

Inventiva reports its 2022 full-year results

- Cash and cash equivalents at €86.7 million and short term deposits at €1 million as of December 31, 2022 compared to €86.6 million and €8.8 million, respectively as of December 31, 2021
- Inventiva entered into a license and collaboration agreement with Sino Biopharm a leading Chinese pharmaceutical group, through CTTQ, to develop, manufacture and commercialize lanifibranor in Greater China
- Under this agreement with Sino Biopharm, Inventiva received a €12.8 million¹ upfront payment
- Inventiva received the first tranche of €25 million under its credit facility with the European Investment Bank (EIB)
- Screening of the first patients in LEGEND, a Phase IIa combination trial with lanifibranor and empagliflozin in patients with NASH and T2D
- Secured a new patent expanding the IP protection of lanifibranor in the U.S.
- In January 2023, Inventiva announced changes to NATiV3, a Phase III trial with lanifibranor in patients with NASH, that are expected to be beneficial to the clinical program

Daix (France), Long Island City (New York, United States), March 29, 2023 – Inventiva (Euronext Paris and Nasdaq: IVA) (the "Company"), a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of patients with non-alcoholic steatohepatitis ("NASH") and other diseases with significant unmet medical needs, today reported its full-year results for 2022.

Frédéric Cren, Chairman, CEO and cofounder of Inventiva, stated: "2022 has been a successful year for Inventiva in many ways. On the clinical front, we achieved substantial progress in the development of lanifibranor starting with clearance by the FDA of our "Investigational New Drug" application for our Phase II clinical trial combining lanifibranor and empagliflozin in patients with NASH and type 2 diabetes. In China, we established a partnership with Sino Biopharm to develop and commercialize lanifibranor in Mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan. As part of this collaboration, we received an upfront payment of ≤ 12.8 million, including ≤ 1.3 million of withholding taxes for net proceeds of ≤ 11.5 million, in November 2022, and are eligible to receive up to ≤ 290 million in potential milestone payments and royalties on potential net sales of lanifibranor in China, subject to marketing approval in China.

¹ This amount includes €1.3 million of withholding taxes, amounting to net proceeds of €11.5 million.



Over the year, we also strengthened our financial position through a loan agreement of up to ≤ 50 million with the European Investment Bank, subject to completion of certain conditions², of which we drew the first ≤ 25 million tranche in December 2022. In July 2022, we raised nearly ≤ 15 million, including more than ≤ 9 million gross proceeds through our "At-The-Market" program and loan agreements with a syndicate of French banks for a total amount of ≤ 5.3 million.

Looking forward, we are continuing our effort to implement the new design of NATiV3 which has been submitted in almost all countries involved in the study and has already been cleared in key countries including the United States. Enrollment in our investigator initiated study, led by Dr. Cusi, was completed in September and we expect the publication of this Phase II clinical study evaluating lanifibranor for the treatment of NAFLD in patients with T2D by the middle of the second quarter of 2023. Finally, both the results from our LEGEND Phase II study combining lanifibranor and empagliflozin in patients with NASH and T2D and the first visit of the last patient in our NATiV3 study, are expected in the second half of 2023."

Key financial results for the full year of 2022

As of December 31, 2022, the Company had &86.7 million of cash and cash equivalents and &1.0 million of short-term deposits³, compared to &86.6 million and &8.8 million, respectively, as of December 31, 2021.

Cash and cash equivalents at year end included the €12.8 million upfront payment (including €1.3 million of withholding taxes, amounting to net proceeds of €11.5 million) received on November 4, 2022 from Chia Tai Tianqing Pharmaceutical Group, Co., LTD ("CTTQ"), a subsidiary of Sino Biopharm, in connection with the previously announced license and collaboration agreement dated September 21, 2022.

Cash and cash equivalents at year end also included the €25.0 million tranche of the previously announced unsecured loan agreement executed with the EIB on May 16, 2022, which the Company received on December 8, 2022, the €9.4 million gross proceeds (€8.8 million net proceeds) raised through the Company's At-The-Market ("ATM") Program on June 15, 2022, and the proceeds of three previously announced loan agreements with a syndicate of French banks for a total amount of €5.3 million. One of the loans was contracted as part of a French state-guaranteed loan facility with Bpifrance, and the two other loans were obtained as part of a French state stimulus economic plan granted by Crédit Agricole Champagne-Bourgogne and Société Générale.

