim data provided January 30, 2017; top-line data expected in June 2017
Hypercholesterolemia – Heterozygous Familial Hypercholesterolemia (HeFH)						ROYAL-1 Phase 2b trial (n=104) ongoing and top-line data expected in 3Q 2017
Hypercholesterolemia – Atherosclerotic Cardiovascular Disease (ASCVD)						
Severe Hypertriglyceridemia (SHTG)						INDIGO-1 Phase 2b trial (n=90) ongoing and top-line data expected in 4Q 2017
Non-alcoholic Steatohepatitis (NASH) / Non-alcoholic Fatty Liver Disease (NAFLD)						AZURE-1 Phase 2 trial protocol being finalized with plans to initiate AZURE-1 in 2017

COBALT-1 Trial Design (GEM-201)

Phase 2b Clinical Trial in Patients with HoFH

COBALT-1 Trial

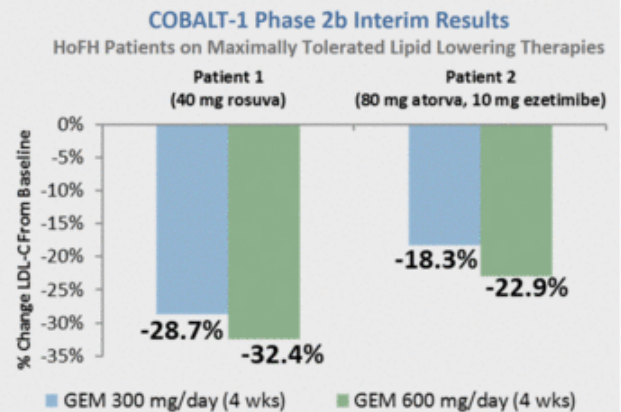
- 12-week multicenter, open-label, dose-escalation trial with clinically diagnosed HoFH patients on stable low-moderate-high statin therapy (and ezetimibe and Repatha)
- LDL-C primary endpoint
- Up to 8 patients at 300 mg, then 600 mg, then 900 mg every 4 weeks
- 5 patients on treatment with additional patients screening at 9 sites in US, Canada, and Israel
- Interim data provided January 30, 2017, and top-line data results in June 2017
- Regulatory pathway precedent set by Juxtapid, Kynamro, Repatha, statins, and ezetimibe for approval in HoFH on LDL-C endpoint
- FDA Orphan Designation granted (in 2014)



Rationale for Potential Meaningful Results in COBALT-1

- Interim COBALT-1 data: **gemcabene 600 mg lowered mean LDL-C by 28%** on top of maximum statin lipid-lowering therapy in 2 HoFH patients
- Gemcabene's novel **MOA is complementary** to the LDL receptor MOA's
- **Preclinical data demonstrated 55% LDL-C reduction** as gemcabene monotherapy (and additive to atorvastatin 72% LDL-C ↓) in HoFH mice model
- **Clinical data (Trial 1027-018) shows up to 31% LDL-C lowering** on top of stable statin therapy

Gemcabene efficacy observed in difficult-to-treat HoFH patients may support potential efficacy in ROYAL-1

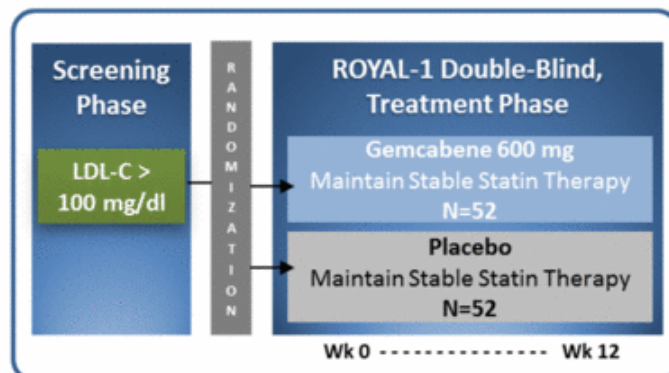


ROYAL-1 Trial Design (GEM-301)

Phase 2b Clinical Trial in Patients with ASCVD/HeFH

ROYAL-1 Trial

- 12-week multicenter, double-blind, placebo-controlled trial in patients with hypercholesterolemia (ASCVD/HeFH) on stable moderate- and high-intensity statin therapy (with or without ezetimibe)
- LDL-C primary endpoint at 12 weeks
- 104 patients (52 in each arm with target commercial dose gemcabene 600 mg and placebo)
 - Each arm balanced 26 moderate intensity statin and 26 high intensity statin
- 28 sites in US
- Enrollment ahead of schedule (~2 months, expected completion in January)
- Top-line data now expected in 3Q 2017
- Regulatory pathway precedent set by PCSK9s for approval with LDL-C endpoint for these high risk patients on maximally tolerated statins assuming favorable benefit/risk

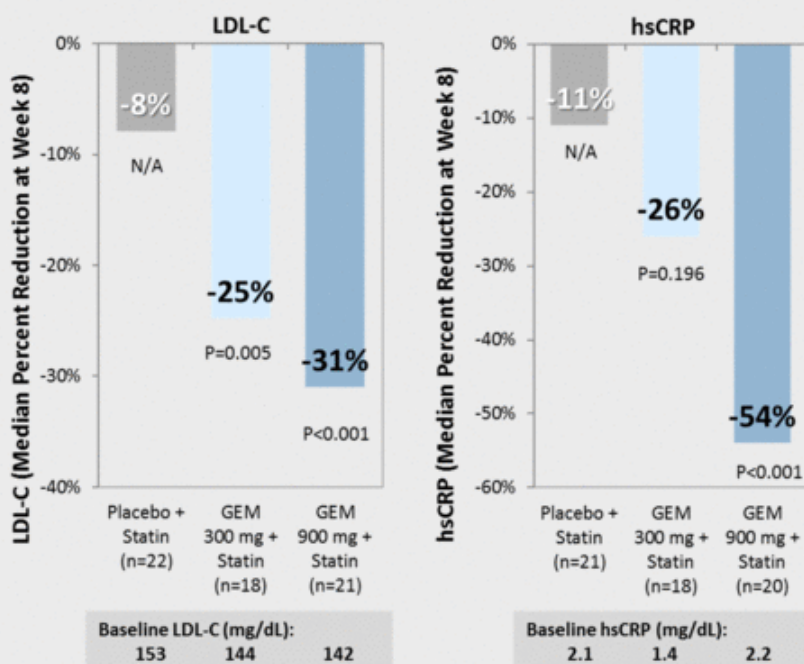


Phase 2 Clinical Data Supports Potential for Meaningful Efficacy

Phase 2 Trial 1027-018

- Randomized, double-blind, placebo-controlled, multicenter trial in hypercholesterolemic subjects to determine efficacy and safety of **gemcabene as add-on to stable statin therapy for patients not at goal**
- All doses of statins were utilized (**77% of patients were on moderate to high intensity statins**)
- **Primary endpoint was met** for significant LDL-C reduction, up to 31% lowering
- **Secondary endpoints were also met**, including lowering of ApoB, TG, VLDL-C and TC as well as hsCRP
- **Recently published** in the *Journal of Clinical Lipidology* (Stein et al, 2016)

