

Inventiva reports 2021 first half financial results and provides a corporate update

- Cash and cash equivalents at €93.6 m as of June 30, 2021 compared to €105.7 m¹ as of December 31, 2020
- ▶ Initiation of the NATiV3 Phase III clinical study with lanifibranor in NASH
- R&D expenses of €19.1 m in H1 2021, up 52% compared to H1 2020, mainly driven by the preparation and initiation of the NATiV3 Phase III clinical trial
- Decision by AbbVie to initiate a Phase IIb clinical trial with cedirogant in patients with moderate to severe psoriasis following the demonstration of clinical proof of concept during AbbVie's Phase Ib clinical trial
- Publication by AbbVie of the design of the Phase IIb clinical trial with cedirogant to be initiated in November 2021 with completion expected in March 2023
- Major recruitments to reinforce Inventiva's clinical expertise, medical team and corporate functions, as well as its presence in France and the United States
- Implementation of an At-The-Market ("ATM") program in the United States providing the Company with important financial flexibility and additional funding possibility of up to \$100.0 m

Daix (France), Long Island City (New York, United States), September 20, 2021 – 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, 2021 and provided a corporate update.

Frédéric Cren, Chairman, Chief Executive Officer and cofounder of Inventiva, stated: "Over the first six months of this year, we continued to progress in the development of our programs for the treatment of NASH and in the area of autoimmune diseases with our partner AbbVie. The initiation of our highly anticipated Phase III clinical trial in NASH, with the opening of the first clinical sites in the United States and the start of patient screening, is a major milestone in the pivotal development phase of our drug candidate lanifibranor. Moreover, the decision by AbbVie to move into Phase IIb clinical development with cedirogant for the treatment of psoriasis and the recent publication of the trial design are excellent news for this program in which Inventiva remains eligible to receive milestone payments as well as sales royalties. Last month, we also took the step to implement an ATM program in the United States, which provides us with the financial flexibility to bolster funding of our R&D portfolio and

¹ The cash position as of December 31, 2020 amounted to \leq 113.7 million as published in the press releases on March 4, 2021, May 12, 2021 and July 28, 2021 and 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 \leq 5.9 million and "exchange gains (losses)" for \leq 1.4 million, respectively.



should allow us to accelerate the development of our pipeline looking ahead. In parallel, we reinforced our teams across key markets through the recruitment of seven highly talented and seasoned professionals, ideally positioning us to master the upcoming milestones."

Key financial results for the first half of 2021

(in thousands of euros, except share and per share amounts)	June 30,	June 30,
	2021	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)	(0.40)
Weighted average number of outstanding shares used for computing basic/diluted loss per share	38,677,187	38,677,187

Revenues for the first half of 2021 reached ≤ 0.1 million, stable compared to the first half of 2020. As part of its collaboration with AbbVie in auto-immune diseases, Inventiva is eligible to receive development, regulatory and commercial milestone payments as well as royalty payments. As such, the Company expects to receive another milestone payment upon the initiation by AbbVie of the Phase IIb clinical trial with cedirogant (*see details in the "Main areas of progress in the R&D portfolio" section below*).

R&D expenses amounted to €19.1 million in the first half of 2021, an increase of 52% compared to €12.6 million in the first half of 2020, mainly driven by the costs associated with the preparation and initiation of the NATiV3 Phase III clinical trial with lanifibranor in NASH.

General and administrative expenses (G&A) amounted to €5.8 million, an increase of 71% compared to €3.4 million in the first half of 2020, mainly due to higher compliance costs resulting from Inventiva's new dual listing status since July 2020.

Other operating income (expenses) stood at (€0.6) million compared to (€1.4) million in the first half of 2020. The lower expenses incurred during the first half of 2021 included costs related to the preparation of the ATM project and the amortization costs of the one-off POSI insurance covering the Company's Initial Public Offering (IPO) on the Nasdaq Global Market.

Net financial income amounted to €0.8 million in the first half of 2021, mainly linked to exchange rate variation.