- Net cash used in operating activities amounted to (€44.9) million for the full year 2022, compared to (€47.6) million in 2021. Net cash used in operating expenses in 2022 was driven primarily by R&D expenses, partially offset by the upfront payment received from CTTQ.
- Net cash generated from (used in) investing activities amounted to €8.9 million for the full year 2022 compared to (€1.8) million net cash used for the same period in 2021. The variance is mainly due to the change in short term deposits between both periods.
- Net cash generated from financing activities amounted to €37.3 million for the full year 2022 compared to €25.4 million for 2021. Net cash generated from financing activities in 2022 has been driven by the proceeds of the first tranche of €25 million from the EIB loan, gross proceeds of €9.4 million from the sale

² The disbursement of the second tranche of €25 million is subject to, among other conditions, (i) the Company issuing warrants to EIB in accordance with the terms and conditions of the warrants agreements entered into July 1, 2022, (ii) the full drawdown of the first tranche, (iii) the receipt by the Company from the date of the EIB credit facility of an aggregate amount of at least €70.0 million (inclusive of the €18.0 million that was a condition for the disbursement of the first tranche), paid either in exchange for Company shares, or through upfront or milestone payments, (iv) an out-licensing,

partnership or royalty transaction with an upfront payment of at least €10.0 million; and (v) operational criteria based on patient enrolment and number of sites activated in the Company's NATiV3 Phase III clinical trial of lanifibranor in patients with NASH

³ Short-term deposits are included in the category "other current assets" in the IFRS consolidated statement of financial position as of December 31, 2022, but are considered by the Company as liquid and easily available.



of securities through the Company's ATM program and proceeds of €5.3 million from three French state partially guaranteed loans, as described above.

For the full year 2022, the Company recorded **a negative exchange rate effect** on cash and cash equivalents of $(\\\in 1.0)$ million, due to the strengthening of USD versus Euro, compared to a positive effect of $\\\in 4.8$ million for 2021.

Considering its current R&D and clinical development programs, the Company estimates that its existing cash, cash equivalents and short-term deposits should allow the Company to **fund its operations until the end of the fourth quarter of 2023**⁴. This cash runway estimate does not include the conditional second tranche of \notin 25.0 million of the EIB loan agreement².

The Company's **revenues** for the full year 2022 amounted to €12.2 million, as compared to €4.2 million for 2021. The revenues recorded in 2022 were driven mostly by the Company's license and collaboration agreement with CTTQ, executed on September 21, 2022, and revenues recorded in 2021 primarily consisted of a €4.0 million milestone payment for a milestone that was recorded following the launch by AbbVie of the Phase IIb clinical trial with cedirogant. As previously disclosed, this trial of cedirogant has since been discontinued by AbbVie and the partnership with AbbVie has been terminated.

Other income amounted to €6.6 million for the full year 2022, as compared to €4.3 million for 2021, increased 54% mainly driven by the French R&D tax credit based on the increasing eligible expenses and to a lesser extent by the U.S. R&D tax credit.

R&D expenses for the fiscal year ended December 31, 2022 amounted to (€60.5) million compared to (€48.5) million for the same period in 2021. This 24.8% increase was driven mostly by the costs associated with the NATiV3 Phase III clinical trial of lanifibranor in NASH, including a full twelve months of operation for the U.S. affiliate and, to a lesser extent, with the LEGEND Phase IIa combination trial with lanifibranor and empagliflozin in patients with NASH and type 2 diabetes ("T2D").

Marketing and business development expenses stood at (≤ 2.6) million for the fiscal year ended December 31, 2022 compared to (≤ 0.4) million for the same period in 2021 mainly linked to the partnership with CTTQ and to a lesser extent to the increasing market access activities.

