

# First-Half 2021 Financial Results

# September 21, 2021





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### Frédéric Cren, MA/MBA, Chairman, CEO and Co-Founder



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### **Summary**

### Highlights

- Pipeline update
- Financials
- Near-term catalysts

# **Highlights**

# First-Half 2021 Highlights

#### Lanifibranor in non-alcoholic steatohepatitis (NASH)

Initiation of the NATiV3 Phase III clinical trial evaluating lanifibranor in adult patients with non-cirrhotic NASH and F2/F3 stage of liver fibrosis, with the activation of the first clinical sites in the United States and the start of patient screening

#### Cedirogant / ABBV-157

- Decision by AbbVie to initiate a Phase IIb clinical trial with cedirogant in patients with psoriasis following the demonstration of clinical proof of concept during AbbVie's Phase I clinical trial
- The 16 week randomized placebo controlled phase IIB study in approx. 200 adult patients with moderate to severe psoriasis is planned to start in November with results expected in March 2023

#### Odiparcil

The review of available options to optimize the development of odiparcil for the treatment of MPS VI continues and is now expected to conclude in 2022 (rather than in 2021 as previously anticipated)

#### **Financials / Other**

- Implementation of an ATM program in the United States providing financial flexibility by issuing and selling ordinary shares in the form of ADS with aggregate gross sales proceeds of up to \$100 million. The ATM program will be effective until August 2, 2024
- Major appointments to reinforce Inventiva's clinical expertise, medical team and core corporate functions, as well as its presence in France and the United States
- Appointment of Martine Zimmerman as Independent Director

# **Pipeline update**

# Lanifibranor in Nonalcoholic Steatohepatitis (NASH)

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

# Lanifibranor: a pan-PPAR agonist entering phase III development in NASH

#### LANIFIBRANOR

#### Moderate and balanced pan-PPAR agonist activity

- Small molecule that activates all three PPAR isoforms in humans
- Differentiated chemical structure: not a fibrate or a TZD
- Once daily oral administration
- Positive Phase IIb trial topline results in NASH
- BREAKTHROUGH THERAPY and FAST TRACK designations granted by the FDA in NASH
- Composition of matter patent delivered in 55 countries and method of use patent granted in the U.S., China and in the EU: limit of exclusivity in the U.S. is 2035

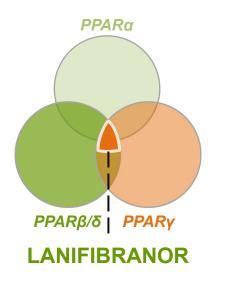
#### Favorable tolerability profile

- Phase I trials with more than 200 healthy volunteers and Phase IIa trial with 47 TD2M patients
- Approximately 250 patients treated for 24 or 48 weeks in Inventiva's completed Phase IIb clinical trials
- FDA confirmation that the non-clinical toxicology package is complete and acceptable for NDA filing

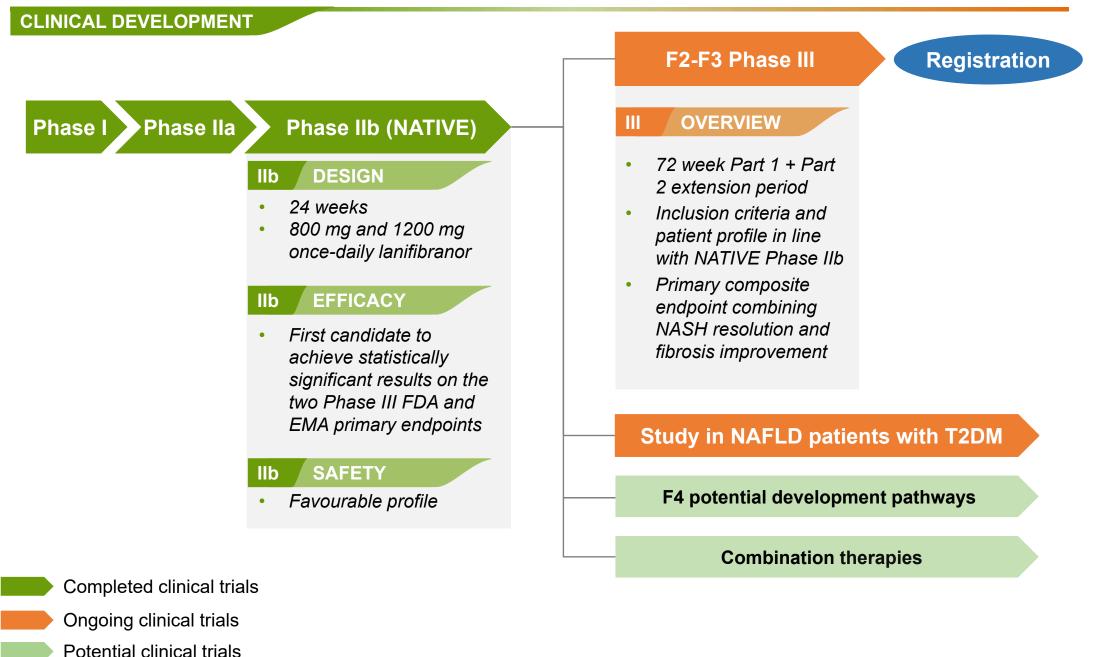
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# The overall development plan builds on the successful outcomes of the NATIVE Phase IIb trial