Median Percent Change from Baseline at Week 8 in Patients with Hypercholesterolemia on Background Stable Statin Therapy

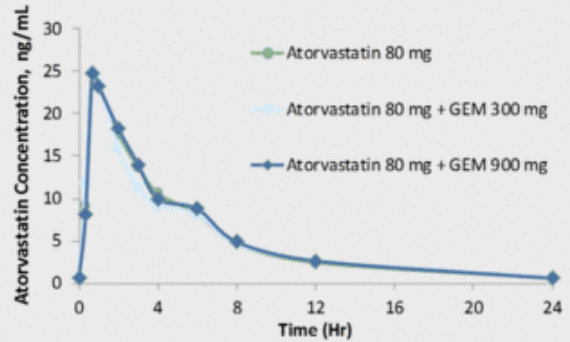


Gemcabene Shows No DDI Effects When Combined with High Dose Statins

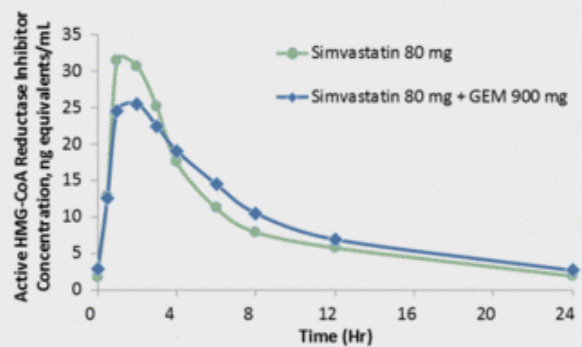
Phase 1 Trials A4141002 and 1027-008

- Gemcabene in combination with atorvastatin or simvastatin was observed to be **well tolerated** in healthy volunteers
- **Exposure was similar** for 80 mg of atorvastatin alone or in combination with either 300 or 900 mg of gemcabene
- **Exposure was similar** for 80 mg of simvastatin (a CYP3A4 substrate) alone or in combination with 900 mg gemcabene
- **Over 150 patients** have received a high intensity statin therapy and gemcabene

Trial A4141002



Trial 1027-008

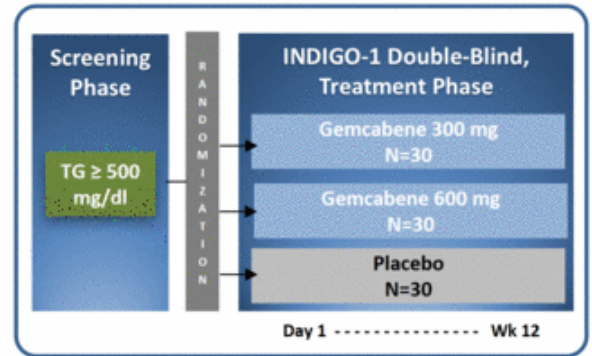


INDIGO-1 Trial Design (GEM-401)

Phase 2b Clinical Trial in Patients with SHTG

INDIGO-1 Trial

- 12-week multicenter, double-blind, placebo-controlled trial with patients with SHTG (TG \geq 500 mg/dL) with or without background statin therapy
- TG primary endpoint at 12 weeks
- 90 patients (30 patients per arm of 300 mg (target commercial dose), 600 mg, and placebo)
- 30+ sites in US and 3 sites in Canada
- Top-line data expected in 4Q 2017
- Regulatory pathway precedent set by fibrates, fish oils, niacin, and statins for approval for reduction in risk of pancreatitis on a TG surrogate endpoint



Rationale for Potential Meaningful Results in INDIGO-1

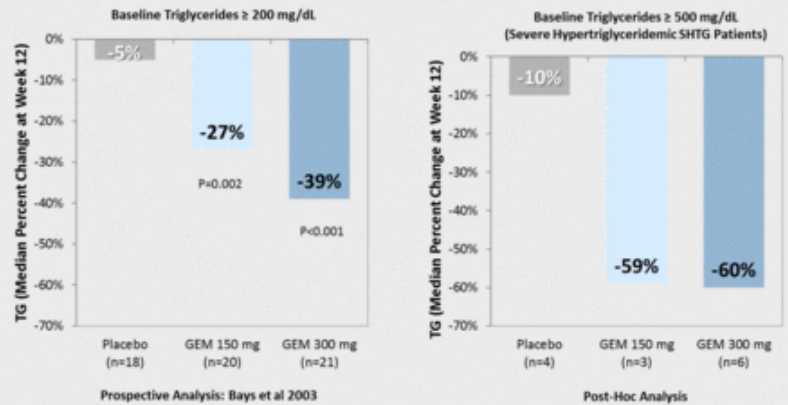
Phase 2 Trial 1027-004

- Phase 2 clinical data supports potential for meaningful efficacy (Trial 1027-004) with ~40% lowering at 300 mg dose
- Post-hoc analysis in limited subset with baseline TGs \geq 500 mg/dL with reductions of ~60% at 300 mg dose
- Observed to be well-tolerated in combination with statins, unlike fibrates

Note: Although patients treated with gemcabene at 600 mg and 900 mg were observed to have lower triglycerides, the lowering effect was not significant when compared to placebo.

Phase 2 Trial 1027-004 Results

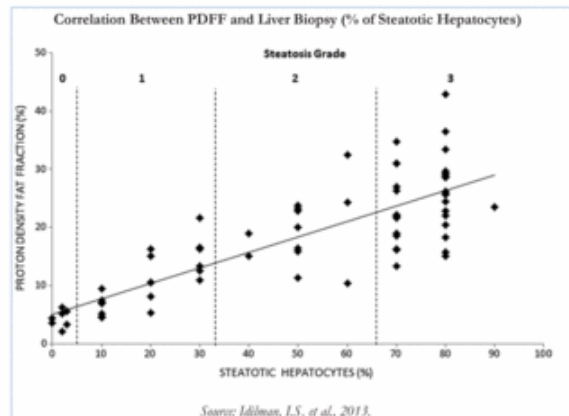
TG \geq 200, GEM Lowers TG 39%; TG \geq 500, GEM Lowers TG 60%



