



# 2017 Full Year Results

March 7 2018



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# Today's speakers

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**Frédéric Cren, MA/MBA, CEO and Co-Founder**



**Pierre Broqua, Ph.D., CSO and Co-Founder**



**Jean Volatier, MA, CFO**

# Summary

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▶ **Full Year 2017 Highlights**

▶ **Update on pipeline**

▶ **Financials**

▶ **Conclusion**

# FY 2017 Highlights

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- ▶ Continued recruitment of patients in NASH Phase IIb NATIVE study evaluating lanifibranor in NASH
- ▶ Enrollment completed for the Phase IIb FASST study evaluating lanifibranor in systemic scleroderma
- ▶ Inclusion of the first patient in the Phase IIa study (iMProveS) with odiparcil in the treatment of MPS VI
- ▶ Start of lead-optimization with the YAP-TEAD program
- ▶ Renewal of the collaboration with AbbVie and first payment received as part of the partnership with Boehringer Ingelheim
- ▶ Strong cash position of €59m, reflecting the successful IPO

# Large pipeline reaching major inflection points

Candidate	Indication	Discovery	Pre clinical	Phase I	Phase II	Phase III	Commercial Rights
Lanifibranor	▶ NASH						
Lanifibranor	▶ SSc						
Odiparcil	▶ MPS VI						
ROR <sub>γ</sub>	▶ Moderate to severe psoriasis						 Sales Royalties for Inventiva
YAP/TEAD	▶ Malignant Mesothelioma, Lung Cancer, ...						
NSD2	▶ Multiple Myeloma						
EPICURE <small>institut Curie</small>	▶ Immuno-oncology						
Undisclosed target	▶ Idiopathic Pulmonary Fibrosis (IPF)						 Sales Royalties for Inventiva

# Lanifibranor NASH and SSc

*A new generation pan-PPAR agonist for a safe and efficacious treatment of fibrotic conditions*

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# Lanifibranor: a next generation panPPAR agonist for a safe and efficacious treatment of fibrotic conditions

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## Activity

- ▶ Unprecedented chemical structure with moderate and balanced panPPAR agonist activity (PPAR $\alpha$ , PPAR $\gamma$  and PPAR $\delta$ )
- ▶ Oral administration
- ▶ Efficacy demonstrated on insulin resistance, dyslipidemia, steatosis, ballooning, inflammation and liver fibrosis. Anti-fibrotic activity also demonstrated in skin, kidney, lung
- ▶ 100 healthy volunteers treated in Phase I trials and 56 patients treated in phase IIa study
- ▶ Phase IIa demonstrated Pan-PPAR agonist activity supporting dose selection for NASH and systemic sclerosis (SSc)
- ▶ Phase IIb SSc FPI December 2015/ LPI October 2017
- ▶ Phase IIb NASH FPI February 2017

## IP

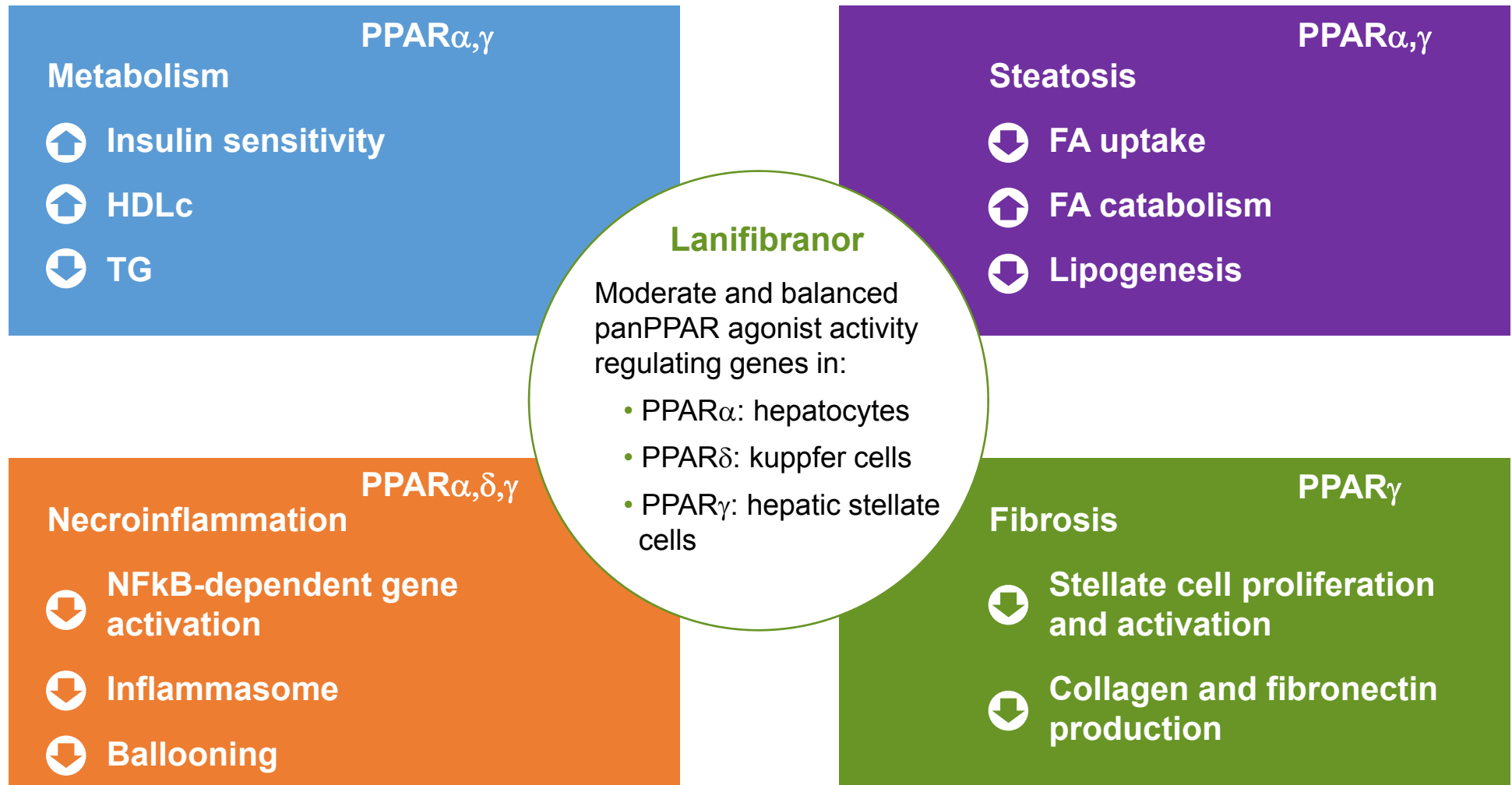
- ▶ Composition of matter patent granted in 59 countries: LOE August 2031 including 5-year extension
- ▶ Use patent filed in 2015 (LOE when granted: 2035)
- ▶ ODD granted in SSc in the US and EU