# Lanifibranor is the first candidate to achieve statistically significant results on the two Phase III FDA and EMA primary endpoints

PHASE IIb

PRIMARY

EFFICACY KEY ENDPOINTS

xx Statistically significant

nificant xx

Non-statistically significant

Key Phase IIb results by endpoint

		N = 247 ITT population			N = 197 PP population		
		Placebo	800 mg	1200 mg	Placebo	800 mg	1200 mg
		(N = 81)	(N = 83)	(N = 83)	(N = 62)	(N = 63)	(N = 69)
FNDPOINT	Decrease of ≥2 points of SAF activity score* and no worsening of fibrosis	27%	<b>41%</b>	49% 0.004	34%	<b>51%</b>	55% 0.015
TS	Resolution of NASH and no worsening of fibrosis**	19%	<b>33%</b>	45% <0.001	23%	<b>40%</b>	49% 0.002
SECONDARY ENDPOINTS	Improvement of fibrosis by at least one stage and no worsening of NASH***	24%	<b>28%</b>	<b>42%</b> 0.011	29%	<b>32%</b>	<b>46%</b> 0.04
ECONDAR	Resolution of NASH and improvement of fibrosis <sup>^</sup>	7%	<b>21%</b>	31% <0.001	10%	24% 0.036	33%
S	Decrease of ≥2 points of NAS score <sup>^^</sup> (NAFLD activity score) and no worsening of fibrosis	32%	<b>52%</b>	64% <0.001	40%	<b>62%</b>	71%

\* Response is defined as a decrease from baseline to week 24 of at least 2 points of the SAF Activity score (SAF-A) with no worsening of the NAS Fibrosis score (NAS-F). No worsening means that score remains stable or decreases ; \*\* Resolution of NASH and no worsening of fibrosis at week 24: NAS-I = 0 or 1 (NAS-Inflammation), NAS-B = 0 (NAS-Ballooning) and no worsening of NAS-F from baseline; \*\*\* Improvement of liver fibrosis  $\geq$  1 stage and no worsening of NASH at week 24; ^ Resolution of NASH and improvement of fibrosis at week 24: NAS-I = 0 or 1, NAS-B = 0 or 1, NAS-B = 0 and an improvement of NAS-F  $\geq$  1 stage; ^ NAS score is a commonly accepted, semi-quantitative evaluation of biopsy results that assesses the severity of steatosis, inflammation and ballooning in the liver.