AZURE-1 Plan*

- Phase 2 trial design being finalized with plans to initiate AZURE-1 in 2017
- Up to 24-week multicenter trial in patients with NASH
 - Diagnosed by biopsy within 12/18 months, Fibrosis stage <3
 - Steatosis by MRI-PDFF >10%
- Estimated 81 patients (27 patients per arm of 300 mg, 600 mg, and placebo), with interest from COBALT / ROYAL / INDIGO sites
- Primary Endpoint will be percent change in hepatic fat fraction determined by MRI-PDFF evaluation (see chart)
- Regulatory pathway evolving with FDA working with sponsors but currently Phase 3 endpoint focusing on NAS and/or fibrosis stage changes is acceptable

**Current design pending final discussions with Health Authorities*

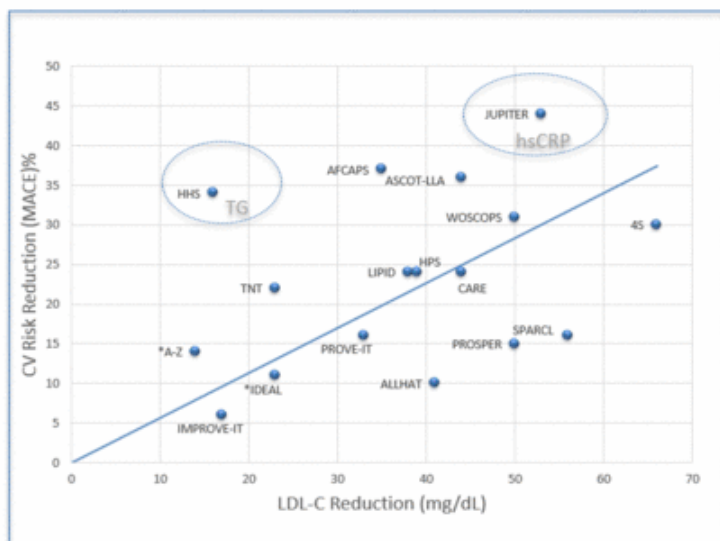


Rationale for Potential Meaningful Results in AZURE-1

- Preclinical data demonstrated reduction in lipogenesis and hepatic fat content**
- Preclinical data in STAM model demonstrated reductions:** liver NAFLD activity score (NAS) (a composite measure of fatty liver disease comprised of measures of steatosis, inflammation, and hepatocyte ballooning), progression of fibrosis, markers of inflammation, and lipid modulation
- Clinical data from Phase 2 trials showed reductions on lipid parameters** (e.g. TG, LDL, apoB) and on inflammation (e.g., hsCRP)
 - Gemcabene lowered TG (and cholesterol) synthesis pathway, likely inhibiting ACC as a fatty acid mimetic, resulting in reduced TG in liver
 - Gemcabene lowered plasma TG (via APOC-III) in patients with elevated TGs; reduced APOCIII enhances remnant clearance and LPL activity
- Gemcabene has not shown any liver toxicities** at doses between 150-900 mg up to 12 weeks as monotherapy or combined with statins/other drugs across 895 patients; no cumulative toxicities in 26 to 52 week monkey studies

Lowering LDL-C Decreases CV Risk

Elevated LDL-C is the #1 Modifiable Risk Factor



LDL-C Lowering Drugs with Successful Trials:

Gemfibrozil: HHS; **Atorvastatin:** IDEAL, TNT, PROVE-IT, ASCOT-LLA, SPARCL;
Rosuvastatin: JUPITER; **Simvastatin:** A-Z, HPS, 4S; **Pravastatin:** ALLHAT, CARE,
 PROSPER, LIPID, WOSCOPS; **Lovastatin:** AFCAPS; **Ezetimibe:** IMPROVE-IT

Sources: CTT Cholesterol Treatment Trialists and Study Papers for each Trial
 MACE = Major Adverse Cardiovascular Events

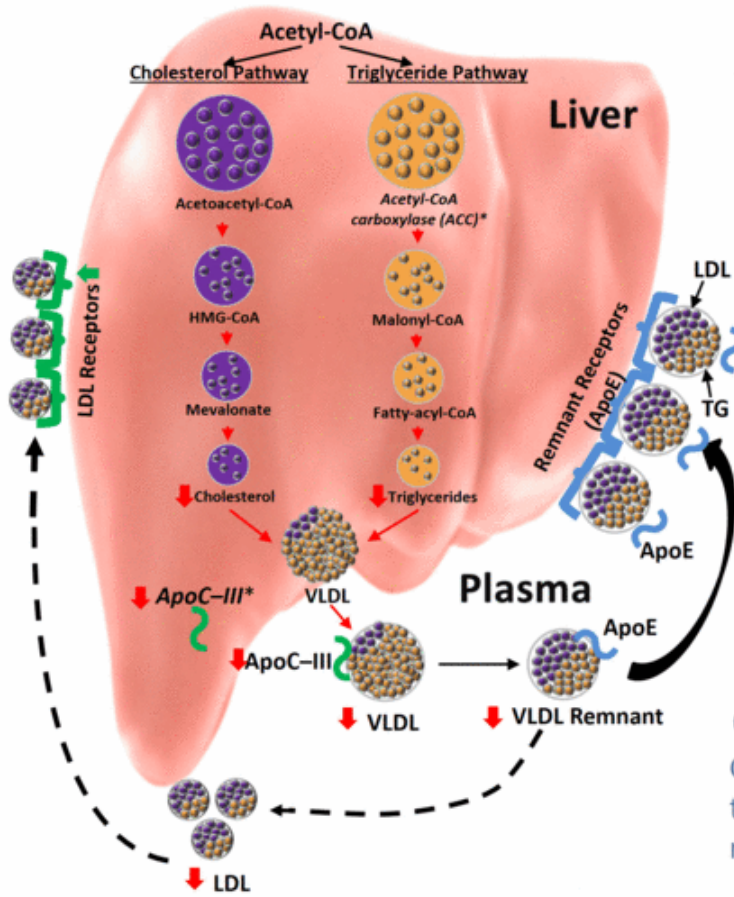
* A-Z p=.14 and IDEAL p=.07

- Over past two decades, all statins and other lipid-lowering drugs, including ezetimibe, were approved on the LDL-C endpoint with broad labels **without CV outcomes trial (CVOT) in US and globally**
- In US the bar was raised in summer 2015, Praluent approved for HeFH/ASCVD and Repatha approved for HeFH/ASCVD/HoFH on the LDL-C endpoint on maximal tolerated statins; **NOT approved for monotherapy (statin-intolerant) and/or primary patients**
- In contrast broad labels for Repatha and Praluent were approved on LDL-C endpoint, including monotherapy (statin-intolerant) and primary patients (familial and mixed dyslipidemia) in Europe