General and administrative expenses (G&A) amounted to (≤ 12.9) million for the fiscal year ended December 31, 2022, increased +15.7% compared to (≤ 11.2) million for the same period in 2021, mainly due to personnel costs linked to the non-cash share-based payment expenses, a full twelve months of operating for the U.S. affiliate and to a lesser extent an increase in compliance and consulting fees related to the dual listing of Inventiva securities and strategic projects

Other operating income (expenses) was €0 million for the fiscal year ended December 31, 2022 compared to (€0.6) million for the same period in 2021.

Net financial income stood at €2.8 million for the fiscal year ended December 31, 2022 compared to €2.8 million for the same period in 2021. The net financial income for both years mainly includes (i) the losses from the change in fair value linked to derivatives (warrants linked to the finance contract with EIB in 2022 and forward currency contracts in 2021) and (ii) the foreign exchange gain generated by cash and cash equivalents denominated in U.S. dollars and the favorable exchange rate of euro against the U.S. dollar over the period.

⁴ This estimate is based on the Company's current business plan and excludes any potential milestones payable to or by the Company and any additional expenditures related to the potential continued development of the odiparcil program or resulting from the potential in-licensing or acquisition of additional product candidates or technologies, or any associated development the Company may pursue. The Company may have based this estimate on assumptions that are incorrect and the Company may end up using its resources sooner than anticipated.



Income tax amounted to €0 million for the 2022 fiscal year, compared to (€0.4) million for 2021.

The Company's **net loss** for the full year 2022 was (€54.3), compared to (€49.6) million for 2021.

The following table presents Inventiva's income statement, prepared in accordance with IFRS, for the 2022 financial year, with comparatives for the 2021 financial year.

(in thousands of euros)	Year ended December 31, 2022	Year ended December 31, 2021
Revenues	12,179	4,194
Other income	6,635	4,307
Research and development expenses	(60,469)	(48,452)
Marketing – business development expenses	(2,583)	(364)
General and administrative expenses	(12,912)	(11,155)
Other operating income (expenses)	40	(644)
Net operating loss	(57,110)	(52,114)
Net financial income	2,816	2,842
Income tax	20	(364)
Net loss for the period	(54,274)	(49,635)
Basic/diluted loss per share (euros/share)	(1.31)	(1.27)
Weighted average number of outstanding shares used for computing basic/diluted loss per share	41,449,732	39,168,152

Main areas of progress in the R&D portfolio

Lanifibranor in non-alcoholic steatohepatitis (NASH)

- Changes to the Phase III NATiV3 trial evaluating lanifibranor in NASH designed to align with the FDA's public communication suggesting that an alternative approach to seek full approval in patients with NASH could be considered upon submission of positive results of a Phase III trial using a histology surrogate endpoint in patients with NASH and a Phase III clinical outcome trial in patients with NASH and compensated cirrhosis— that the Company believes will be beneficial to the overall lanifibranor clinical program by reducing the number of biopsies during the trial, reducing the trial duration from 7 years to 72 weeks or potentially expanding the addressable patient population to include patients with NASH and compensated cirrhosis— January 4, 2023
- Approval of a new patent, protecting the use of lanifibranor for the treatment of cirrhotic patients at risk of
 progressing from compensated stage to decompensated stage, in the United States until November 2039 by
 the United States Patent and Trademark Office ("USPTO") November 28, 2022
- Completion of the recruitment for the investigator-initiated Phase II trial of lanifibranor in patients with Non-Alcoholic Fatty Liver Disease ("NAFLD") and with T2D, conducted by Dr. Cusi from the University of Florida – September 22, 2022
- Screening in the United States of the first patient in Inventiva's proof-of-concept LEGEND Phase IIa combination trial with lanifibranor and empagliflozin for the treatment of patients with NASH and T2D. All 36



sites in France, the United Kingdom, Belgium, the Netherlands, and the United States anticipated to participate in the trial have been qualified. Topline results are expected to be published in the second half of 2023 – July 7, 2022

 Completion by the FDA of its safety review of Inventiva's Investigational New Drug application (IND) for the LEGEND Phase II combination trial with lanifibranor and empagliflozin in patients with NASH and T2D – March 8, 2022

Odiparcil in mucopolysaccharidosis type VI (MPS VI)