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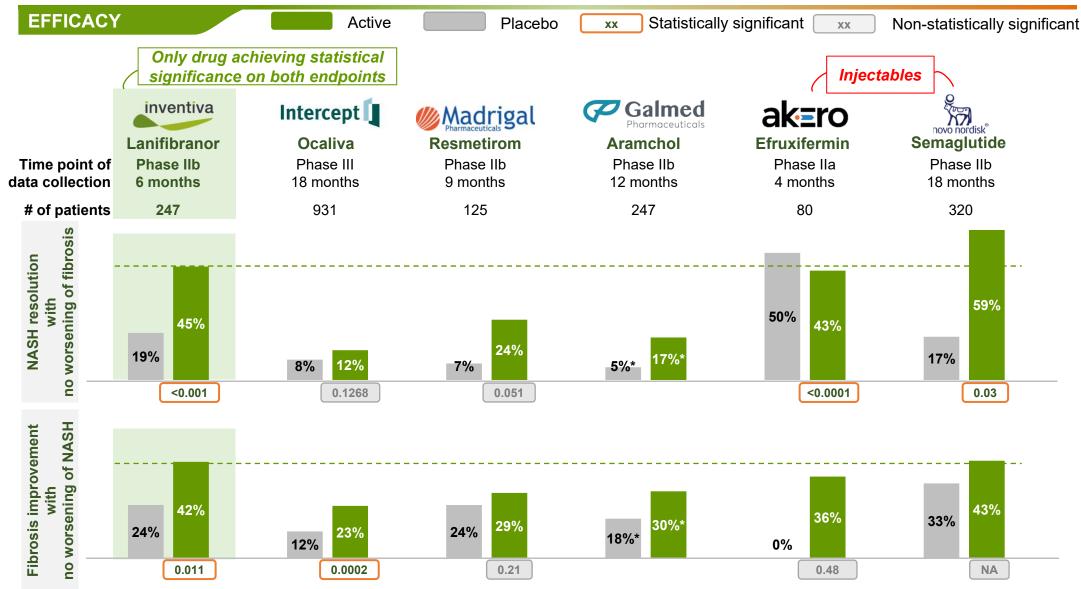
# Compared to key competitors, lanifibranor is the only asset that addresses all key features of NASH

EFFICACY

	Lanifibranor (PPAR)	Ocaliva (FXR)	Resmetirom (THR-β)	Aramchol (Other)	Efruxifermin (FGF)	Semaglutide (GLP-1)
	inventiva	Intercept [	Madrigal Pharmaceuticals	Calmed Pharmaceuticals	ak≘ro	novo nordisk <sup>®</sup>
ROUTE OF ADMINISTRATION	Oral	Oral	Oral	Oral	Injectable	Injectable
INSULINO- RESISTANCE	$\checkmark$	×	×	×	$\checkmark$	$\checkmark$
STEATOSIS	$\checkmark$	×	$\checkmark$	$\checkmark$	×	$\checkmark$
NECRO- INFLAMMATION	$\checkmark$	×	$\checkmark$	Unclear	$\checkmark$	$\checkmark$
FIBROSIS	$\checkmark$	$\checkmark$	Unclear	×	$\checkmark$	×

Source: Newsome et al., 2020; Company websites

# Lanifibranor compares favourably in its ability to target both fibrosis improvement and NASH resolution



No head-to-head clinical trials have been conducted; results obtained from different trials, with different designs, endpoints and patient populations. Results may not be comparable. \* Efruxifermin 70mg results only. Placebo N = 2. No information available regarding statistical significance of trial results; histology results reported only for patients achieving a  $\geq$ 30% reduction of hepatic fat at week 12

Source: lanifibranor native results 1200 mg/day, ITT population; ocaliva 25mg : REGENERATE Phase II trial: company press release February 19, 2019; Newsome et al., 2020: Ratziu et al, Gastorenterology 2016; 150:1147-1159 ; resmetirom 80mg ± 20mg: Harrison et al, Lancet 2019 ; S0140-6736(19) 32517-6; Aramchol 600mg :AASLD 2018 presentation

# Physicians are positive about anifibranor's value proposition, noting its ability to target both fibrosis and NASH resolution

EFFICACY	The benefits of a pan-PPAR targeting multiple isoforms are clear to most physicians, who comment positively on lanifibranor's efficacy on fibrosis and NASH resolution whilst also improving glycaemic control and insulin sensitivity
	" This product is a dream come true, it targets all the things I would want it to; it resolves the NASH, the fibrosis and you get improvement of glycaemic control and insulin resistance" Physician #1, US
Physicians valued Lanifibranor's efficacy on multiple	" You have to attack both NASH and fibrosis because if you reverse fibrosis and still have NASH, that's going to lead to more fibrosis" Physician #2, US
endpoints	" It is attractive, I do like that it has an effect on HbAC1 as the most common co-morbidity is T2DM" Physician #3, US
	<ul> <li>Physicians confirm F2-F3 is a correct patient population to target, noting lanifibranor's MoA (targeting multiple metabolic pathways) makes it highly suited to the F2-F3 population</li> <li>clinicians also want to treat the disease at its asymptomatic stage prior to complications occurring; some prefer this population over F4, as the latter is considered irreversible</li> <li>some also suggested they would like to use it in F0-1 if possible, in order to slow or prevent progression to F2-F3</li> </ul>
A once a day oral is considered optimal	Lanifibranor's oral administration is considered attractive, highlighting a once-daily oral pill will increase ease of use to the patient "… It is a once a day oral drug so compliance will be as good as you can get. At this point it would all be about education – it is important to educate the patient that they need to take this product, even if they are asymptomatic …" Physician #5, US