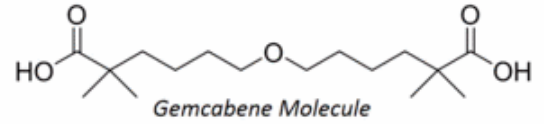


Repatha's FOURIER CVOT met the primary endpoint for CV risk reduction, continues to confirm and strengthen the LDL-C endpoint for regulatory approval in high risk patients

Gemcabene Novel MOA and Clinical Safety



Production Mechanism:
Gemcabene reduces production of cholesterol and triglycerides pathways inside the liver

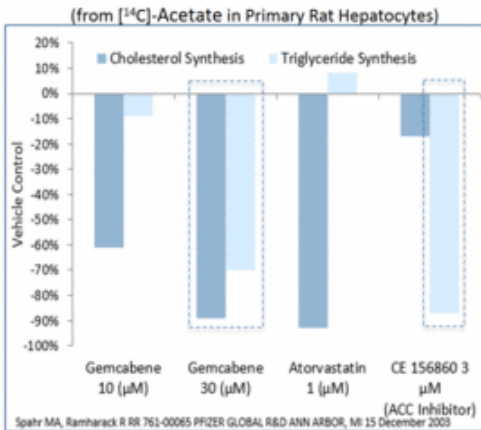


- Plasma half life of 32 to 41 hours
- Liver is target organ
- Gemcabene is the active compound
- Renal elimination

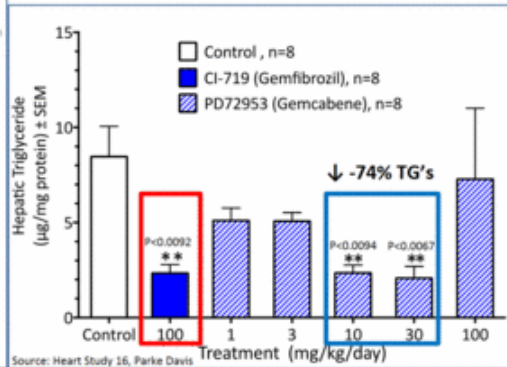
*Potential molecular targets in the liver (ApoC-III, ACC)

Clearance Mechanism:
Gemcabene clears VLDL efficiently due to a reduction in ApoC-III followed by rapid uptake by the remnant receptor

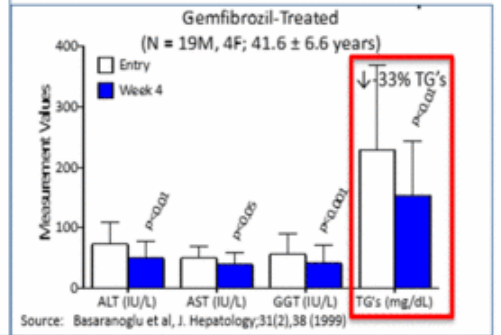
Gemcabene Inhibits *de novo* Synthesis of Both Cholesterol and Triglycerides



Gemcabene Reduces Hepatic Triglycerides in Sprague Dawley Rat Model



A Controlled Trial of Gemfibrozil in the Treatment of Patients with NASH



In-vitro Rat Liver POC TG

Gemcabene has been shown to reduce hepatic *de novo* cholesterol and TG synthesis from acetate

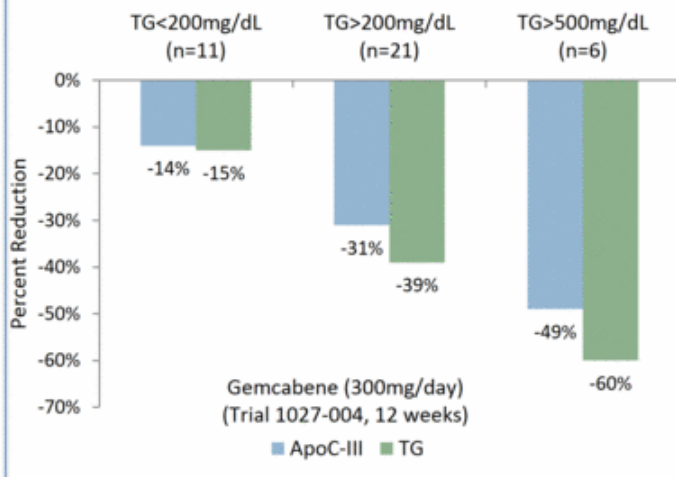
In-vivo Rat Liver POC TG

Gemcabene significantly reduces hepatic triglycerides by -74% in a rat model similar to reductions seen by gemfibrozil

In-vivo Human POC TG

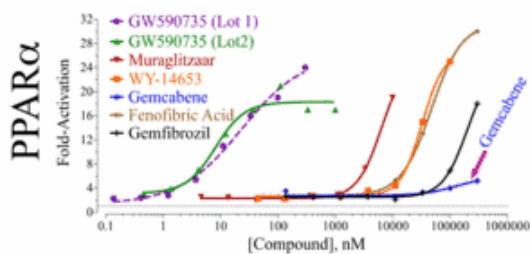
Gemfibrozil reduces TG and other NASH biomarkers in human trials; potentially promising for gemcabene

Gemcabene Reduces Plasma ApoC-III and TG in Humans



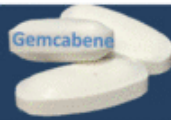
- ApoC-III protein is causal for cardiovascular disease
- Lowering ApoC-III enhances VLDL clearance and reduces LDL-C
- Gemcabene potentially binds to NFkB, a transcription factor, and disrupt its interaction with the promoter region common for both the ApoC-III and hsCRP genes (AHA 2015 poster)
- Recent in vitro assays for the FDA show gemcabene has little to no direct binding to the mouse, rat, and human PPAR alpha (human shown in chart), PPAR gamma, and PPAR delta when compared to known reference agents; PPARα effects seen in rodents are likely secondary
- Nevertheless, given our classification by the FDA as a PPAR agonist, which limits our clinical exposure up to 6 months until studies are completed, we have initiated 2 year mice and rat carcinogenicity studies

In-Vitro PPAR Receptor Assay (Human)