The Company's **net loss** stood at (€23.1) million compared to (€15.7) million in the first half of 2020.

Inventiva's **net cash flow** (excluding any exchange rate effect) amounted to (€15.0) million in the six months ended June 30, 2021 compared to €16.4 million in the same period in 2020.



Net cash used in operating activities amounted to €19.8 million and €7.2 million in the first half of 2021 and 2020, respectively. This increase in cash use is due to higher R&D and G&A expenses.

Cash flow from operating activities was also positively impacted in the first half of 2021 by the payment of \notin 8.0 million of Research Tax Credit (CIR - Crédit Impôt Recherche) (\notin 3.8 million related to complementary filings following the 2020 Conseil d'État judgement covering prior years, and \notin 4.2 million related to the 2020 Research Tax Credit) received on June 30, 2021.

Net cash generated by investing activities amounted to \notin 4.7 million² in the first half of 2021 compared to (\notin 1.0) million for the same period in 2020. This variation is essentially due to the decrease in short term deposits.

No net cash from financing activities was generated over the first half of 2021 while Inventiva recorded \notin 24.6 million of net cash from financing activities for the same period in 2020, notably related to the issuance of \notin 14.7 million (gross proceeds) of ordinary shares in February 2020 and the entry into a \notin 10.0 million State-guaranteed loan with a syndicate of French banks in May 2020.

Over the first half of 2021, the Company recorded a **positive exchange rate effect** on cash and cash equivalents of €3.0 million².

As of June 30, 2021, Inventiva's **cash and cash equivalents** stood at €93.6 million compared to €105.7 million² as of December 31, 2020.

Considering its current R&D and clinical development programs, and excluding additional financial resources that may originate from funding activities such as the ATM program, Inventiva's cash runway will allow the Company to fund its operations through the third quarter of 2022.

The financial statements of the first half of 2021 were approved by Inventiva's Board of Directors on September 16, 2021. The statutory auditors have issued a limited review report. For more details, the Half-Year Financial Report is available on the Company's website at: <u>www.inventivapharma.com</u>.

Main areas of progress in the R&D portfolio

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 – September 8, 2021

Odiparcil in mucopolysaccharidosis type VI (MPS VI)

Inventiva continues to review all available options to optimize the development of its second clinical-stage asset odiparcil for the treatment of MPS VI. All MPS-related R&D activities remain on hold pending the outcome of this review process, now expected to conclude in 2022 (rather than in 2021 as previously anticipated).³

² The cash position as of December 31, 2020 amounted to ≤ 113.7 million, as published in the press releases on March 4, 2021, May 12, 2021 and July 28, 2021, and 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.

³ Please refer to Inventiva's press release entitled "Inventiva receives positive FDA feedback to advance its lead drug candidate lanifibranor into pivotal Phase III in NASH" and published on November 10, 2020.



Collaboration with AbbVie on cedirogant in autoimmune diseases

- Decision by AbbVie to initiate a Phase IIb clinical trial with cedirogant⁴ in patients with moderate to severe psoriasis after having achieved clinical proof of concept during AbbVie's Phase Ib clinical trial – May 12, 2021⁵
- Publication by AbbVie of the study design of the Phase IIb clinical trial with cedirogant: a multicenter, randomized, double-blind, placebo-controlled, dose-ranging study to evaluate the safety and efficacy of cedirogant in adult patients with moderate to severe psoriasis. AbbVie plans to enroll about 200 adult participants in approximately 45 sites, who will receive oral daily doses of cedirogant or placebo capsules for 16 weeks. The primary endpoint has been defined as the percentage of participants achieving >=75% reduction from baseline on the Psoriasis Area Severity Index (PASI) score (PASI 75)⁶. The trial is expected to start in November 2021 and be completed in March 2023 September 14, 2021⁷

