

## H1 2020 financial results and corporate business update

- ▶ Cash and cash equivalents at €52.3 m as of June 30, 2020
- ▶ Successful \$107.7 m (€94.9 m<sup>1</sup>) initial public offering on the Nasdaq Global Market, extending the Company's cash runway through Q4 2022
- ▶ Publication of positive topline results from the Phase IIb NATIVE clinical trial evaluating lanifibranor in NASH and decision to move into pivotal Phase III development
- ▶ New data from Phase IIb NATIVE clinical trial in NASH showing significant decrease of fibrosis, apoptosis and inflammation biomarkers after 24 weeks of treatment with lanifibranor
- ▶ Appointment of Dr Arun J. Sanyal to Inventiva's Scientific Advisory Board (SAB), further strengthening the Board's expertise in the field of NASH
- ▶ Acceptance of Investigational New Drug (IND) application for odiparcil in MPS VI by the U.S. Food and Drug Administration (FDA) enabling U.S. clinical trials

**Daix (France), September 16, 2020** – Inventiva (Euronext Paris and Nasdaq: IVA), a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of non-alcoholic steatohepatitis (NASH), mucopolysaccharidoses (MPS) and other diseases with significant unmet medical need, today reported its interim financial results for the six months ended June 30, 2020, and provided an update on its business activities.

**Frédéric Cren, Chairman, Chief Executive Officer and cofounder of Inventiva, stated:** *“The first half of 2020 has been one of the most decisive periods since the founding of Inventiva in 2012. Looking at the development of our R&D portfolio, our lead drug candidate lanifibranor has shown very promising results in our Phase IIb clinical trial in NASH: with statistically significant results on both the FDA and European Medical Agency (EMA) primary endpoints relevant for seeking accelerated approval during Phase III clinical development, this trial has paved the way for lanifibranor to enter into pivotal Phase III. In parallel, we have progressed in the development of odiparcil for the treatment of MPS VI: the recent acceptance of our IND application by the FDA will allow us to launch our first clinical trial with odiparcil in the USA and will lay the groundwork for its future development in this important market. I would also like to thank the whole Inventiva team who worked tirelessly over the last few months in a difficult context. I am proud of their work and commitment that contributed to these achievements. Looking ahead, we are now fully focused on moving forward with the clinical development of lanifibranor in NASH with the anticipated pivotal Phase III trial, while continuing to advance our different programs across MPS, psoriasis and oncology, in line with our multi-asset strategy.”*

<sup>1</sup> Based on an exchange rate of \$1.1342 per euro, the exchange rate published by the European Central Bank on July 9, 2020.

**Jean Volatier, Chief Financial Officer of Inventiva, added:** *“In addition to the significant progress of our R&D portfolio, especially in NASH, we were also able to considerably strengthen our financial position despite the challenging environment linked to the COVID-19 pandemic. Of particular note is our successful initial public offering on the Nasdaq Global Market in the U.S., which increases our visibility in this key market and has enabled us to extend our cash runway through the fourth quarter of 2022. Backed by a very solid financial position and important advances across our R&D portfolio, we are in an ideal position to pursue the development of our different drug candidates.”*

### **Key financial results for the first half of 2020**

<i>(in thousands of euros, except share and per share amounts)</i>	<b>June 30, 2020</b>	<b>June 30, 2019</b>
<b>Revenue</b>	<b>161</b>	<b>1,333</b>
Other income	1,607	2,198
Research and development expenses	(12,574)	(19,646)
Marketing – business development expenses	(123)	(135)
General and administrative expenses	(3,383)	(3,132)
Other operating income (expenses)	(1,354)	(1,274)
<b>Operating profit (loss)</b>	<b>(15,665)</b>	<b>(20,656)</b>
<b>Financial income (loss)</b>	<b>6</b>	<b>111</b>
Income tax	-	-
<b>Net loss for the period</b>	<b>(15,659)</b>	<b>(20,545)</b>
<b>Basic / diluted loss per share (euros/share)</b>	<b>(0.52)</b>	<b>(0.93)</b>
Weighted average number of outstanding shares used for computing basic/diluted loss per share	29,894,757	22,160,448

**Revenues** for the first half of 2020 reached €0.2 million compared to €1.3 million in the first half of 2019 and related primarily to research services in connection with Inventiva’s collaboration with Boehringer Ingelheim, which has since been terminated.