Potential Pleiotropic Mechanisms of Actions

Lipid Metabolism, Inflammation, Atherosclerosis, Glucose and NASH/Fibrosis



Lipid Metabolism

- ↓ LDL-C
- ↓ TG's (ApoC-III)
- ↓ VLDL
- ↑ HDL-C
- ↓ ACC



Atherosclerosis

- ↓ IL-6 β & IL-1 β



NASH

- ↓ Inflammation
- ↓ Ballooning
- ↓ Fibrosis
- ↓ NAS Score



Glucose Metabolism

- ↑ Insulin Sensitivity



Inflammation

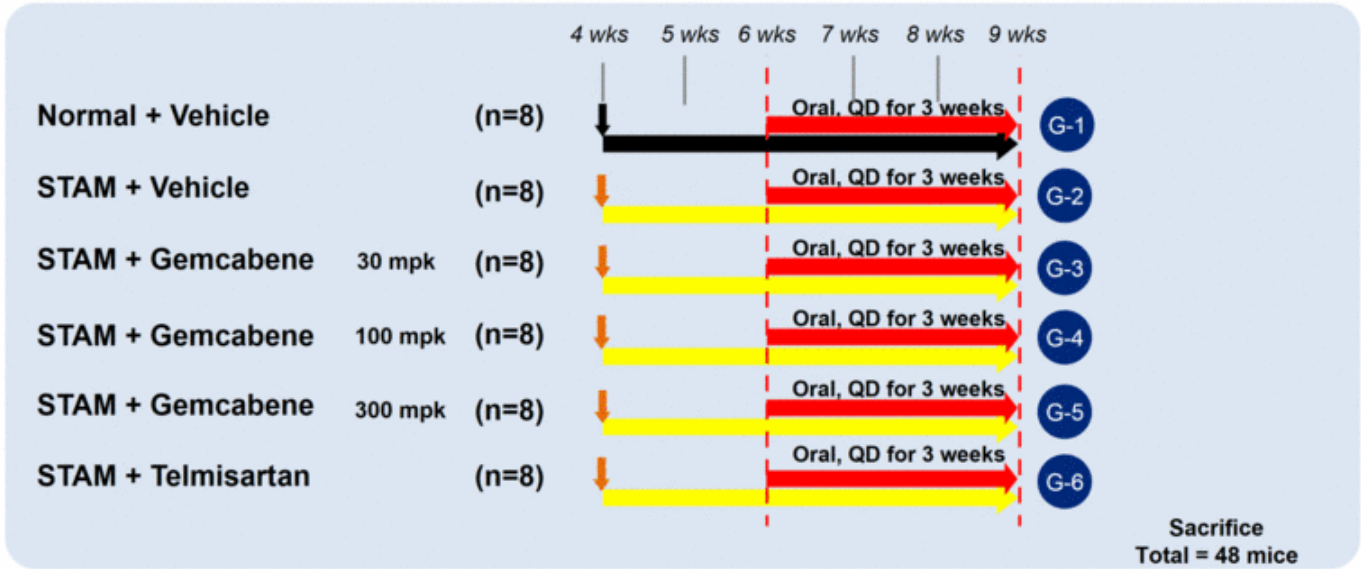
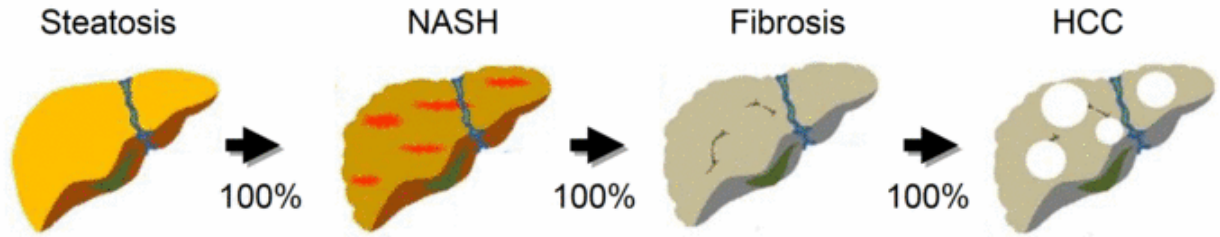
- ↓ HsCRP
- ↓ NF κ B
- ↓ CCR2 & CCR5

- Gemcabene was well tolerated at single doses up to 1500 mg and multiple doses up to 900 mg/day for up to 12 weeks (837 subjects)
- Safety evaluation of AE monitoring, clinical lab assessments, ECGs, physical exams and vital sign assessments were conducted across all trials (1,289 adult subjects):
 - 10 healthy volunteers or patients reported a treatment-emergent serious adverse effect (SAE), none of which were related to gemcabene
 - No deaths occurred
 - AEs were generally mild to moderate (e.g., headache, weakness, nausea)
 - No myalgia (muscle effects) as monotherapy, no increase in myalgia when added to statin
 - Small mean increases in serum creatinine and blood urea nitrogen (BUN) observed in some trials, reversible within approximately two weeks of cessation of gemcabene
 - No clinically meaningful changes in liver enzymes (0.23% of gemcabene patients compared to 0.26% of placebo patients had ALT or AST > 3 times upper limit of normal)
 - No clinically meaningful changes were observed in physical examinations, blood pressure, vital signs and ECGs

NASH Proof of Concept in STAM™ Model

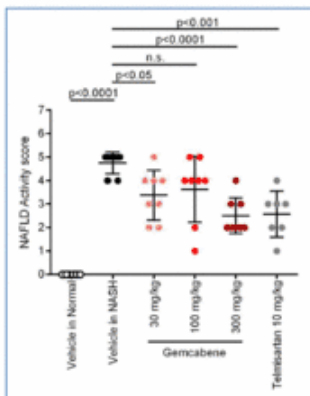
NASH Preclinical Mouse Model Study Design

STAM™: In Vivo Predictive Pharmacology Model of NASH and HCC

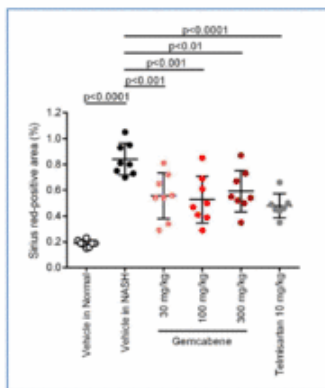


Gemcabene

NAS* score decreased 1.2 to 2.3 pts (25% to 48%) compared to vehicle



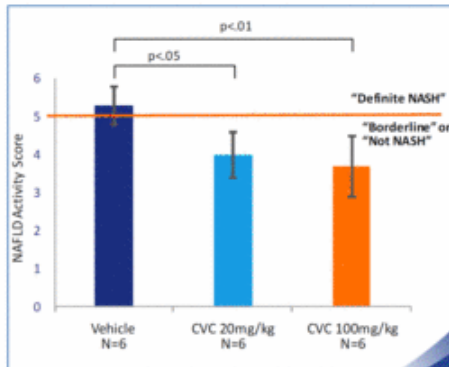
Liver fibrosis reduced ~33% compared to vehicle