## Safety

- ▶ Favorable safety profile different from other PPAR compounds demonstrated in 6-month rodent and monkey studies
- ▶ 52 weeks toxicity studies in primates completed and carcinogenicity studies ongoing (HR mid-2018)
- ▶ Safety profile in phase I and phase IIa T2DM studies similar to placebo



# Lanifibranor: a mechanism of action addressing all the key features of NASH



# NATIVE Phase IIb in NASH



## Trial design

### Status

- ▶ Trial enrolling

### Randomisation

- ▶ 1/1/1, stratification on T2DM patients
- ▶ Study powered with 75 patients per group

### Clinicaltrials.gov identifier:

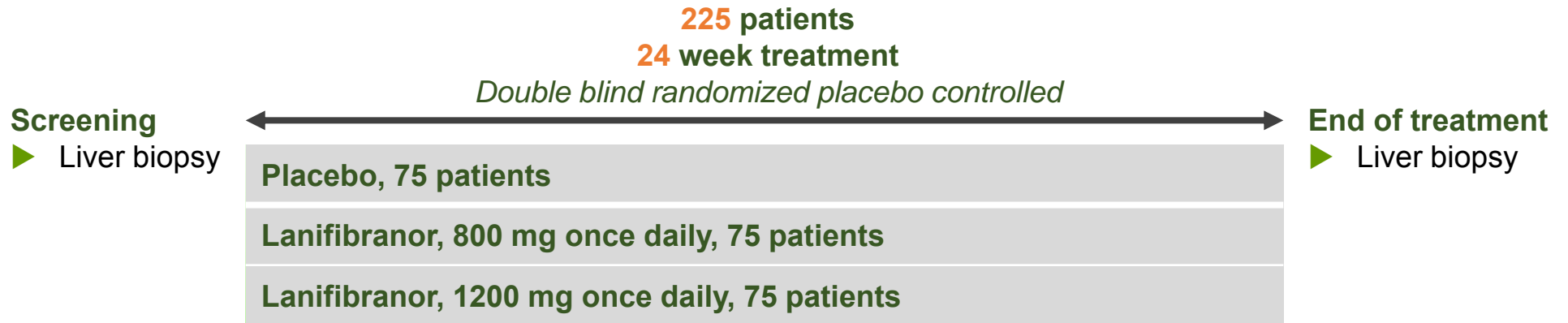
- ▶ NCT03008070

### Inclusion criteria

- ▶ Liver biopsy
- ▶ Moderate to severe patients with a inflammation and ballooning score of 3 or 4
- ▶ Steatosis score  $\geq 1$  and fibrosis score  $< 4$  (no cirrhosis)

### Primary endpoint

- ▶ Decrease from baseline  $\geq 2$  points of the inflammation and ballooning score without worsening of fibrosis
- ▶ Central reading for pre- (before randomization) and post treatment biopsy