**R&D expenses** amounted to €12.6 million in the first half of 2020, down 36% compared to the first half of 2019. These expenses were mainly dedicated to the development of lanifibranor in NASH and odiparcil in MPS VI. The decrease compared to the previous year is mainly due to the halt in the clinical development of lanifibranor in the treatment of systemic sclerosis in February 2019 and the savings generated by the Employment Safeguard Plan subsequently introduced, with the first half of 2020 recording the full effect of the savings generated.

**General and administrative expenses** amounted to €3.4 million, compared to €3.1 million in the first half of 2019, up 8%, mainly due to increased labor costs.

**Other operating income (expenses)** amounted to (€1.4) million (compared with (€1.3) million in the first half of 2019). The first half of 2019 took into account the recording of a provision of €1.1 million relating to the Employment Safeguard Plan, while the first half of 2020 takes into account part of the expenses incurred as part of the Initial Public Offering in the United States.

Company’s **net loss** stood at (€15.7) million, compared to (€20.5) million in the first half of 2019.

Inventiva's **net cash flow** amounted to €16.4 million in the six months ended June 30, 2020 compared to (€19.6) million in the first half of 2019. Net cash used in operating activities was (€7.2) million and (€18.7) million in the first half of 2020 and 2019, respectively.

In addition to the decrease in R&D expenses mentioned above, in the first half of 2020, **cash flow from operating activities** was positively impacted by the receipt in January 2020 of €4.2 million in respect of the 2018 Research Tax Credit (CIR), and the receipt in April and June 2020 of €4.2 million in total in respect of the 2019 CIR.

Net **cash from financing activities** amounted to €24.6 million in the first half of 2020, driven by: the issuance of €15 million (gross proceeds) of ordinary shares in February 2020 to certain existing investors in the Company and the entry into a €10.0 million credit agreement, guaranteed by the French State, with a syndicate of French banks.

Consequently, Inventiva's **cash and cash equivalents** stood at €52.3 million as of June 30, 2020 compared to €35.8 million as of December 31, 2019.

The financial statements of the first half of 2020 were approved by the Board of Directors on September 15, 2020. The statutory auditors have issued a limited review report. For more details, Inventiva's Half-Year Financial Report is available on the Company's website at: [www.inventivapharma.com](http://www.inventivapharma.com).

### Financial information after closing of the accounts

On July 15, 2020, Inventiva successfully closed its initial public offering on the Nasdaq Global Market of an aggregate of 7,478,261 new ordinary shares in the form of American Depositary Shares (ADSs), each representing one ordinary share, at an offering price of \$14.40 per ADS. Aggregate gross proceeds of the initial public offering, before deducting underwriting commissions and estimated expenses payable by the Company, were approximately \$107.7 million (€94.9 million<sup>2</sup>). All of the securities as part of the initial public offering were offered by Inventiva. The Company's ADSs, listed under the symbol "IVA", began trading on the Nasdaq Global Market on July 10, 2020.

The Company believes its cash, cash equivalents, short-term investments and non-current financial assets, together with the net proceeds of its successful initial public offering on the Nasdaq Global Market and its cash flow from operations will be sufficient to fund its operations through the fourth quarter of 2022.

### Main areas of progress in the R&D portfolio

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

- Following the publication of the positive results from the NATIVE Phase IIb clinical trial evaluating lanifibranor in NASH in June 2020, Inventiva has progressed with the analysis of the circulating biomarkers. The first results of this analysis have shown a positive and statistically significant decrease of some biomarkers under lanifibranor treatment. Of importance and in line with the mechanism of action of lanifibranor, patients treated with the drug candidate showed improvements on biomarkers of fibrosis (Pro-C3 - a marker of fibrogenesis and ratio TIMP-1/MMP2 – a ratio depicting the inhibition of matrix remodeling process), apoptosis (CK18-M30 - a marker of apoptosis) and inflammation (Ferritin and hs-CRP – markers of inflammation). These findings, including the table in appendix of this press release, will be presented in more detail during tomorrow's webcast and conference call (see below for logistical details) – *September 17, 2020*
- Following higher than expected observed effects of lanifibranor in reducing steatosis during the Phase IIb NATIVE clinical trial in NASH, Professor Kenneth Cusi, the investigator of the trial, decided to reduce the number of patients in the ongoing Phase II clinical trial evaluating lanifibranor in type 2 diabetes patients (T2DM) with Non-Alcoholic Fatty Liver Disease (NAFLD); results are expected in 2021 – *July 6, 2020*

<sup>2</sup> Based on an exchange rate of \$1.1342 per euro, the exchange rate published by the European Central Bank on July 9, 2020.

