2019 Full-Year Results: Significant progress in NASH, MPS VI and psoriasis, and extended cash runway

- Lanifibranor: Confirmation of the publication of the results of the Phase IIb NATIVE clinical study evaluating lanifibranor in NASH in H1 2020 following the completion of patient recruitment
- Odiparcil: Publication of the positive results of the Phase IIa iMProveS clinical study evaluating odiparcil in MPS VI
- ABBV-157: Enrollment of the first psoriasis patient in the clinical study led by AbbVie and receipt of a €3.5 m milestone payment earlier than expected
- Extension of cash runway until the end of Q2 2021

Daix (France), March 10, 2020 – Inventiva (Euronext: IVA), a clinical-stage biopharmaceutical company developing oral small molecule therapies for the treatment of diseases in the areas of fibrosis, lysosomal storage disorders and oncology, today reported its full-year results for 2019.

Frédéric Cren, Chairman, CEO and cofounder of Inventiva, stated*: "In 2019, we have made significant progress in our most advanced programs for the treatment of NASH and MPS VI, and in the area of autoimmune diseases with our partner AbbVie. In NASH, we have completed patient enrollment in the Phase IIb clinical study and obtained 'Fast Track' designation for lanifibranor from the FDA, giving us the opportunity to accelerate its development. Regarding MPS VI, the receipt of 'rare pediatric disease' status for odiparcil in this indication and the publication of positive results from the Phase IIa clinical study enable us to continue the clinical development of odiparcil with confidence. Our partnership with AbbVie has successfully progressed with the early enrollment of the first psoriasis patient in the clinical study with ABBV-157, triggering a milestone payment of €3.5 million. Thanks in particular to the support of our principal investors, we have strengthened our financial resources and extended our cash runway until the end of the second quarter of 2021. Building on the various clinical advances and our strong cash position, we look forward to 2020 with confidence and focus on the next key milestone: the publication of the results of the Phase IIb clinical study with lanifibranor in NASH."*

Key financial results

Inventiva's key financial figures for its 2019 full-year results are as follows:

As at December 31, 2019, the Company's cash and cash equivalents amounted to €35.8 million, compared to €35.3 million at September 30, 2019 and €56.7 million at December 31, 2018.

- In 2019, **net cash from operating activities** amounted to - €28.4 million, against - €34.2 million for the same period in 2018, mainly related to the increase in R&D expenses *(see income statement below)* which were up by 7%. This figure also includes a €3.5 million milestone payment received from AbbVie in December 2019 following the enrollment of the first psoriasis patient in the clinical study underway with ABBV-157, a drug candidate jointly discovered by AbbVie and Inventiva for the treatment of autoimmune

diseases. Other contributing factors were the receipt of a €3.6 million payment for the 2017 research tax credit in the fourth quarter, as well as a €1.7 million VAT credit refund covering 2018. In addition, the Company received €4.2 million for the 2018 research tax credit on January 24, 2020.

- **Net cash from investing activities** over the period amounted to - €0.9 million, compared to - €0.4 million in 2018.

- Finally, **net cash from financing activities** amounted to €8.5 million in 2019, compared to €32.3 million over the same period in 2018, which included the proceeds of the private placement from April 2018 amounting to €32.5 million. In 2019, the Company recorded gross proceeds totaling €8.9 million received from leading US and European biotechnology investors through two capital increases carried out in September and October. With the €15 million capital increase completed on February 11, 2020 *(see "Other significant milestones" below)*, the Company's cash runway has been extended until the end of the second quarter of 2021.

In 2019, Inventiva's **revenues** more than doubled, reaching €7.0 million, compared to €3.2 million in 2018.

- This significant increase is linked firstly to the €3.5 million milestone payment received from AbbVie in December 2019 following the enrollment of the first psoriasis patient in the clinical study underway with ABBV-157 (vs. €0.8 million in 2018), and secondly to the revenue of €2.6 million recorded as part of the collaboration with Boehringer Ingelheim (vs. €1.0 million in 2018).

- As the Company had fulfilled all its commitments as part of its partnership with Boehringer Ingelheim, which ended on September 30, 2019, all amounts accounted as "contract liabilities" at December 31, 2018, in accordance with IFRS 15 "Revenue from Contracts with Customer", were written back over the period, generating a positive impact of €2.1 million on IFRS revenues for the year.

Other recurring operating revenues amounted to €4.3 million in 2019, versus €4.9 million in 2018, down 11.5%, due to the inclusion of amended declarations relating to the research tax credit in 2018, which constitute the majority of these other recurring operating revenues.