Source: L.E.K. Interviews, research and analysis (dated August 2020)

# Physicians perceive weight gain due to lanifibranor as manageable, with the risk profile viewed positively

#### SAFETY

Weight gain appears acceptable and manageable, with limited concerns expressed around edemas

- Physician express differing views on the importance of weight gain
  - the majority of physicians believed that given lanifibranor's efficacy profile the risk-benefit ratio was acceptable, and with proper patient counselling around weight loss some of the weight gain could be offset
  - some suggested combination therapy could be used to manage or reduce weight gain (e.g., GLP-1, SGLT2)

"...Weight increase can be limiting, but I don't think it be a problem if we can find something to use in combination to offset potential increase in fat tissue ..." – Physician, U.S., August 2020

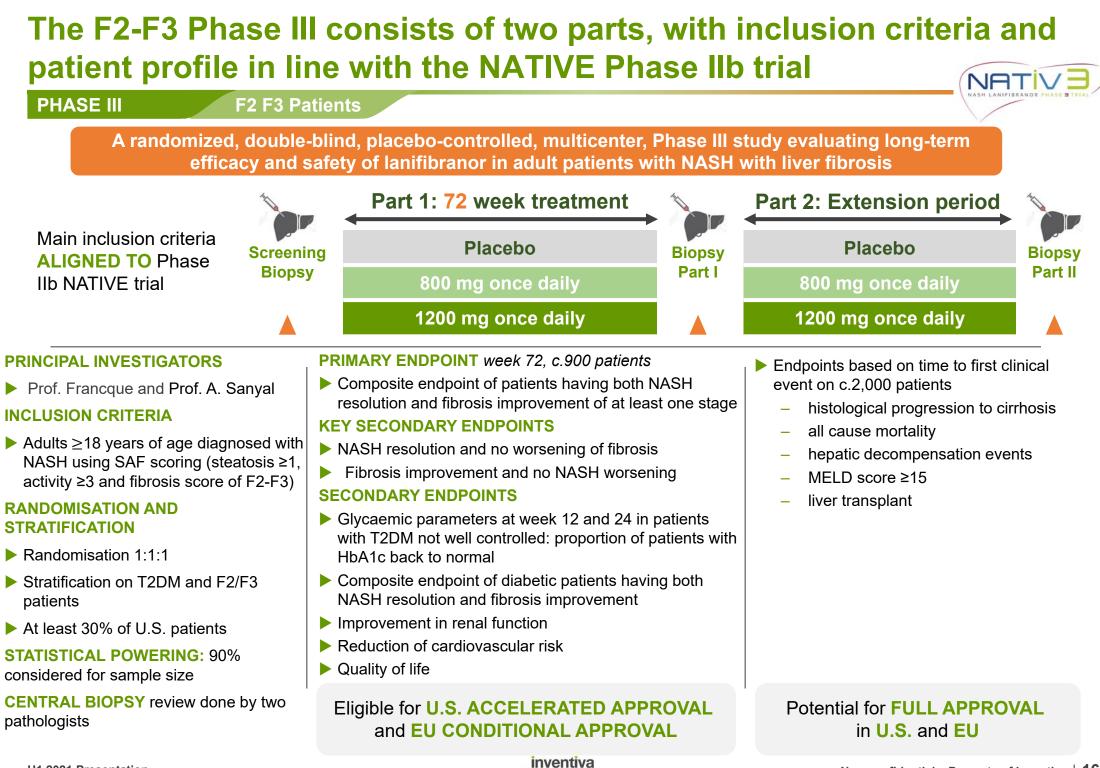
"... I am surprised by the weight gain but I do not see it as a big concern. It would only become an issue if the weight gains happens continuously, for example if you increase 2-3kgs every 2 months... Physician, DE, August 2020

Physicians express less concerned about oedema noting the majority are mild

*"… The mechanism of edema determines how bad it is, it is not alarming…" – Physician, FR, August 2020* 