- Publication of positive topline results from the Phase IIb NATIVE (*NASH Trial to Validate IVA337 Efficacy*) clinical trial; decision to continue the clinical development of lanifibranor in NASH and enter into pivotal Phase III development – *June 15, 2020*

Inventiva announced positive topline results from the Phase IIb NATIVE clinical trial evaluating lanifibranor for the treatment of NASH on June 15, 2020.

In this 24-week clinical trial, lanifibranor met the primary endpoint with a statistically significant reduction of the Steatosis Activity Fibrosis score (SAF), which combines assessments of hepatocellular inflammation and ballooning, with no worsening of fibrosis in the Intention To Treat (ITT<sup>3</sup>) and Per Protocol populations (PP<sup>4</sup>). The drug candidate also met key secondary endpoints, including NASH resolution with no worsening of fibrosis<sup>5</sup> and improvement of liver fibrosis with no worsening of NASH<sup>6</sup> in both ITT and PP populations. With these results, lanifibranor is the first drug candidate to achieve statistically significant results on NASH resolution with no worsening of fibrosis and improvement of fibrosis with no worsening of NASH, the two Food and Drug Administration (FDA) and European Medicine Agency (EMA) primary endpoints relevant for seeking accelerated approval during Phase III clinical development. Based on these positive topline results, Inventiva has decided to continue with the clinical development of lanifibranor in NASH and enter into pivotal Phase III development.

- Approval of a new patent directed at the use of lanifibranor for the treatment of several fibrotic diseases, including NASH, in China until June 2035 by the China National Intellectual Property Administration (CNIPA) – *May 25, 2020*

### **Odiparcil in mucopolysaccharidosis type VI (MPS VI)**

- Acceptance of the Investigational New Drug (IND) application for odiparcil in MPS VI by the U.S. Food and Drug Administration (FDA) – *August 10, 2020*

On August 10, 2020, the FDA accepted Inventiva's IND application for odiparcil for the treatment of MPS VI, allowing the Company to initiate clinical trials with this drug candidate in the United-States.

- Decision by Inventiva to extend the duration of the Phase I/II SAFE-KIDDS (SAFEty, pharmacokinetics and pharmacodynamics, Dose escalating Study) clinical trial evaluating odiparcil in MPS VI children from 6 to 12 months following a scientific advice meeting with the EMA in July; launch of the trial is expected in the first half of 2021 – *July 23, 2020*
- Publication of Inventiva's latest research on odiparcil's mechanism of action in the leading peer-reviewed scientific journal *PLOS ONE*, showing that the drug candidate was associated with decreased glycosaminoglycan (GAG) accumulation and increased GAG excretion, and highlighting its distribution in MPS VI disease-relevant tissues and organs – *May 18, 2020*

<sup>3</sup> ITT: includes all patients randomized in the trial.

<sup>4</sup> PP: includes all patients with paired biopsies and without deviation impacting efficacy assessment.

<sup>5</sup> *NASH resolution and no worsening of fibrosis* defined as CRN Lobular inflammation score equal to 0 or 1 and CRN Hepatocyte ballooning score equal to 0 and no worsening of the CRN-Fibrosis score.

<sup>6</sup> *Improvement of liver fibrosis with no worsening of NASH* defined as improvement of CRN-Fibrosis score  $\geq 1$  stage and no increase of CRN-Steatosis score and no increase of CRN-Inflammation score and no increase of CRN-Ballooning score.

### Other significant milestones

- Appointment of Dr Arun J. Sanyal to Inventiva's Scientific Advisory Board (SAB), further strengthening the Board's expertise in the field of NASH – *July 29, 2020*

Inventiva has further reinforced its SAB in the field of NASH with the appointment of Dr Arun J. Sanyal on July 29, 2020. Professor of Medicine, Physiology and Molecular Pathology in the Division of Gastroenterology at Virginia Commonwealth University (VCU) Medical Center in Richmond, Virginia, Dr Sanyal's research focuses on all aspects of NAFLD and NASH as well as complications of cirrhosis and End-stage Liver Disease. He also serves as Chairman of the National Institutes of Health (NIH) NASH Clinical Research Network, the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) consortium and the Liver Forum for NASH and Fibrosis. In addition to his participation in the SAB, Dr Sanyal is involved in preparing the protocol of the Phase III clinical trial for the development of lanifibranor in NASH.