More information on: <http://www.native-trial.com/>

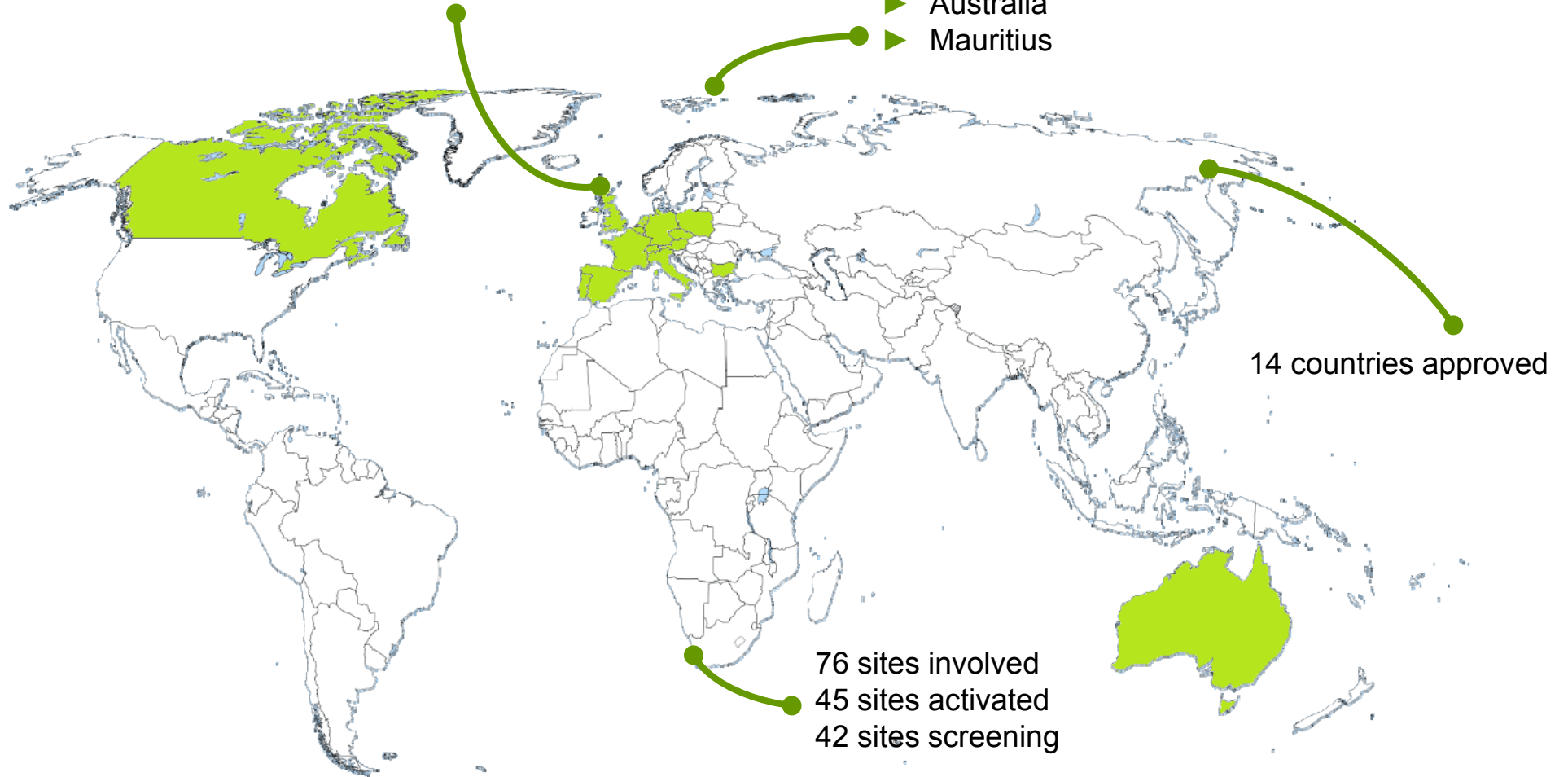
# NATIVE: Phase IIb in NASH



Principal investigator: Pr Sven Francque, Belgium

16 countries worldwide

- ▶ 13 in EU
- ▶ Canada
- ▶ Australia
- ▶ Mauritius



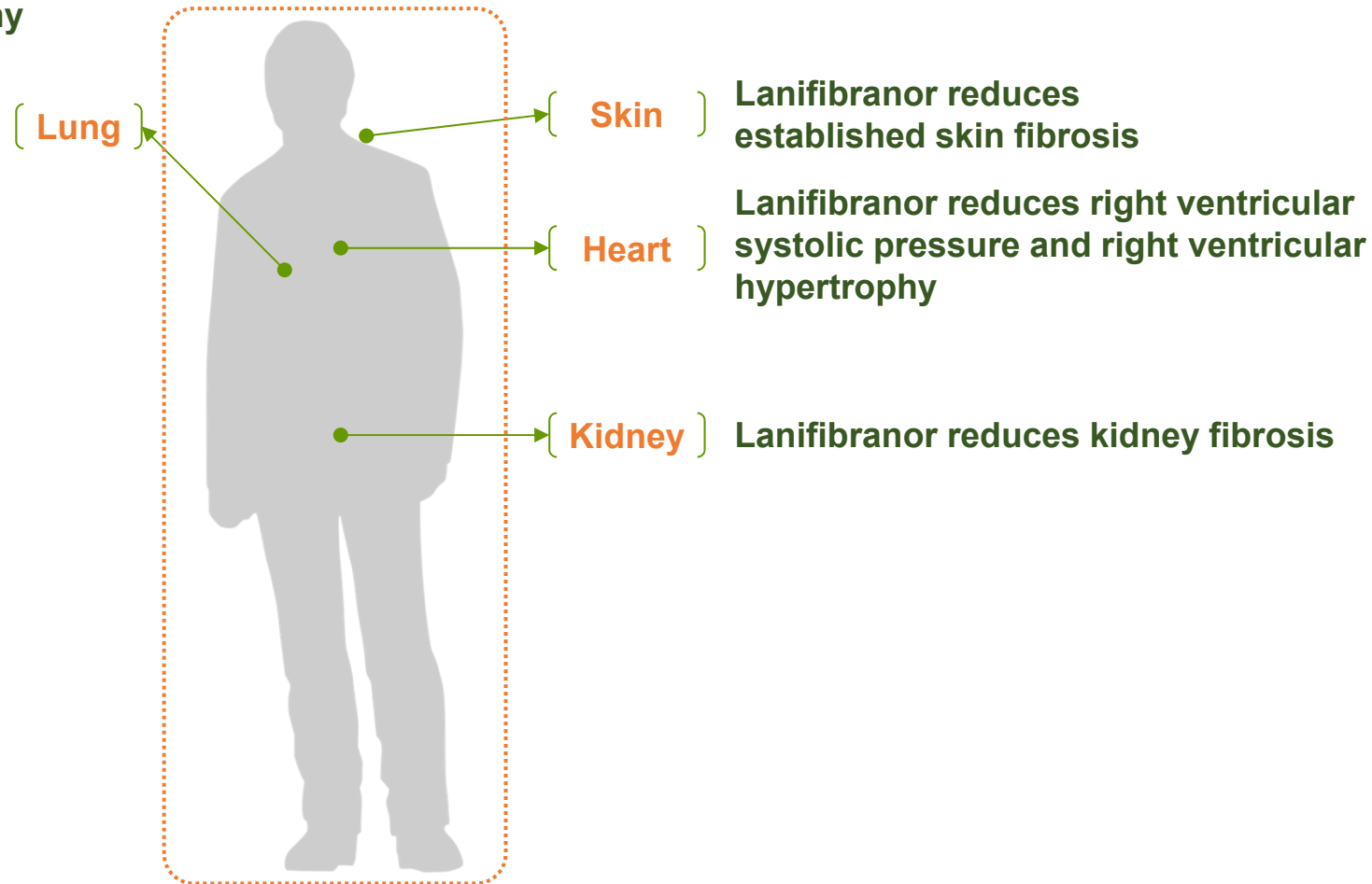
Results expected second-half 2019

# Lanifibranor could address all the relevant clinical features of systemic sclerosis

Lanifibranor reduces vasculopathy and inflammatory driven lung fibrosis

Lanifibranor restores lung functional capacity

Lanifibranor inhibits pulmonary arteries remodeling with positive impact on pulmonary artery pressure



Data generated in several relevant preclinical models demonstrate that lanifibranor positively impacts the most relevant clinical features of SSc

## Trial design

### Status

- ▶ Last patient recruited in October 2017.