Full details available under CDA or upon publication

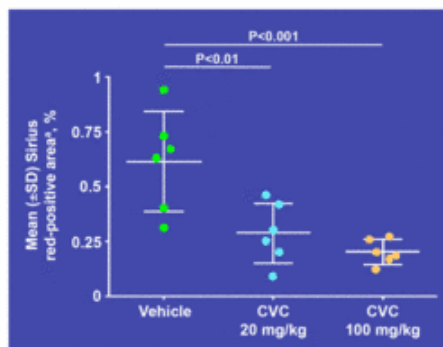
CVC – Tobira**

NAS* score decreased 1.3 to 1.6 pts (25% to 30%) compared to vehicle



*NAS composited comprised of steatosis, inflammation, & ballooning

Liver fibrosis reduced ~60% compared to vehicle



**This comparison is for illustrative purposes as these were separate studies
E. Lefebvre et al., The Liver Meeting AASLD, Abstract 30 presentation, 2013

FXR Agonists

Intercept's OCA (10 mg/kg) decreased NAS* score 1 pt (23%) compared to vehicle

Enanta's EDP-305 (3 - 10mg/kg) decreased NAS* score ~1.6 pts (~30%) compared to vehicle

Enanta Pharmaceuticals
Company Presentation, 2016

Hepatic Gene Expression and Plasma Markers Indicative of Inflammation (e.g., CRP and CCR2/CCR5) and Lipid Modulation (e.g., ApoC-III and ACC1) were Significantly Reduced

	Vehicle in NASH <small>(vs Vehicle in Normal)</small>	Gemcabene 100 mg/kg <small>(vs Vehicle in NASH)</small>	
CRP	-	▼	Inflammation
CCR2	▲	▼	Inflammation
CCR5	▲	▼	Inflammation
ApoC-III	▼	▼	Lipid Metabolism
ACC1	-	▼	Lipid Metabolism

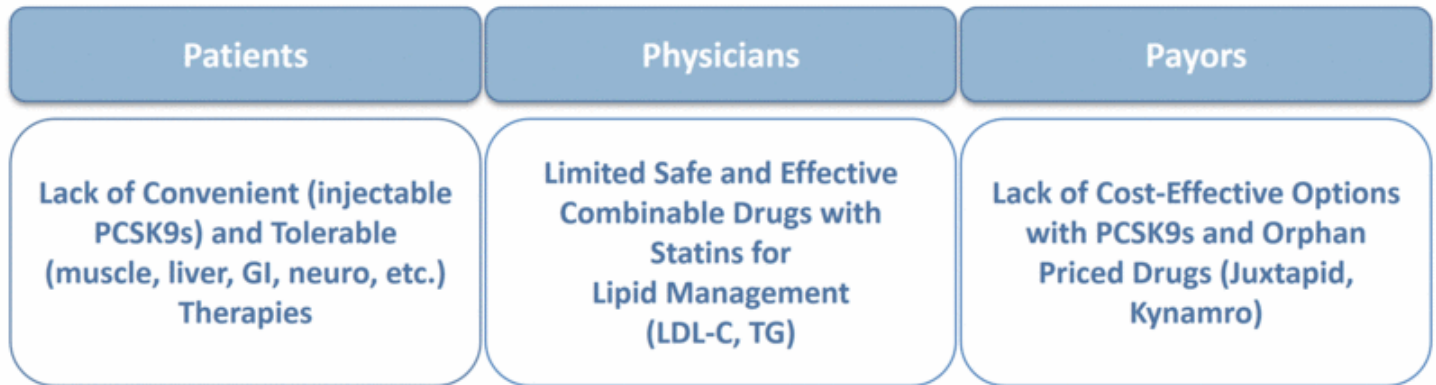
- no significant difference
 ▲ significant increase
 ▼ significant decrease

Plasma TG and hsCRP were Significantly Lowered in NASH Preclinical Model, Consistent with Gemcabene Effects Observed in Clinical Trials

Full details available under CDA or upon publication



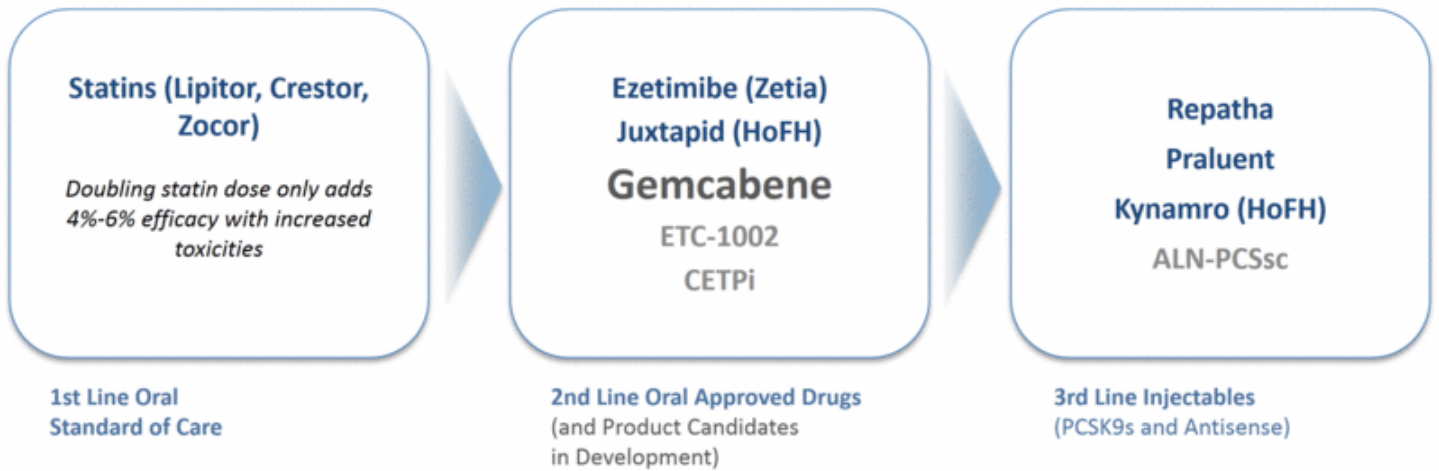
Competitive Differentiation, Commercial Strategy, Team, and Milestones



Gemphire is well positioned with its product profile to capitalize on the large unmet market opportunity in dyslipidemic patients

Gemcabene 2nd Line Oral LDL-C Positioning

Differentiated Profile for ASCVD/HeFH and HoFH Patients



Gemcabene is a differentiated drug candidate as an add-on to all doses of stable statin therapy that offers lowering of LDL-C, inflammation, and triglycerides particularly for 'diabesity' patients