"... edema is not relevant ..." Physician, DE, August 2020

Source: L.E.K. Interviews, research and analysis (dated August 2020)



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# The primary endpoint combining NASH resolution and fibrosis improvement will help differentiate from key competitors

PHASE III

DESIGN

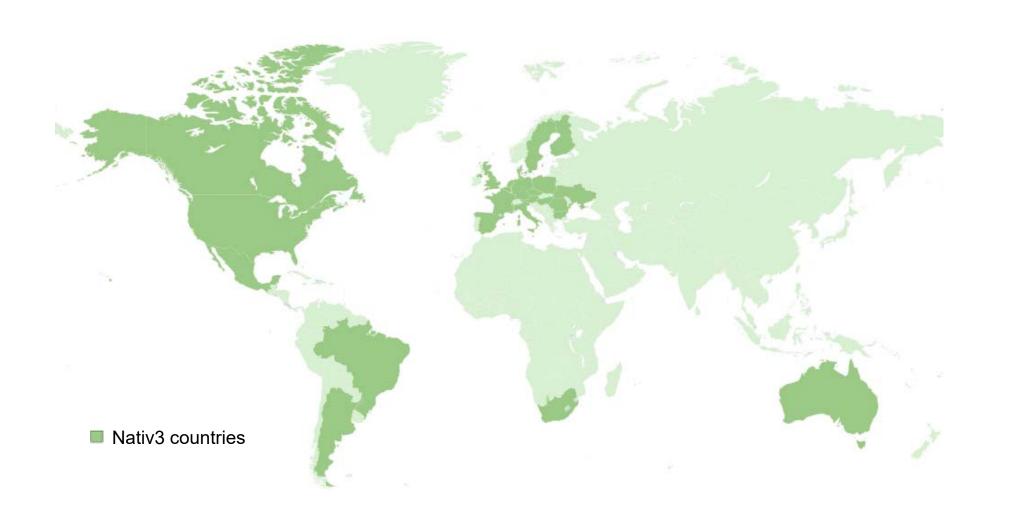
- The primary endpoint "resolution of NASH and improvement of fibrosis" addresses the major pathways of the disease: achieving both of these histological outcomes reflects a stronger impact on disease modification compared with improvement in either steatohepatitis or fibrosis alone
- If met, a label for the treatment of NASH and the improvement in liver fibrosis in adult non-cirrhotic NASH patients will be requested

Phase III study	lanifibranor (800 - 1200mg) At W72	Obeticholic acid (10 - 25mg) At W72	Resmetirom (80 - 100mg) At W52
Resolution of NASH <u>and</u> improvement of fibrosis	Primary	Secondary (not met)	/
Fibrosis improvement and no worsening of NASH	Key secondary	Primary (met)	Secondary
NASH resolution and no worsening of fibrosis	Key secondary	<b>Primary</b> (not met)	<b>Primary</b> (with reduction of at least 2 pts of NAS)
NASH resolution and fibrosis improvement in patients with diabetes	Secondary	/	/

Note:\* / : information not available

# The Phase III patients will be randomised across approximately 300 sites worldwide

PHASE III DESIGN SITE SELECTION



25 countries worldwide with more than 330 sites expected to participate

### Key milestones of the Phase III study in NASH (Part 1)

**MILESTONES PHASE III** 2021 2022 2023 2024 F2-F3 Phase III **Q3 2021** H2 2022 H1 2024 Activation of Part 1: Last Part 1: Last Patient first clinical First Visit Patient Last Visit sites and start (c.900 patients) (c.900 patients) of screening H2 2024 Part 1: Headline results

NATI



# SAVE THE DATE AASLD Nov. 12-15, 2021 The Liver Meeting

# **KOL Meeting**

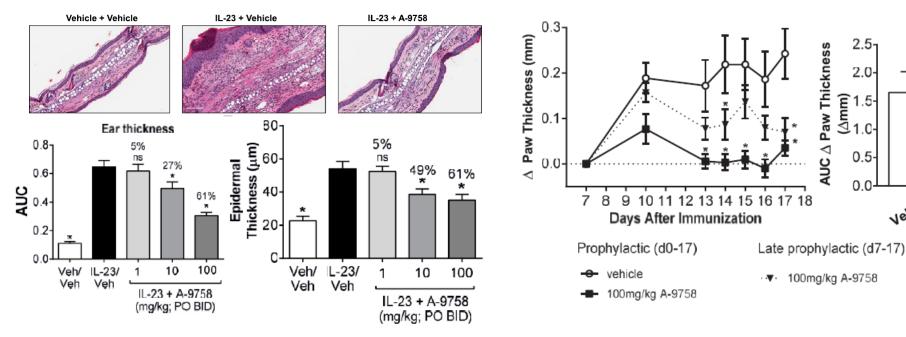
# Cedirogant - ABBV-157 Obbvie

# Cedirogant: a clinical stage RORy inverse agonist co-discovered by Inventiva with potential in several auto-immune diseases (I)