### Clinicaltrials.gov identifier:

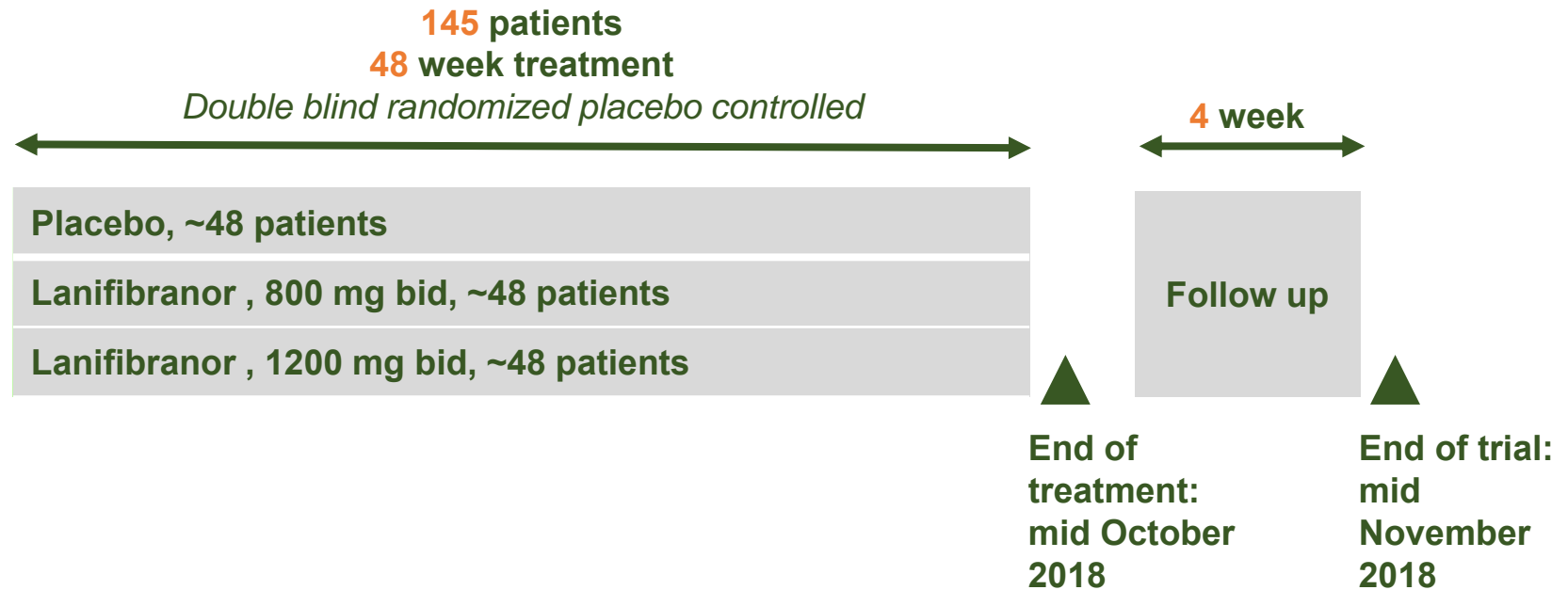
- ▶ NCT02503644

### Inclusion criteria

- ▶ MRSS (Modified Rodnan Skin Score) between 10 and 25
- ▶ SSc diagnosed from less than 3 years