Gemphire Differentiated in Both Dyslipidemia & NASH

Dyslipidemia								Gemcabene Phase 2b	NASH						MOA
Statin Class	PCSK9 Antibodies	MDCO PCSK9si	ESPR ETC-1002	Fibrates	Fish Oil	Ionis Volanesorsen	ICPT OCA		Genfit Elafibranor	Gilead GS-4997	Nimbus / Gilead GS-0976 p2	Tobira CVC	Conatus Emricasan		
Approved	Approved	P3 ready	P3 started	Approved	Approved	P3 (FCS, FPL)	P3 (Approved PBC)		P3	P3 ready	p2	P3 ready	P2		
MOA	HMG-CoA reductase inhibitor	PCSK9 inhibitors	RNAi	ACL inhibitor	PPAR- α agonist	Omega-3	APOC-III antisense inhibitor	ApoC-III, also ACC inhibitor	FXR agonist	PPAR- α & δ agonist	ASK-1 inhibitor	ACC Inhibitor	CCR2/CCRS inhibitor	Caspase inhibitor	
Once-Daily Oral	✓	✗	✗	✓	✓	○	✗	✓	✓	✓	✓	✓	○	Once-Daily Oral	
Low Cost	✓	✗	✗	✓	✓	✓	✗	✓	✓	✓	✓	✓	✓	NAS Score Reduction Preclinical	
↓ LDL	✓	✓	✓	✓	✗	✗	✗	✓	✓	✓	unknown	✓	✓	Anti-Fibrotic Effect	
↓ TG	✓	✗	✗	✗	✓	✓	✓	✓	✓	✓	✓	✗	✗	↓ Fat / TG	
↓ α -CRP	✓	✗	✗	✓	✗	○	✗	✓	✓	unknown	✗	✓	unknown	↓ α -CRP	
Combine Safely w/ Statins		✓	✓	✗	✗	✓	Unknown	✓	○	unknown	unknown	unknown	✗	unknown	Combine Safely w/ Statins

✓	Yes
✗	No
○	Somewhat
	Not Applicable

Sources: Gemphire Estimates, ClinicalTrials.gov, Analyst Research Reports, Company Websites and Presentations

Recent Events for PCSK9i Drug Class

Competitor Scarcity and Payor Market Dynamics

Amgen Announces Repatha® (Evolocumab) Significantly Reduced The Risk Of Cardiovascular Events In FOURIER Outcomes Study

PR Newswire February 2, 2017

Jan 05, 2017, 21:34 ET

Court Grants Permanent Injunction For Infringement Of Amgen's Repatha® Patents



Original Investigation | August 16, 2016

Cost-effectiveness of PCSK9 Inhibitor Therapy in Patients With Heterozygous Familial Hypercholesterolemia or Atherosclerotic Cardiovascular Disease

Dhruv S. Kazi, MD, MSc, MS^{1,2,3,4,5}; Andrew E. Moran, MD, MPH^{6,7}; Pamela G. Coxson, PhD^{1,2,4}; Joanne Penko, MS, MPH^{1,2}; Daniel A. Ollendorf, PhD⁸; Steven D. Pearson, MD, MSc⁹; Jeffrey A. Tice, MD⁹; David Guzman, MSPH¹; Kirsten Bibbins-Domingo, PhD, MD, MAS^{1,2,3,4}

Medscape Medical News > Neurology

Pfizer Stops Development of Novel PCSK9 Inhibitor, Halts Ongoing Trials

Deborah Brauser
November 01, 2016

August 2, 2016 10:54 AM EDT

Pfizer Backs Off Competitive PCSK9

- Amgen's Repatha met the primary endpoint of CV risk reduction in the FOURIER CVOT, as well as the secondary endpoint of CV death, non-fatal MI, or non-fatal stroke
- Praluent (by Sanofi/Regeneron with sales estimates of \$1-3B) could be pulled from the market if appeal is denied, leaving a single PCSK9i drug Repatha with no pricing competition (~\$14K current list price)
- Cost-effectiveness in HeFH/ASCVD determined at ~\$4500/year by JAMA August paper
- Limited sales after launch for Repatha and Praluent due to access and price (2016 analyst estimates PCSK9i combined sales ~\$200-300M)
- Pfizer discontinued injectable PCSK9 due to high level of immunogenicity (not fully humanized) and attenuated LDL-C lowering
- Pfizer discontinued oral PCSK9 program

NASH

Allergan to buy Tobira in deal valued at up to \$1.7 billion

Published: Sept 20, 2016 8:10 a.m. ET

Total Deal up to **\$1.7B**
Up front ≈ \$600M

Phase 2

September 21, 2016

Allergan Snaps Up Akarna in Second NASH-Related Purchase This Week

Total Deal **\$50M+**
with milestones/royalties undisclosed
Up front ≈ \$50M

Preclinical

UPDATED: Gilead bags early-stage NASH drug in \$1.2B Nimbus deal

by John Carroll | Apr 4, 2016 8:46am

Total Deal up to **\$1.2B**
Up front ≈ \$400M

Phase 1

CASH FOR NASH

Caspase embraced: Novartis, Conatus \$700M deal proves once-doubted class is no FXR-upper

By Randy Osborne

Total Deal up to **\$700M**
with tiered double-digit royalties
Up front ≈ \$50M

Phase 2

Dyslipidemia

Novartis in \$1.6 bln deal for Ionis, Akcea drugs

By Denise Roland

Published: Jan 6, 2017 6:26 a.m. ET

Total Deal up to **\$1.6B**
Up front/Equity ≈ \$175M

Phase 1/2

September 16, 2015

For Up to \$1.55B, Amgen Acquires Dezima Pharma

Total Deal up to **\$1.55B**
Up front ≈ \$300M

Phase 2

Gemphire has retained all global commercial and manufacturing rights to gemcabene

Commercial

- In US, we may commercialize gemcabene for the orphan indication of HoFH with our own targeted sales force to 50 lipid centers and 500 lipidologists
- In US, we may directly sell or co-promote with a partner gemcabene for SHTG with our internal sales force and distributor(s)
- In US, we may partner to commercialize gemcabene in the larger indications such as HeFH and ASCVD
- Outside of the US, we would plan to seek global and regional partners to commercialize in key markets for all indications

Clinical Development

- We may consider co-development of gemcabene in Phase 3 (CVOT for example)
- We may consider co-development of gemcabene in Phase 2/3 for NASH