R&D expenses amounted to €33.8 million in 2019, versus €31.6 million in 2018, up 7%. This increase is due to the evolution of the R&D expenses mainly dedicated to the development of lanifibranor in the treatment of non-alcoholic steatohepatitis (NASH) and of odiparcil in the treatment of mucopolysaccharidosis type VI (MPS VI).

General and administrative expenses remained stable in 2019 at €6.1 million, compared to €6.0 million in 2018.

Other non-recurring operating income and expenses amounted to - €1.5 million in 2019, compared to - €3.4 million in 2018. This evolution mainly reflects the €1.2 million charge related to the redundancy plan (*Plan de Sauvegarde de l'Emploi*, PSE), which was implemented following termination of the systemic sclerosis (SSc) program in February 2019 due to the Phase IIa FASST (For A Systemic Sclerosis Treatment) clinical study missing its primary endpoint. Moreover, in 2018, Inventiva had recorded a provision for risk relating to the ongoing tax audit, as well as advisory expenses related to fundraising activities.

Accordingly, Inventiva's **net loss** came to - €30.2 million in 2019, compared with a loss of - €33.6 million in 2018.

The following table presents Inventiva's income statement, prepared in accordance with IFRS, for the 2019 financial year, with comparatives for the 2018 financial year:

(in thousands of euros, except share and per share amounts)	December 31, 2019	December 31, 2018
Revenues	**6,998**	**3,197**
Other income	4,293	4,853
Research and development expenses	(33,791)	(31,638)
Marketing – business development expenses	(249)	(225)
General and administrative expenses	(6,088)	(6,045)
Other operating income (expenses)	(1,475)	(3,395)
Operating profit (loss)	**(30,312)**	**(33,253)**
Financial income	175	142
Financial expenses	(81)	(253)
Financial income (loss)	**93**	**(111)**
Income tax	-	(253)
Net loss for the period	**(30,218)**	**(33,617)**
Basic / diluted loss per share (euros/share)	**(1.28)**	**(1.64)**
Weighted average number of outstanding shares used for computing basic/diluted loss per share	23,519,897	20,540,979

Main areas of progress in the R&D portfolio

Lanifibranor in non-alcoholic steatohepatitis (NASH)

- Receipt of the U.S. Food and Drug Administration (FDA) "Fast Track" designation for lanifibranor in NASH enabling the Company to facilitate the development and expedite the review and potential approval of the drug candidate – *September 26, 2019*
- Positive recommendation by the fourth Data Safety Monitoring Board (DSMB) of the Phase IIb NATIVE (NAsh Trial to Validate IVA337 Efficacy) clinical study to continue the study without modification of the protocol, confirming the good safety profile of lanifibranor– *September 10, 2019*
- Completion of patient recruitment for the Phase IIb NATIVE clinical study – *September 4, 2019*
- Approval of a new patent protecting the use of lanifibranor in 38 European countries for the treatment of several fibrotic diseases, including NASH, until June 2035 by the European Patent Office (EPO) – *August 28, 2019*
- Approval of a new patent protecting the use of lanifibranor in the United States for the treatment of fibrotic diseases until June 2035 by the United States Patent and Trademark Office (USPTO) – *August 20, 2019*
- Lifting of the target class clinical hold applying to peroxisome proliferator activated receptor (PPAR) agonists for lanifibranor by the FDA, confirming its good safety profile – *May 23, 2019*

Odiparcil in mucopolysaccharidosis type VI (MPS VI)

- Completion of patient recruitment and publication of positive results from the Phase IIa iMProveS (improve MPS treatment) clinical study ; decision to continue the clinical development of odiparcil in MPS VI – *June 11, 2019* and *December 18, 2019*
- Launch of a new biomarker study in adults and children with MPS VI – *September 2, 2019*
- Grant of Rare Pediatric Disease Designation (RPDD) to odiparcil for the treatment of MPS VI by the FDA, confirming the eligibility of the drug candidate to receive a Priority Review Voucher – *March 5, 2019*

Partnerships with AbbVie and Boehringer Ingelheim

- Receipt of a €3.5 million milestone payment earlier than excepted following the enrollment of the first psoriasis patient in the clinical study underway with ABBV-157, a RORγ inverse agonist jointly discovered by AbbVie and Inventiva within their multi-year drug discovery collaboration for the treatment of autoimmune diseases – *December 3, 2019*
- End of the collaboration with Boehringer Ingelheim in the field of idiopathic pulmonary fibrosis (IPF) for portfolio prioritization reasons – *September 30, 2019*