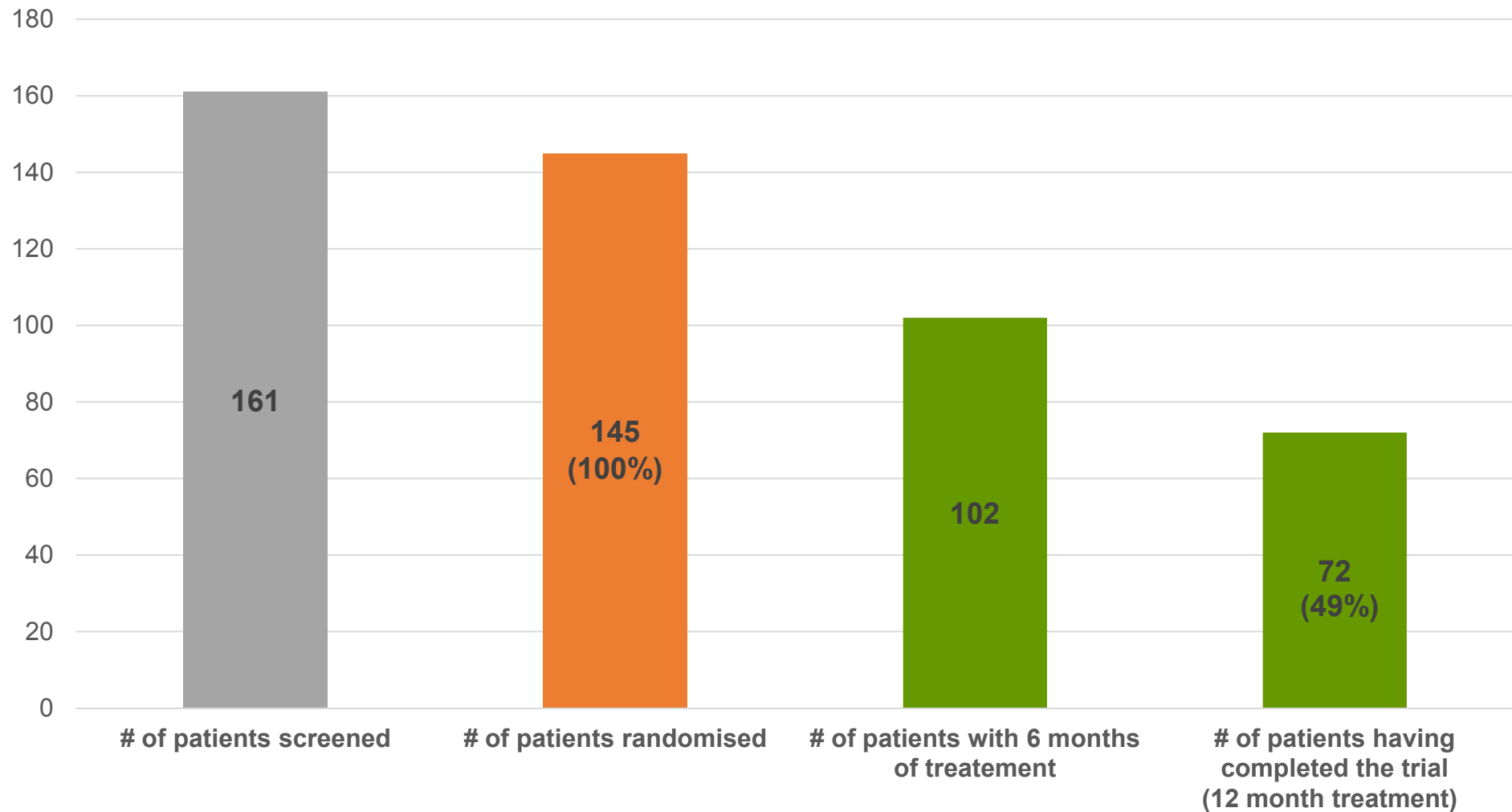
### Primary endpoint

- ▶ Mean change of the MRSS from baseline to 48 weeks



More information on: <http://www.fassttrial.com/>

# FASST: 100% of patients randomized and close to 50% of patients have already completed the trial

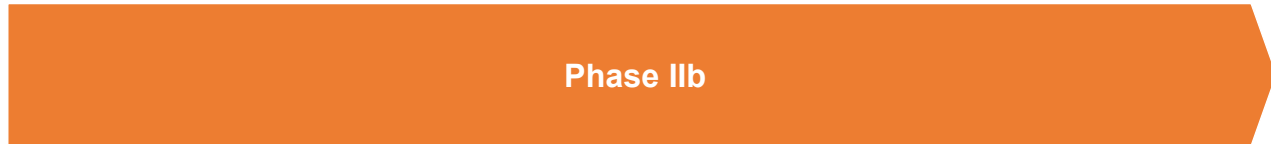


**Positive January 2018 DSMB recommendation to continue the study unchanged  
Results expected early 2019**

# Lanifibranor: a phase III ready program in both SSc and NASH by 2019



Systemic sclerosis

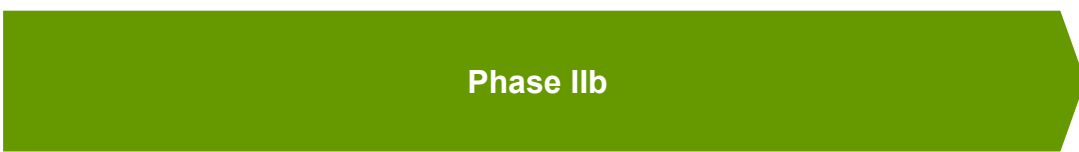


★ FDA preIND  
★ FDA IND  
▲ Results

★ EMA conditional marketing authorisation submission  
★ FDA potential breakthrough therapy status

▲ Start of pivotal Phase III study (EU & US)

NASH

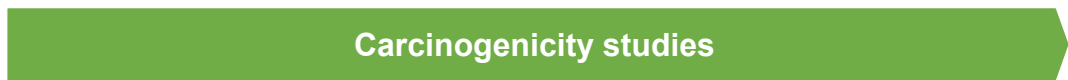


★ FDA IND

▲ Results

▲ Start of pivotal Phase III study (EU & US)

Toxicology



▲ Results

Start of FASST and NATIVE trials corresponds to first patient screened

# Odiparcil

*The first oral therapy to treat five forms of mucopolysaccharidosis (MPS): MPS I, II, IV, VI and VII*

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# Odiparcil, the first orally available therapy to treat several forms of MPS

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## Activity

- ▶ Mechanism of action via modulation of GAG synthesis which accumulation triggers MPS
- ▶ Oral administration
- ▶ Odiparcil reduction of GAG intracellular accumulation demonstrated in in vitro and in vivo relevant models
- ▶ Odiparcil widely distributed in tissues that are poorly treated by enzyme replacement therapy
- ▶ Odiparcil has the potential to replace current ERT treatments, especially in MPS VI patients
- ▶ 1,809 healthy volunteers and patients treated in 32 phase I and II clinical trials for up to 16 weeks
- ▶ US biomarker study finalized and Phase IIa study in MPS VI initiated with first patient enrolled in December 2017

## IP

- ▶ Use patent filed in 2013 and granted in EU (Nov. 2015) and the US (Feb. 2017)
- ▶ LOE 2039 including 5-year extension
- ▶ MPS VI ODD granted in the US and in the EU

## Safety

- ▶ Good safety profile
- ▶ Very low toxicity *in vivo*
- ▶ Well tolerated and safe in multiple phase I and phase II clinical studies allowing the commencement of a POC study in MPS VI patients

# Inventiva's observational study to evaluate intracellular GAG in leukocytes

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## Leukocytes are promising cells

- ▶ Low invasiveness of collection procedure
- ▶ GAG intracellular levels are increased in animal model of MPS
- ▶ Odiparcil decreases intra-cellular GAG level

## Objectives of Inventiva's non-interventional study to validate use of intracellular GAG in leukocytes

- ▶ Develop a robust quantification method to measure intracellular heparan sulfate (HS), chondroitin sulfate (CS) and dermatan sulfate (DS)
- ▶ Obtain an activity biomarker on intracellular GAG levels to be used in odiparcil clinical trials, including iMProveS phase IIa study

## Population

- ▶ 6 MPS VI patients receiving enzyme replacement therapy for  $10 \pm 3.1$  years (range 6-14 years)
- ▶ 6 control subjects not affected with MPS (age matched with MPS VI patients)