Proven and Successful Management Team

Many Worked Together at First Esperion and Pfizer

Mina Sooch, MBA
Chief Executive Officer



Charles Bisgaier, PhD
Chief Scientific Officer & Cofounder



Jeff Mathiesen, CPA
Chief Financial Officer



Lee Golden, MD
Chief Medical Officer



Seth Reno, MBA
Chief Commercial Officer



Daniela Oniciu, PhD
VP, Manufacturing & Preclinical R&D



Rebecca Bakker-Arkema, RPh, MS, FAHA
VP, Drug & Clinical Development



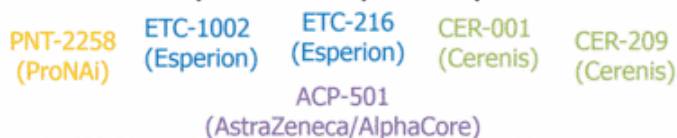
Liz Masson
VP, Clinical Operations



Prior Marketed Products Experience



Prior Pipeline Development Experience



Dyslipidemia

John Kastelein, MD, PhD
Amsterdam, Netherlands



Evan Stein, MD, PhD
Illinois, USA



Rob Hegele, MD
Toronto, Canada



Dirk Blom, PhD
Cape Town, South Africa



Harold Bays, MD
Kentucky, USA



Peter Toth, MD
Illinois, USA



NASH

Jay Horton, MD
Texas, USA



David Cohen, MD
New York, USA



Rohit Loomba, MD
California, USA



Mechanism

Brian Krause, PhD
Michigan, USA



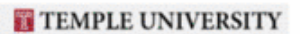
Gerald Watts, PhD
Perth, Australia



Todd Leff, PhD
Michigan, USA



Kevin Williams, MD
Pennsylvania, USA



2017 Potential Transformational Year with Data Readouts in All 3 Dyslipidemia Trials

1H 2017	2H 2017	1H 2018
<ul style="list-style-type: none">✓ Report interim data from COBALT-1 Phase 2b trial <i>Repatha reported positive FOURIER CVOT</i>• Report top-line COBALT-1 Phase 2b trial results• Submit NASH preclinical and other clinical abstracts and manuscripts for publication	<ul style="list-style-type: none">• Report top-line ROYAL-1 Phase 2b trial results• Report top-line INDIGO-1 Phase 2b trial results• Initiate AZURE-1 Phase 2 trial in NAFLD/NASH• Presentation(s) at industry meetings (if accepted)• Complete in-life 2 year rodent carcinogenicity studies	<ul style="list-style-type: none">• Hold ROYAL, INDIGO, and COBALT EOP2 meetings with FDA• Launch Phase 3 programs in Dyslipidemia

Appendix

- No upfront payment
- 15% equity grant at first round of equity financing
- Future payments totaling up to \$37 million upon completion of various milestones including regulatory approvals and key sales levels
- Future milestone payments under the Pfizer Agreement, if any, are not expected to begin for at least several years and extend over a number of subsequent years.
- Tiered royalties on country by country basis based upon annual amount of net sales

Gemcabene (CI-1027) Program

- ✓ Completed multiple MOA studies with PPAR and lipid metabolic pathways
- ✓ Completed multiple exploratory efficacy studies in mice, rats and monkeys
- ✓ Completed over 30 nonclinical GLP toxicology studies, including:
 - 26-week repeat dose study in rats and monkeys
 - 52-week repeat dose study in monkeys
- ✓ Completed 11 Phase 1 clinical trials, including:
 - Trial 1027-003
 - Trial 1027-008
 - Trial A4141002
- ✓ Completed 7 Phase 2 clinical trials, including:
 - Trial 1027-018
 - Trial 1027-004
 - Trial A4141001

POTENTIAL FOR MARKET EXCLUSIVITY (New Molecular Entity)

- U.S. (5 years or more); U.S. HoFH Orphan (7 years); Europe (up to 10 years); Japan (up to 10 years)

EXPANDING INTELLECTUAL PROPERTY ESTATE

- In total, 28 issued patents (4 in US) and 23 pending applications (9 in US)
- Original patents in-licensed from Pfizer directed to composition, formulations, and combinations
- Gemphire filed applications since 2011 around novel methods as a result of mining clinical data from trials 1027-004, 1027-018 and A4141001 (respectively below)
 - *SHTG: Method for Treating Pancreatitis – US Patent #8,846,761 (expiry 2032)*
 - *Add on Stable Statin Therapy: Methods for Reducing CV Risk – US Application #14/370,722 (filed 2013)*
 - *Treatment of Mixed Dyslipidemia and NASH – US Provisional Application #62/252,195 (filed 2015), PCT filed 2016*
- Gemphire filed additional applications on FDC formulations and improved manufacturing process
 - *Fixed Dose Combination Formulations – US Provisional Application #62/252,147 (filed 2015), PCT filed 2016*
 - *Processes & Intermediates for Manufacturing – US Application #14/942,765 (filed 2015)*

GEMCABENE MANUFACTURING

- Drug substance and drug product manufactured to GMP specifications
- Cost-effective manufacturing, drug substance scalable to 100 kg to meet commercial needs



Large Unmet Need to Help Dyslipidemia Patients Reach Goals

Potentially 14M or More Addressable Patients in the U.S. – Most on Statins

LDL-C ≥ 130 mg/dL	LDL-C ≥ 130 mg/dL 150 ≤ TG < 500 mg/dL	LDL-C ≥ 190 mg/dL	LDL-C ≥ 500 mg/dL	TG ≥ 500 mg/dL
ASCVD (Atherosclerotic Cardiovascular Disease)		HeFH (Heterozygous Familial Hypercholesterolemia)	HoFH (Homozygous Familial Hypercholesterolemia)	SHTG (Severe Hypertriglyceridemia)
NonFamilial Hypercholesterolemia	Mixed Dyslipidemia			
<ul style="list-style-type: none"> • US ~ 5 – 6M • RoW* ~ 100 – 120M • Patients who have experienced or are at risk of a cardiovascular event and cannot achieve LDL-C goal • Increased risk for CV disease 	<ul style="list-style-type: none"> • US ~ 4 – 5M • RoW* ~ 80 – 100M • Patients who have experienced or are at risk of a cardiovascular event and cannot achieve LDL-C and triglyceride goals • Increased risk for CV disease 	<ul style="list-style-type: none"> • US ~ 0.5 – 1.5M • RoW ~ 15 – 30M • Usually caused by a mutation in one allele of the LDL receptor gene • Increased risk for CV disease 	<ul style="list-style-type: none"> • US ~ 300 – 2,000 • RoW ~ 6,000 – 45,000 • Usually caused by a mutation in both alleles of the LDL receptor gene • Increased risk for CV disease 	<ul style="list-style-type: none"> • US ~ 3 – 3.5M • RoW* ~ 60 – 75M • Caused by an inherited disorder, obesity, poorly controlled diabetes, hypothyroidism, etc. • Increased risk for pancreatitis and other co-morbidities

Note (*): Addressable market for rest of the world is estimated by extrapolating from the U.S. addressable market.

Definitions: M = millions, CV = cardiovascular, TG = triglycerides.

Source: Company estimates.