FDA feedback that odiparcil can be dosed in pediatric MPS VI patients and that the single Phase II/III trial design presented by the Company could potentially support a future odiparcil marketing application. Inventiva continues to review potential options to further development of odiparcil for the treatment of MPS VI, which may include pursuing a partnership – August, 2022

Collaboration with AbbVie on cedirogant in autoimmune diseases

- Decision by AbbVie to stop the development of cedirogant following the analysis of a nonclinical toxicology study – October 31, 2022
- Receipt of a €4 million milestone payment from AbbVie following the inclusion of the first patient in the nowterminated Phase IIb clinical trial with cedirogant in patients with moderate to severe psoriasis – January 31, 2022

Other significant milestones

- Receipt of the €25 million payment under the first tranche of the unsecured loan agreement with the EIB on May 16, 2022, with a maturity date of December 2026 – December 12, 2022
- Appointment of Dr. Lucy Lu as Director on Inventiva's Board of Directors in lieu of Sofinnova Partners, effective on November 9th, 2022, after Dr. Lu had been Sofinnova Partners' representative on Inventiva's Board of Directors since January 4th, 2020. – *November 21, 2022*
- Entry into a license and collaboration agreement with Sino Biopharm through their CTTQ subsidiary, Chia Tai Tianqing Pharmaceutical Group, to develop and commercialize lanifibranor for the treatment of NASH and other metabolic diseases in Greater China September 21, 2022
- Entry of Inventiva in the Euronext Tech Leaders segment, a new Euronext segment which includes more than 100 high-growth and leading tech companies across Europe – June 7, 2022
- Entry into a credit facility agreement for up to €50 million, subject to conditions precedent², with the European Investment Bank with the plan to use any potential borrowings under the facility towards Inventiva's preclinical and clinical pipeline, including to help fund a portion of its Phase III clinical trial of lanifibranor in patients with NASH, subject to satisfaction of conditions precedent May 16, 2022

Anticipated key milestones expected

After having finalized patient recruitment in September 2022, publication of the topline results of the investigator-initiated study with lanifibranor in patients with NAFLD and T2D – anticipated by the middle of the second quarter of 2023



- Publication of the topline results of the LEGEND Phase IIa combination trial of lanifibranor in combination with empagliflozin in patients with NASH and T2D – anticipated in the second half of 2023
- Last Patient First Visit of the NATiV3 Phase III clinical trial evaluating lanifibranor in NASH anticipated in the second half of 2023

Upcoming investor conference participation

- Evercore ISI NASH Renaissance March 30 Virtual
- Kempen Life Sciences Conference April 25-26 Amsterdam
- Jefferies Global Healthcare Conference June 7-9 New York City

Upcoming scientific conference participation

Digestive Disease Week - May 6-9 - Chicago, IL

Conference call

A conference call in English will be held tomorrow, Thursday, March 30, 2023 at 8:00 am (New York time)/2:00 pm (Paris time) to discuss 2022 financial results and business updates.

The conference call and the slides of the presentation will be webcast live at <u>https://edge.media-server.com/mmc/p/jdzcm24d</u> and also available on Inventiva's onwards in the "Investors" – "Financial results" section.

In order to receive the conference access information necessary to join the conference call, it is required to register in advance using the following link: https://register.vevent.com/register/BI64f8e310179a49e2a675a18f401f7241.

In the 10 minutes prior to the call start time, participants will need to use the conference access information provided in the e-mail received at the point of registering (dial-in number and access code).

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

Revenues and cash, cash equivalents and short-term deposits for the first quarter of 2023: Monday, May 16, 2023 (after U.S. market close)

About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the research and development of oral small molecule therapies for the treatment of patients with NASH, mucopolysaccharidoses ("MPS") and other diseases with significant unmet medical need. The Company benefits from a strong expertise and experience in the domain of compounds targeting nuclear receptors, transcription factors and epigenetic modulation. Inventiva is currently advancing one clinical candidate, has a pipeline of two preclinical programs and continues to explore other development opportunities to add to its pipeline.