- Entry into a €10.0 million non-dilutive loan facility guaranteed by the French State ("Prêt Garanti par l'Etat"), with the support of Bpifrance, Crédit Agricole Champagne-Bourgogne and Société Générale, contributing to strengthening the Company's cash position in the context of the COVID-19 pandemic – *May 19, 2020*
- Capital increase of €15 million subscribed by BVF Partners L.P., New Enterprise Associates (NEA), Novo Holdings A/S and Sofinnova Partners – *February 11, 2020*

### COVID-19 update

Following the updated recommendations of domestic public health authorities and a continuous risk assessment of the COVID-19 pandemic situation, Inventiva is pursuing the implementation of measures to minimize risks for its employees and support their health and safety in this unprecedented time. As of today, the R&D internal and support activities are not expected to be significantly impacted in the future.

The global pandemic of COVID-19 continues to evolve, and its ultimate impact remains uncertain. The Company cannot predict the full extent of potential delays or impacts on its clinical trials, or potential impact on its business. Inventiva is committed to continuing to implement measures aimed at minimizing any further potential business impact from the COVID-19 pandemic and continue to comply with the updated guidance documents of the regulatory authorities. The Company continues to closely monitor, assess and respond to the situation as it evolves overtime and continues to work closely with authorities, its contract research organizations, trial sites and investigators to critically reassess all its existing programs and communicates further when and if appropriate.



### Next expected key milestones

- End of NATIVE Phase IIb clinical trial meeting with the FDA and Scientific Advice meeting with the EMA – *planned for fourth quarter of 2020*
- AbbVie's completion of its ongoing Phase I clinical trial with ABBV-157 in psoriasis patients – *expected fourth quarter of 2020*
- Preparation for commencement of the Phase III clinical trial evaluating lanifibranor in NASH – *planned for the first half of 2021*
- Initiation of the Phase I/II SAFE-KIDDS (SAFety, pharmacoKinetics and pharmacoDynamics, Dose escalating Study) clinical trial evaluating odiparcil in MPS VI children – *planned for the first half of 2021*

- Initiation of the Phase IIa extension clinical trial with odiparcil in MPS VI patients who completed the prior Phase IIa clinical trial (iMProVeS) – *planned for the first half of 2021*

#### Upcoming investor conference participation

- H.C. Wainwright 22<sup>nd</sup> Annual Global Investment Virtual Conference, September 15-16, 2020
- Roth Analyst Management Talk Series, September 21, 2020
- 20th Annual Biotech in Europe Forum, September 21-24, 2020
- KBC Securities Virtual Life Sciences Conference, September 22-23, 2020
- Lyon Pôle Bourse Investment forum, Lyon, September 30, 2020
- Portzamparc Health/Biotech Virtual Seminar, October 1, 2020
- HealthTech Innovation Days, Paris, October 5-6, 2020
- European Midcap Hybrid Event, Paris, October 19-20, 2020
- Stifel Healthcare Conference 2020, New York, November 17-18, 2020
- Jefferies 11<sup>th</sup> Global Healthcare conference, London, November 17-19, 2020
- Piper Sandler 32<sup>nd</sup> Annual Healthcare Conference, New York, December 1-3, 2020

#### Upcoming scientific conference presentations

- Presentation of the Phase IIb NATIVE clinical trial results at The Liver Meeting® of the AASLD (American Association for the Study of Liver Diseases), November 13-16, 2020

#### Conference call

A **conference call** in English will be held **on Thursday, September 17, at 2:00 pm (Paris time)**. To join the conference call, please use the code **6617599** after dialing one of the following numbers:

France: +33 1 70 70 07 81

Belgium: +32 27 93 38 47

Germany: +49 69 22 22 26 25

Netherlands: +31 20 79 56 614

Switzerland: +41 44 58 07 145

United Kingdom: +44 207 19 28 338

United States: +1 646-741-3167

The presentation accompanying this conference call will be available on Inventiva's website in the "Investors" – "Results & Presentations" section at the same time and can be followed live at: <https://edge.media-server.com/mmc/p/z3ek3api>.

A replay of the conference call and the presentation will be available from 6:00 pm (Paris time) onwards at: <https://inventivapharma.com/investors/financial-results-presentations/>.

#### Next financial results publication

- **Q3 2020 Revenues and cash position:** Thursday, November 12, 2020 (after market close)



**Appendix**

**Measure of circulating biomarkers in NATIVE Phase IIb trial: significant decrease under lanifibranor treatment compared to placebo after 24-weeks**

Median relative change from baseline at week 24 (%)		Lanifibranor	Placebo	P-value
Fibrosis	Pro-C3	-13.9%	-4.1%	p= 0.005*
	Pro-C3 >14 µg/mL <sup>(1)</sup> at baseline	-20.5%	-12.8%	p= 0.017*
	Ratio TIMP-1/MMP2	-22.5%	-4.6%	p < 0.001*
Apoptosis	CK18-M30	-41.1%	0.5%	p < 0.001*
Inflammation	Ferritin	-29.4%	-9.1%	p < 0.001*
	hs-CRP	-35.5%	13.0%	p < 0.001*

(1) Level where it is estimated that fibrogenesis is active and corresponding to F2/F3 patients

FAS (Full Analysis Set) population with available data at baseline (pre-treatment) and at week 24 (post-treatment)

\* Median change under lanifibranor are statistically significantly different compared to placebo, using the common threshold of 5% (Exploratory Wilcoxon test)

**About Inventiva**

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of NASH, MPS and other diseases with significant unmet medical need.