RORy is believed to be a master regulator of Th17 differentiation and IL-17 expression, an approach validated by several successful biologics

- Pharmacological inhibition of RORy by small molecules has been observed to suppress Th17 production, block cutaneous inflammation in animal models of psoriasis and inhibit TH17 signature gene expression by cells isolated from psoriatic patient samples
- ROR $\gamma$  is therefore a validated drug target for the treatment of psoriasis and potentially other cutaneous inflammatory disorders

A-9758<sup>(1)</sup> attenuates IL-23 mediated skin inflammation A-9758<sup>(1)</sup> blocks GPI-mediated arthritis



Effect of RORy inhibition on IL-23 mediated psoriasiform dermatitis

Effect of RORy inhibition on paw swelling both on prophylactic and late prophylactic treatment

AUC  $\Delta$  Paw Thickness

2.5

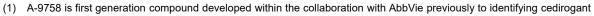
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0.5

0.0

Vehicle



Source: Inhibition of interleukin-32 mediated inflammation with a novel small molecule inverse agonosit RORyt: The Journal of Pharmacology and Experimental Therapeutics 371:208-218. October 2019

inventiva

late

prophylactic

(7-17)

41%

A-9758

prophylactic (0-17)

84%

A-9758

# Cedirogant: a clinical stage RORγ inverse agonist co-discovered by Inventiva with potential in several auto-immune diseases (II)

#### Cedirogant (ABBV-157) is targeting indications where competitors have reached block-buster status

	Brand	Company	Target	Posology	2020 sales <sup>(1)</sup>
<ul> <li>Cedirogant Target Product Profile: Humira in a pill + better safety</li> <li>Inventiva to receive development, regulatory, commercial milestones and tiered royalties from the</li> </ul>	Humira	AbbVie	Anti-TNF $\alpha$	Injectable	\$19,8b
	Stelara	Janssen	IL-12/23	Injectable	\$7,7b
	Cosentyx	Novartis	IL-17A	Injectable	\$3,9b
mid-single to low-double digits	Otezla	Celgene	TNFα	Oral	\$2,2b
	Taltz	Eli Lilly	IL-17A	Injectable	\$1,8b
	Skyrizi	BI / AbbVie	IL-23	Injectable	\$1,6b

Cedirogant (ABBV-157) is currently being developed in moderate to severe psoriasis, a common skin condition that affects 2-4% of the population in Western countries

- Single ascending dose and multiple ascending dose trials in healthy volunteers completed with no safety signals
- > Phase Ib in patients with chronic plaque psoriasis completed: clinical proof of efficacy achieved
- Following Phase Ib results, AbbVie has communicated its plans to initiate a Phase IIb in H2 2021

"In our Phase Ib study, 157 <u>showed promising activity as an oral psoriasis agent and we plan to move the asset forward to</u> <u>a larger Phase IIb dose-ranging study in the second half of this year</u> ... with respect to oral psoriasis agents, we would want to come in from an efficacy perspective with something that clearly exceeded the threshold that existed in the past with Otezla ... <u>we'd be looking for that Humira-like efficacy or greater</u> as something that we would like to use to enter the space within oral, obviously, coupled with a strong safety profile."