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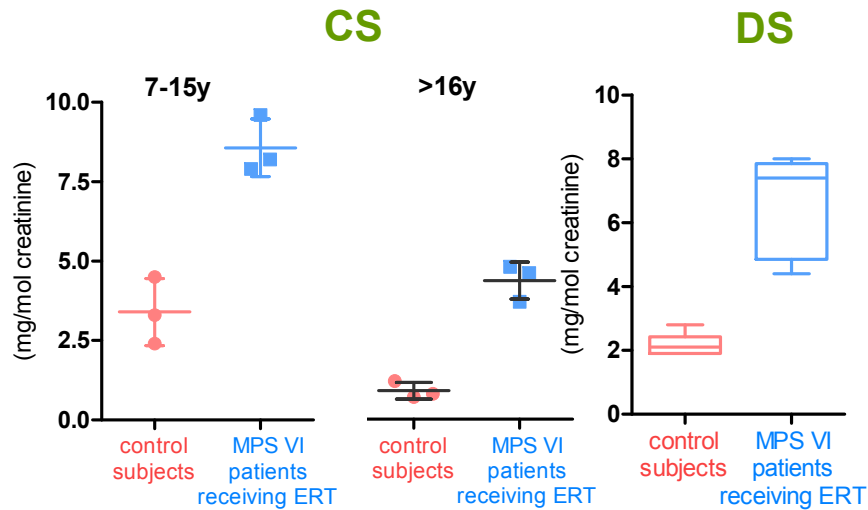
## Investigational site



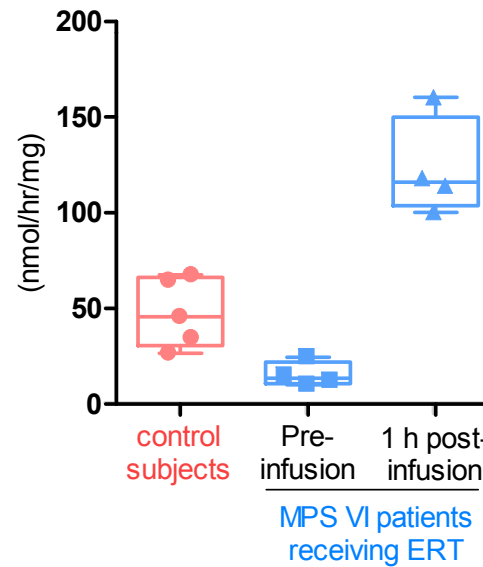
- ▶ Dr. Paul Harmatz (PI), Oakland Children's Hospital, Oakland, CA
-

# Study confirms Inventiva has developed a promising biomarker for MPS VI and the limited ERT efficacy in reducing leukoGAGs

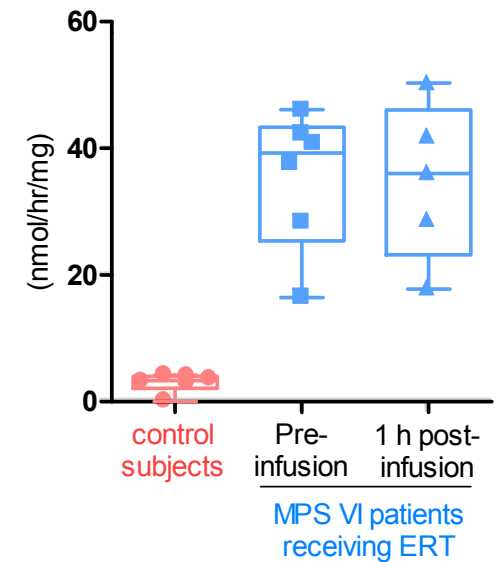
MPS VI patients treated with ERT have increased CS and DS levels in urine



ARSB activity in leukocytes is increased by 8 fold after ERT infusion



MPS VI patients treated with ERT have increased CS (and DS levels) in leukocytes



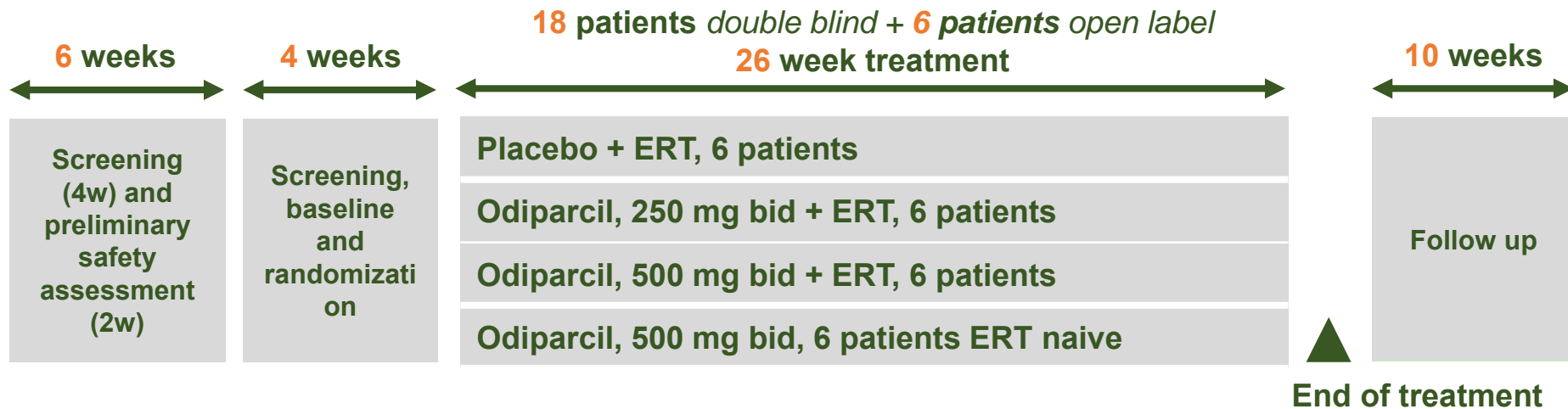
MPS VI patients treated with Naglazyme maintained a high level of intracellular DS and CS levels in leukocytes compared to age matched healthy volunteers suggesting the possibility to further reduce this level with odiparcil

# Odiparcil iMProveS phase IIa study in MPS VI patients



## Trial design

- ▶ **Inclusion criteria:** MPS VI patients (≥ 16 year-old)
- ▶ **Status:** First patient recruited December 2017.