Inventiva's lead product candidate, lanifibranor, is currently in a pivotal Phase III clinical trial, NATiV3, for the treatment of adult patients with NASH, a common and progressive chronic liver disease for which there are currently no approved therapies.

Inventiva's pipeline also includes odiparcil, a drug candidate for the treatment of adult MPS VI patients. As part of Inventiva's decision to focus clinical efforts on the development of lanifibranor, it suspended its clinical efforts relating to odiparcil and is reviewing available options with respect to its potential further development. Inventiva is also in the process of selecting an oncology development candidate for its Hippo signaling pathway program.

The Company has a scientific team of approximately 90 people with deep expertise in the fields of biology, medicinal and computational chemistry, pharmacokinetics and pharmacology, and clinical development. It 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 B of the regulated market of Euronext Paris (ticker: IVA, ISIN: FR0013233012) and on the Nasdaq Global Market in the United States (ticker: IVA). <u>www.inventivapharma.com</u>

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Important Notice

This press release contains "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release are forward-looking statements. These statements include, but are not limited to, statements regarding forecasts and estimates with respect to Inventiva's pre-clinical programs and clinical trials, including design, duration, timing, recruitment costs, screening and enrolment for those trials, including the ongoing NATiV3 Phase III clinical trial with lanifibranor in NASH, the LEGEND Phase IIa combination trial with lanifibranor and empagliflozin in patients with NASH and type 2 diabetes, and the Phase II clinical study evaluating lanifibranor for the treatment of NAFLD in patients with T2D, the potential benefits of the modification of the Phase III NATIV3 trial evaluating lanifibranor in NASH, the potential development of and regulatory pathway for odiparcil including a potential partnership, clinical trial data releases and publications, the information, insights and impacts that may be gathered from clinical trials, the addressable patient population, the potential therapeutic benefits of Inventiva's product candidates, including lanifibranor, potential regulatory submissions and approvals, Inventiva's pipeline and preclinical and clinical development plans, future activities, expectations, plans, growth and prospects of Inventiva, the potential receipt of the second tranche under the EIB loan and any potential transaction or receipt of additional funds, and the sufficiency of Inventiva's cash resources and cash runway and the ability of the Company to continue as a going concern. 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", "would", "could", "might", "should", "plans", "designed", "hopefully", "target", "aim", and "continue" and similar expressions. Such statements are not historical facts but rather are statements of future

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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. Future 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, that product candidates will receive the necessary regulatory approvals, or that any of the anticipated milestones by Inventiva or its partners will be reached on their expected timeline, or at all. 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, in the absence of which, Inventiva may be required to significantly curtail, delay or discontinue one or more of its research or development programs or be unable to expand its operations or otherwise capitalize on its business opportunities and may be unable to continue as a going concern, 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's expectations with respect to the changes to the clinical development plan for lanifibranor for the treatment of NASH may not be realized and may not support the approval of a New Drug Application, 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, the ability of Inventiva to recruit and retain patients in clinical studies, enrolment 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 and geopolitical events, such as the conflict between Russia and Ukraine, related sanctions and related impacts and potential impacts on the initiation, enrolment and completion of Inventiva's clinical trials on anticipated timelines, and macroeconomic conditions, including global inflation, uncertain financial markets and disruptions in banking systems. 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, 2021, filed with the Autorité des Marchés Financiers on March 11, 2022, the Annual Report on Form 20-F for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 11, 2022, and the financial report for the first half of 2022 filed with the Securities and Exchange Commission on September 22, 2022, for additional information in relation to such factors, risks and uncertainties, in addition to the Universal Registration Document for the year ended December 31, 2022 expected to be filed with the Autorité des Marchés Financiers on March 30, 2023 and the Annual Report on Form 20-F for the year ended December 31, 2022 expected to be filed with the Securities and Exchange Comment 51, 2022 expected to be filed with the Securities and Exchange Comber 31, 2022 expected to be filed with the Autorité des Marchés Financiers on March 30, 2023 and the Annual Report on Form 20-F for the year ended December 31, 2022 expected to be filed with the Securities and Exchange Commission on March 30, 2023.

All information in this press release is as of the date of the release. 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.