Other significant milestones

- Major recruitments to reinforce Inventiva's clinical expertise, medical team and corporate functions, as well as its presence in France and the United States – September 16, 2021
- Implementation of an ATM program in the United States, to be activated if and when required, providing the Company with important financial flexibility to strengthen funding of its R&D pipeline by issuing and selling ordinary shares in the form of American Depositary Shares (ADSs), with aggregate gross sales proceeds of up to \$100 million. The ATM program will be effective until August 2, 2024 August 2, 2021
- Appointment of Martine Zimmerman as Independent Director to Inventiva's Board of Directors to replace Nawal Ouzren. Martine Zimmerman's appointment will be submitted to Inventiva's shareholders for ratification at the Company's next Combined Shareholders' Meeting – April 19, 2021

Next expected key milestones

- Initiation by AbbVie of the Phase IIb clinical trial with cedirogant in patients with moderate to severe psoriasis
 planned for November 2021
- Strategy update on the development of odiparcil planned for 2022 vs the second half of 2021 as previously anticipated
- Publication of the results of the Phase II clinical trial evaluating lanifibranor for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD) in patients with type 2 diabetes (T2DM) led by Professor Cusi – planned for the first half of 2022

Upcoming investor conference participation

- Lyon Pôle Bourse Forum, September 27-28, 2021
- HealthTech Innovation Days 2021, October 4-5, 2021
- Portzamparc Health Biotech Seminar 2021, October 6, 2021

⁴ Cedirogant is a clinical stage RORγ inverse agonist co-discovered by Inventiva with potential in several auto-immune diseases.

⁵ See AbbVie Q1 2021 earnings call on April 30, 2021, 9 AM ET; Transcript from FactSet. The Phase Ib clinical trial led by AbbVie was a randomized, doubleblind, placebo-controlled, multiple-dose trial to evaluate the pharmacokinetics, safety and tolerability of cedirogant in 60 healthy volunteers and patients with chronic plaque psoriasis (clinicaltrials.gov identifier: NCT03922607).

⁶ 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 a more severe form of the disease.

⁷ For more details regarding the Phase IIb clinical trial, please refer to <u>clinicaltrials.gov</u> (NCT05044234).



- H.C. Wainwright 5th Annual NASH Investor Conference, October 11, 2021
- Stifel Healthcare Conference 2021, November 16-17, 2021
- Jefferies 2021 London Healthcare Conference, *November 16-18, 2021*

Upcoming scientific conference presentations

AASLD The Liver Meeting, November 12-15, 2021

Conference call

A conference call in English will be held tomorrow, Tuesday, September 21, 2021 at 2:00 pm (Paris time). To join the conference call, please use the code 8573858 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" – "Financial Results & Presentations" section at the same time and can be followed live at: <u>https://edge.media-server.com/mmc/p/2kk6k5k7</u>.

A replay of the conference call and the presentation will be available after the event at: <u>https://inventivapharma.com/investors/financial-results-presentations/</u>.

Next financial results publication

• Q3 2021 Revenues and cash position: Wednesday, November 10, 2021 (after U.S. market close)

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 preclinical 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. In 2020, Inventiva announced positive topline data from its Phase IIb clinical trial evaluating lanifibranor for the treatment of patients with NASH and obtained Breakthrough Therapy and Fast Track designation for lanifibranor in the treatment of NASH. Lanifibranor is currently being evaluated in a pivotal Phase III clinical trial.

Inventiva is also developing odiparcil, a second clinical stage asset, for the treatment of patients with subtypes of MPS, a group of rare genetic disorders. Inventiva announced positive topline data from its Phase IIa clinical trial



evaluating odiparcil for the treatment of adult MPS VI patients at the end of 2019 and received FDA Fast Track designation in MPS VI for odiparcil in October 2020.

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 (ticker: IVA - ISIN: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). 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 is a clinical-stage company with no approved products and no historical product revenues, 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

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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 adverse drug reactions 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, and 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 for the year ended December 31, 2020 filed with the Autorité des Marchés Financiers on March 15, 2021, the Annual Report on Form 20-F for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 15, 2021 as well as the half-year financial report for the six months ended June 30, 2021 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 forwardlooking statements referred to above. Consequently, Inventiva accepts no liability for any consequences arising from the use of any of the above statements.