Leveraging its expertise and experience in the domain of compounds targeting nuclear receptors, transcription factors and epigenetic modulation, Inventiva is currently advancing two clinical candidates, as well as a deep pipeline of earlier stage programs.

Lanifibranor, its lead product candidate, is being developed for the treatment of patients with NASH, a common and progressive chronic liver disease for which there are currently no approved therapies. Inventiva recently announced positive topline data from its Phase IIb clinical trial evaluating lanifibranor for the treatment of patients with NASH.

Inventiva is also developing odiparil, a second clinical stage asset, for the treatment of patients with subtypes of MPS, a group of rare genetic disorders. A Phase I/II clinical trial in children with MPS VI is currently under preparation following the release of positive results of the Phase IIa clinical trial in adult MPS VI patients at the end of 2019.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. Furthermore, the Company has established a strategic collaboration with AbbVie in the area of autoimmune diseases. AbbVie has started the clinical development of ABBV-157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. This collaboration enables Inventiva to receive milestone payments upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, in addition to royalties on any approved products resulting from the collaboration.

The Company has a scientific team of approximately 70 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology, as well as in clinical development. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, approximately 60% of which are proprietary, as well as a wholly-owned research and development facility.

Inventiva is a public company listed on compartment C of the regulated market of Euronext Paris (Euronext: IVA – ISIN: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). [www.inventivapharma.com](http://www.inventivapharma.com)

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## Important Notice

*This press release contains forward-looking statements, forecasts and estimates with respect to Inventiva's clinical trials, clinical trial data releases, clinical development plans and anticipated future activities of Inventiva. Certain of these statements, forecasts and estimates can be recognized by the use of words such as, without limitation, "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will" and "continue" and similar expressions. Such statements are not historical facts but rather are statements of future expectations and other forward-looking statements that are based on management's beliefs. These statements reflect such views and assumptions prevailing as of the date of the statements and involve known and unknown risks and uncertainties that could cause future results, performance or future events to differ materially from those expressed or implied in such statements. Actual events are difficult to predict and may depend upon factors that are beyond Inventiva's control. There can be no guarantees with respect to pipeline product candidates that the clinical trial results will be available on their anticipated timeline, that future clinical trials will be initiated as anticipated, or that candidates will receive the necessary regulatory approvals. Actual results may turn out to be materially different from the anticipated future results, performance or achievements expressed or implied by such statements, forecasts and estimates, due to a number of factors, including that Inventiva has incurred significant losses since inception, Inventiva has a limited operating history and has never generated any revenue from product sales, Inventiva will require additional capital to finance its operations, Inventiva's future success is dependent on the successful clinical development, regulatory approval and subsequent commercialization of current and any future product candidates, preclinical studies or earlier clinical trials are not necessarily predictive of future results and the results of Inventiva's clinical trials may not support Inventiva's product candidate claims, Inventiva may encounter substantial delays in its clinical trials or Inventiva may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside Inventiva's control, Inventiva's product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, or limit their commercial potential, Inventiva faces substantial competition and Inventiva's business, preclinical studies and clinical development programs and timelines, its financial condition and results of operations could be materially and adversely affected by the current COVID-19 pandemic. Given these risks and uncertainties, no representations are made as to the accuracy or fairness of such forward-looking statements, forecasts and estimates. Furthermore, forward-looking statements, forecasts and estimates only speak as of the date of this press release. Readers are cautioned not to place undue reliance on any of these forward-looking statements.*



*Please refer to the Universal Registration Document filed with the Autorité des Marchés Financiers on June 19, 2020 under n° D.20-0551 and its amendment filed on July 10, 2020 under n° D. 20-0551-A01 as well as the half-year financial report on June 30, 2020 for additional information in relation to such factors, risks and uncertainties.*

*Except as required by law, Inventiva has no intention and is under no obligation to update or review the forward-looking statements referred to above. Consequently, Inventiva accepts no liability for any consequences arising from the use of any of the above statements.*