Dr. Michael Severino AbbVie Vice Chairman and President<sup>(2)</sup>

# Next milestone expected for phase IIb initiation which is planned for November 2021

(1) Company Q1 2021 and full year 2020 press releases; (2) ABBV-157 is Cedirogant Abbviecode; AbbVie Q1 2021 earnings call April 30 2021 9 AM ET; Transcript from FactSet;

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### Cedirogant Phase IIb in in adults with moderate to severe psoriasis

#### A Phase IIb, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Safety and Efficacy of Cedirogant (ABBV-157) in Adult Subjects With Moderate to Severe Psoriasis

#### Status

- Sponsor: AbbVie
- ClinicalTrials.gov Identifier: NCT05044234
- Approx. 200 adult participants with moderate to severe plaque psoriasis will be enrolled at approx. 45 sites
- Estimated study start date: November, 2021
- Estimated study completion date: March, 2023

#### **Inclusion criteria**

Participants with stable moderate to severe plaque psoriasis of at least 6 months duration and who are candidates for systemic therapy or phototherapy

#### **Primary outcome measures**

Percentage of participants achieving >=75% reduction from baseline in Psoriasis Area Severity Index<sup>(1)</sup> (PASI) score (PASI 75)

#### Secondary outcome measures

- Percentage of participants achieving a Static Physician Global Assessment<sup>(2)</sup> (sPGA) score of clear or almost clear
- Percentage of participants achieving >=50% / >=90% / 100% reduction from baseline in PASI Score (PASI 50; PASI 90; PASI 100)
- Percentage of participants achieving Psoriasis Symptoms Scale<sup>(3)</sup> (PSS) total score of 0 for participants with PSS >0 at baseline
- Percentage of participants achieving an Itch Numerical Rating Scale<sup>(4)</sup> (NRS) >=4 point improvement from baseline for participants with Itch NRS >=4 at baseline

#### 200 patients / 16 week treatment / ~45 sites

Double blind randomized placebo controlled

# Placebo, 50 patients Cedirogant, dose A once daily, ~50 patients Cedirogant, dose B once daily, ~50 patients Cedirogant, dose C once daily, ~ 50 patients

(1) The PASI is a tool that provides a numeric scoring for participants' overall psoriasis disease state, ranging from 0 to 72, with a higher score indicating more severe disease; (2) The sPGA is a 5-point score ranging from 0 to 4, based on the physician's assessment of the average thickness, erythema, and scaling of all psoriatic lesions. A lower score indicates less body coverage, with 0 being clear and 1 being almost clear; (3) The PSS is a 4-item patient-reported outcome instrument that assesses the severity of psoriasis symptoms in patients with moderate to severe psoriasis. Current symptom severity is assessed using a 5-point Likert-type scale ranging from 0 (none) to 4 (very severe); (4) The Itch NRS is an 11-point scale that participants complete daily to describe the intensity of their itch using a 24-hour recall period. Scores vary between 0, representing "no itching" and 10, representing "worst itch imaginable

Source: clinicaltrials.gov

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### **Competitive landscape**

Product name	Company	Development Phase
Cedirogant	abbvie	Phase 2
Bevurogant	Boehringer Ingelheim	Phase 2
AUR-101	A U R I G E N E Accelerating Discovery	Phase 2
JTE-761	JAPAN TOBACCO INTERNATIONAL	Phase 1
IMU-935	Immunic THERAPEUTICS	Phase 1

#### Selected ROR $\gamma$ programs stopped

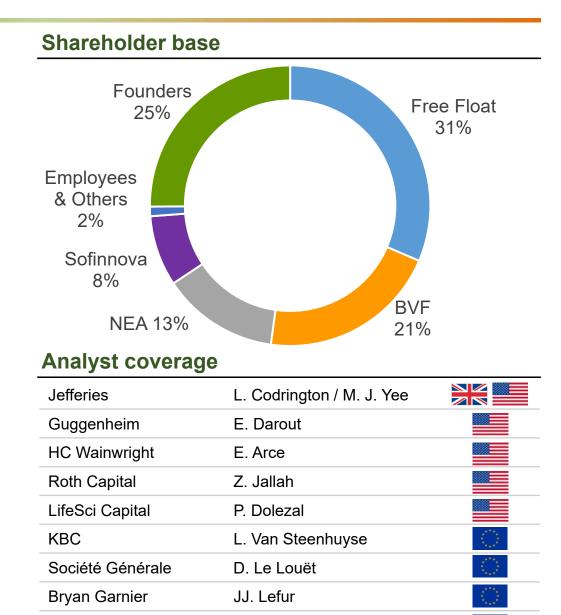


# **Financials**

## Key financials and shareholder base

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Key financials				
IVA LISTED EURONEXT	Nasdaq IVA NasdaqListed			
ISIN code	FR0013233012 / US46124U1079			
Market	Euronext Paris / Nasdaq GM			
Shares outstanding	38,659,361 (incl. 7,478,261 shares of the July 9 2020 Nasdaq IPO)			
Market cap (September 20, 2021)	Euronext Paris: €458m Nasdaq Global Market: \$541m			
Cash position (as of June 30,2021)	€93.6m (vs €105.7m as of December 31, 2020) <sup>(1)</sup> Current expected cash runway through Q3 2022			
Revenues (H1 2021)	€0.1m compared to €0.2m in H1 2020			
R&D expenditures (H1 2021)	€19.1m compared to €12.6m in Q1 2020			