## Endpoints

### Safety

- ▶ Clinical and biological assessments (standard tests)

### Efficacy

- ▶ Leukocyte, skin and urinary GAG content
- ▶ Activity and mobility tests (6 minutes walk test, upper limb function, shoulder mobility range)
- ▶ Cardiac, vascular and respiratory functions
- ▶ Eye impairment, hearing capacity, pain assessment, quality of life questionnaires

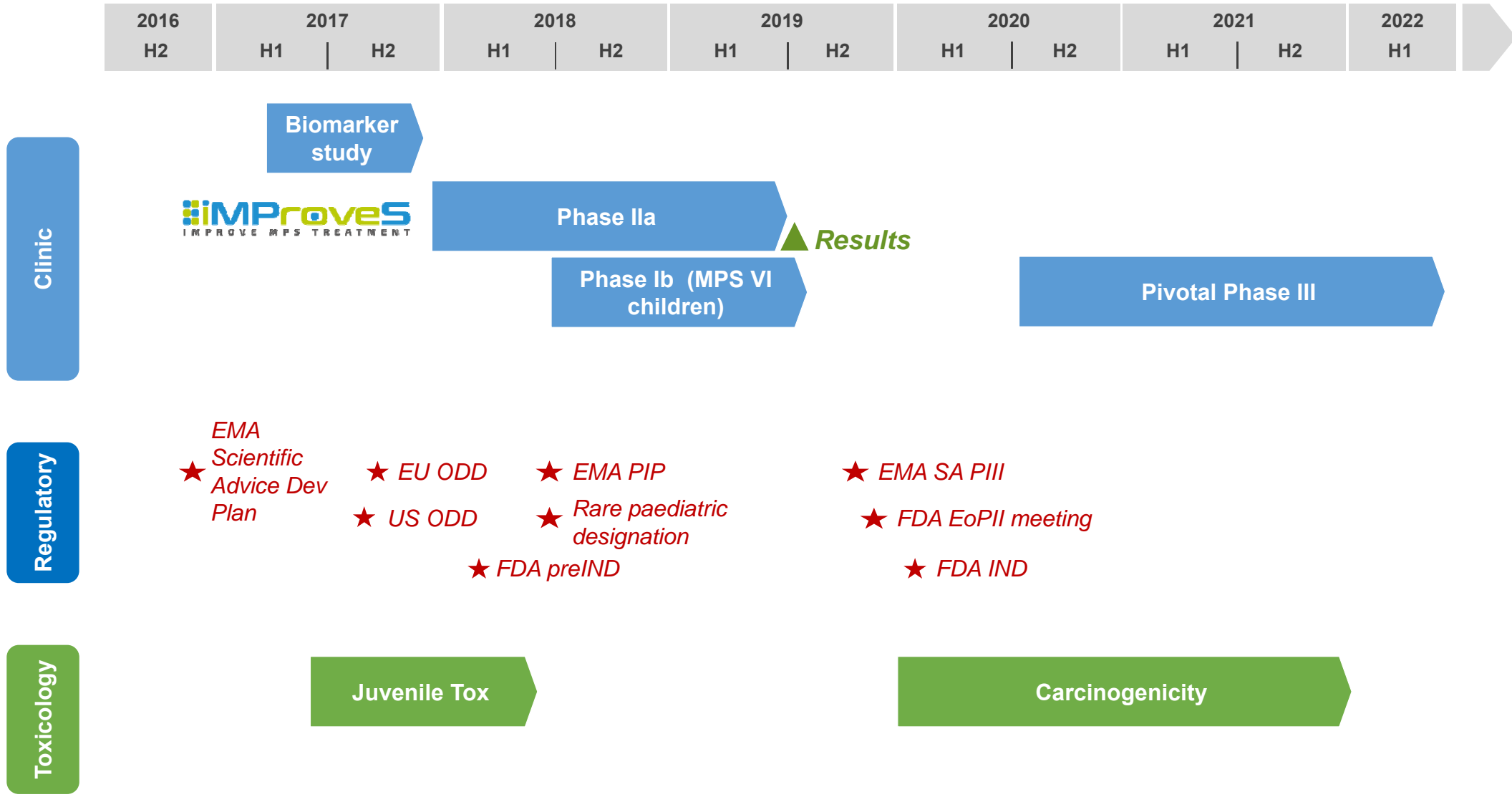
### Pharmacokinetics

- ▶ Odiparcil plasma levels

**Results expected first semester 2019**

More information on: <http://www.improves-mpsvi-trial.com/>

# Odiparcil overall development plan in MPS VI



*Start of iMProves trial corresponds to first patient screened*

# Two collaborations with leading pharma companies

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abbvie



# Two successful collaborations in place with AbbVie and Boehringer Ingelheim

abbvie

## RORy collaboration

- ▶ RORy program addresses large markets currently dominated by biologics
- ▶ RORy could prove to be superior to biologics
- ▶ Inventiva and AbbVie identified clinical and preclinical compounds
- ▶ Inventiva eligible to multiple milestones payments and sales royalties on a product with block-buster potential



## Collaboration in fibrosis

- ▶ Multi-year R&D collaboration and licensing partnership
- ▶ Joint team until pre-CC stage. BI to take full responsibility of clinical development and commercialization
- ▶ Following the validation of this new target supporting its therapeutic potential in fibrotic conditions, Boehringer Ingelheim exercised the option to jointly develop this target triggering a milestone payment of 2,5 M€
- ▶ Inventiva eligible to up to 170 M€ in milestones plus royalties