Other significant milestones

- Capital increase of €8.2 million subscribed by New Enterprise Associates (NEA), BVF Partners L.P. and Novo Holdings A/S – *September 19, 2019*
- Capital increase of €625,000 subscribed by Sofinnova Partners – *September 30, 2019*
- Capital increase of €15 million subscribed by BVF Partners L.P., NEA, Novo Holdings A/S and Sofinnova Partners – *February 11, 2020*

Next key milestones expected

- Publication of the results of the Phase IIb NATIVE clinical study evaluating lanifibranor in the treatment of NASH – *first half of 2020*
- Launch of the Phase I/II SAFE-KIDDS (SAFEty, pharmacoKInetics and pharmacoDynamics, Dose escalating Study) clinical study evaluating odiparcil in MPS VI children – *planned for the end of the year 2020*
- Completion of AbbVie's ongoing clinical study with ABBV-157 in psoriasis patients – *fourth quarter of 2020*

Next investor conferences

- One-Stop Shop: Heart, Liver, Renal Roth Healthcare Investor Conference, New York, April 2, 2020
- European SmallCap Event, Paris, April 14-15, 2020
- H.C. Wainwright Conference, London, April 19-21, 2020
- Jefferies Global Healthcare Conference, New York, June 2-4, 2020
- HealthTech Innovation Days, Paris, June 22-23, 2020

Next scientific conferences

- The International Liver Congress™ 2020 (European Association for the Study of the Liver, EASL), London, April 15-19, 2020 – *KOL and analysts meeting organized by Inventiva*

- MPS 2020 – 16th International Symposium on MPS and Related Diseases, Barcelona, July 31 to August 2, 2020 – *Presentation of the positive results of the Phase IIa iMProveS clinical study and symposium on residual needs in MPS VI, organized by Inventiva*

Conference call

A **conference call** in English will be held **today at 6:15 pm (Paris time).** To join the conference call, please use the code **9820348** after dialing one of the following numbers:

France: +33 (0) 1 70 73 27 27
Belgium: +32 (0) 1 039 1206
Denmark: +45 32 72 75 18
Germany: +49 (0) 69 2222 4910
Netherlands: +31 (0) 20 715 7366
Switzerland: +41 (0) 44 580 4873
United Kingdom: +44 (0) 203 009 5710
United States: +1 917-720-0178

The presentation accompanying this conference call will be available on Inventiva's website from 6:15 pm (Paris time) onwards in the "Investors" – "Financial results" section and can be followed live at: https://edge.media-server.com/mmc/p/tq3vwt6s

A replay of the conference call and the presentation will be available from 10:00 pm (Paris time) onwards today at: http://inventivapharma.com/investors/financial-results-presentations/

Next financial announcement

- **Revenues and cash position for the first quarter of 2020:** Thursday, May 14, 2020 (after market close)

About Inventiva

Inventiva is a clinical-stage biopharmaceutical company focused on the development of oral small molecule therapies for the treatment of diseases with significant unmet medical needs in the areas of fibrosis, lysosomal storage disorders and oncology.

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 – lanifibranor and odiparcil – in non-alcoholic steatohepatitis ("NASH") and mucopolysaccharidosis ("MPS"), respectively, 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. Inventiva is currently evaluating lanifibranor in a Phase IIb clinical trial for the treatment of this disease for which there are currently no approved therapies.

Inventiva is also developing odiparcil, a second clinical stage asset, for the treatment of patients with MPS, a group of rare genetic disorders. A Phase I/II clinical study in children with MPS VI is currently under preparation following the positive results of the Phase IIa clinical study in adult MPS VI patients published 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 partnership with AbbVie in the area of autoimmune diseases. AbbVie has started the clinical development phase of ABBV-157, a drug candidate for the treatment of moderate to severe psoriasis resulting from its collaboration with Inventiva. This collaboration entitles 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 this partnership.

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 a well as in clinical development. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, around 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). www.inventivapharma.com

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Important Notice

This press release contains forward-looking statements, forecasts and estimates with respect to the clinical development plans, business and regulatory strategy, and anticipated future performance of Inventiva and of the market in which it operates. 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 candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. Therefore, 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. Given these 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 Reference Document filed with the Autorité des Marchés Financiers on February 7, 2020 under n° D.20-0038 for additional information in relation to such factors, risks and uncertainties.

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.