M. Kaabouni

(1) The cash position as of December 31, 2020 amounted to €113.7 million published in the press releases on March 4, 2021, May 12, 2021 and July 28, 2021 included cash and cash equivalents as well as short-term deposits which were included in the category "other current assets" in the IFRS statement of financial position. Under IFRS, the variation of short-term deposits and its related exchange effects are reflected in the line items "net cash flows from investing activities" for €5.9 million and "exchange gains (losses)" for €1.4 million, respectively.

Portzamparc

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# H1 2021 financial position

#### **Income Statement**

(in thousands of euros, except share and per share amounts)	June 30, 2021	June 30, 2020
Revenues	139	161
Other income	2,009	1,607
Research and development expenses	(19,109)	(12,574)
Marketing – business development expenses	(258)	(123)
General and administrative expenses	(5,779)	(3,383)
Other operating income (expenses)	(607)	(1,354)
Net operating loss	(23,605)	(15,665)
Net financial income	824	6
Income tax	(355)	-
Net loss for the period	(23,136)	(15,659)
Basic/diluted loss per share (euros/share)	(0.60)	(0.52)
Weighted average number of outstanding shares used for computing basic/diluted loss per share	38,677,187	29,894,757

Cash Position				
Key Figures (in thousands of euros)	June 30, 2021	Dec 31, 2020		
Cash & cash equivalents	93,633	<b>105,687</b> <sup>1</sup>		

### Highlights

- ► Revenues of €0.1 m, stable compared to H1 20
  - Inventiva eligible to receive a milestone payment in Q4 upon the initiation by AbbVie of the Ph2b clinical trial (cedirogant collaboration)
- ► 52% increase in R&D investment, €19.1 m vs €12.6 m in H1 20
  - Accelerated efforts dedicated to the development of lanifibranor (NASH) to prepare and initiate the NATiV3 Phase III clinical trial
- ▶ 71% increase in G&A, €5.8 m vs €3.4 m in H1 20
  - As expected, due to Inventiva's new dual listing status and related higher compliance costs in H1 21 vs H1 20 (*Nasdaq listing July 2020*)
- Cash position allowing to operate through Q3 2022, at €93.6 m vs €105.7<sup>(1)</sup> m as of December 31, 2020
  - Net operating cash flow at (€19.8) m vs (€7.2) m reflecting the increase in R&D and G&A; Monthly burn rate acceleration at €4.6 m in H1 21 vs €2.5 m in H1 20 (excluding R&D tax credit payments), heading towards c. €6.0 m per month in average by the end of 2021, in line with the ongoing Phase III study

#### **Financial Calendar**

#### November 10, 2021: Publication of Q3 2021 financial results (revenues and cash) (after U.S. market closing)

(1) The cash position as of December 31, 2020 amounted to €113.7 million published in the press releases on March 4, 2021, May 12, 2021 and July 28, 2021 included cash and cash equivalents as well as short-term deposits which were included in the category "other current assets" in the IFRS statement of financial position. Under IFRS, the variation of short-term deposits and its related exchange effects are reflected in the line items "net cash flows from investing activities" for €5.9 million and "exchange gains (losses)" for €1.4 million, respectively.

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# **Near-term catalysts**

#### Lanifibranor

- Positive topline results of NATIVE Phase IIb trial in NASH
- ✓ Breakthrough Therapy Designation granted by FDA
- ✓ NATIVE Phase IIb meeting with FDA and EMA Scientific Advice
- ✓ Activation of first clinical sites and start of patient screening in phase III trial in NASH H2 2021
- Results of Phase II trial in T2DM patients with NAFLD H1 2022

#### Odiparcil

Strategy update on odiparcil development – 2022

### Cedirogant abbvie

- Clinical POC trial (Phase IB) in psoriasis
- Launch of phase IIB trial in psoriasis and milestone from AbbVie H2 2021

# Q&A

#### Contacts

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