**ABBV-157 expected to enter phase I in 2018**

**LO milestone expected in 2019**

# Financials

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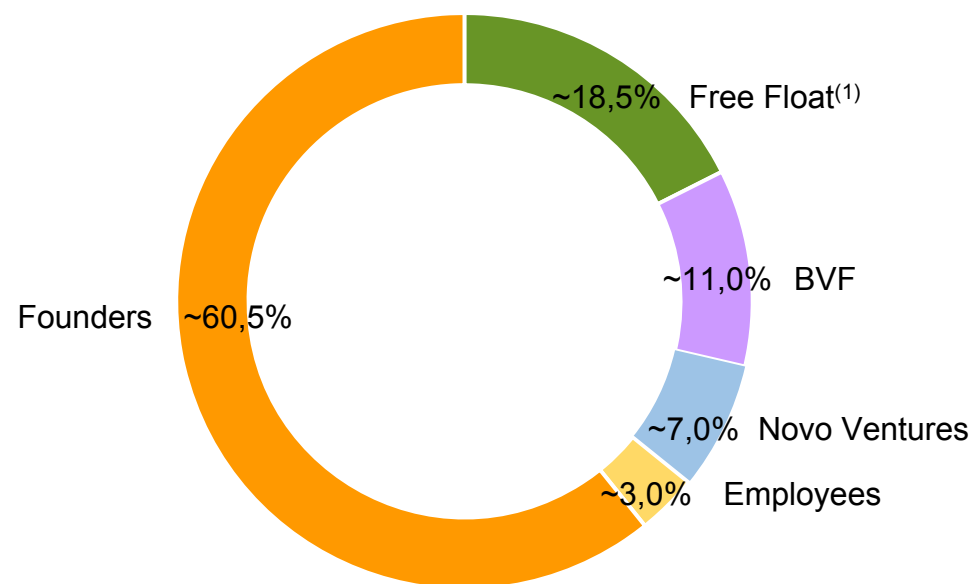
# Strong cash position and shareholder base

## Key financials



ISIN code	FR0013233012
Market	Euronext Paris
Shares outstanding	16 444 477
Market cap (28 February 2018)	€99,32m
Cash in 2017 (31 December 2017)	€59m (including €45m raised at the IPO) compared to €24.8m in 2016
Revenues in 2017 (31 December 2017)	€6.5m (including €2.5m from Boehringer Ingelheim) compared to €9.4m in 2016
R&D expenditures in 2017 (31 December 2017)	€26.7m compared to €22.1m in 2016

## Shareholder base



(1) Including: Perceptive (US), Sphera (IL), Arbevel (F)

## Analyst Coverage



# FY 2017: a sound financial position

## Income Statement

<i>Key figures</i> <i>(in thousands euros)</i>	As of 31 December 2017	
	2017	2016
Revenues	6,521	9,446
Other recurring operating income	5,161	4,906
Research and development costs	(26,733)	(22,145)
Marketing – Business development costs	(353)	(492)
General and administrative costs	(5,063)	(3,764)
Recurring operating income (loss)	(20,467)	(12,049)
Operating income (loss)	(20,916)	(13,019)
Net financial income	278	460
Net income (loss)	(17,229)	(7,045)

## Cash Position

<i>Key figures</i> <i>(in thousands of euros)</i>	As of 31 December 2017	
	2017	2016
Cash & cash equivalents	59,051	24,868

### ► Revenues of €6.5m compared to €9.4m in 2016

- Decrease in non-recurring income vs 2016:
  - 2016: Two milestone payments from AbbVie totaling €4.5m
  - 2017: Payment of €2.5m from Boehringer Ingelheim

### ► Increase in R&D investment

- €26.7m, + 20.7% vs 2016
- Major efforts devoted to the lanifibranor (NASH and SSC) and odiparcil (MPS) projects in the clinical development phase
- R&D expenses accounted for 83% of total operating expenses - 2/3 related to clinical development

### ► Significant increase in cash-flow

- €59m including €48.5m in gross proceeds following the IPO on Euronext Paris in February 2017
- To note:
  - €3.6m research tax credit (CIR) received on 08/10/2017
  - €2.5m milestone payment from Boehringer Ingelheim received on 09/22/2017
  - End of Abbott's financial support (last instalment of €6.2m in H1 2017)

### Financial calendar:

- **May 15, 2018 : Publication of Q1 2018 financial results (revenues and cash) (after market closing)**

# Conclusion

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# Key 2017 achievements and near-term catalysts

	2017	2018	2019
<b>Lanifibranor</b>	<ul style="list-style-type: none"> <li>✓ 12 month monkey study finalized</li> <li>✓ Lanifibranor INN name from WHO</li> <li>✓ Last patient phase IIb SSc</li> </ul>	<ul style="list-style-type: none"> <li>▶ Last patient phase IIb NASH</li> <li>▶ 2 year carcinogenicity study results</li> <li>▶ SSc IND</li> <li>▶ NASH IND</li> </ul>	<ul style="list-style-type: none"> <li>▶ <b>Results Phase IIb SSc</b></li> <li>▶ <b>Results Phase IIb NASH</b></li> </ul>
<b>Odiparcil</b>	<ul style="list-style-type: none"> <li>✓ MPS patent granted in US</li> <li>✓ US orphan status designation</li> <li>✓ EU orphan status designation</li> <li>✓ First patient Phase IIa in MPS VI</li> </ul>	<ul style="list-style-type: none"> <li>✓ MPS VI biomarker study results</li> <li>▶ Rare pediatric disease designation MPS VI</li> <li>▶ Start Phase Ib in children</li> <li>▶ Juvenile tox results</li> </ul>	<ul style="list-style-type: none"> <li>▶ <b>Results Phase IIa MPS VI</b></li> <li>▶ <b>Results Phase Ib in children</b></li> </ul>
<b>Collab.</b>	<ul style="list-style-type: none"> <li>✓ 2,5M€ milestone from Boehringer Ingelheim (option exercise)</li> <li>✓ ABBV-157 preclinical nomination</li> <li>✓ AbbVie ROR<math>\gamma</math> collaboration renewal</li> </ul>	<ul style="list-style-type: none"> <li>▶ Start Phase I with ABBV-157</li> </ul>	
<b>Discovery</b>	<ul style="list-style-type: none"> <li>✓ Yap-Tead: in vivo activity obtained</li> <li>✓ Epicure: target validated</li> </ul>	<ul style="list-style-type: none"> <li>▶ Yap-Tead: Vivo POC</li> <li>▶ Epicure: HTL</li> </ul>	<ul style="list-style-type: none"> <li>▶ <b>Yap-Tead: start of Phase I-enabling preclinical development</b></li> </ul>
<b>Finance</b>	<ul style="list-style-type: none"> <li>✓ IPO on Euronext</li> </ul>		

# Q&A

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