2018 Full-Year Results : Important Progress in R&D Portfolio and Solid Cash Position

- Reinforcement of the clinical development of lanifibranor for the treatment of NASH with the extension of the Phase IIb NATIVE clinical study to the United States
- Results from the Phase IIb FASST clinical study for the treatment of diffuse systemic sclerosis and decision to discontinue lanifibranor's development in this indication
- Acceleration of the clinical development of odiparcil and positive results obtained from the biomarker study in patients with MPS VI
- Significant progress of the oncology program YAP-TEAD with the launch of preliminary toxicology studies to select a clinical drug candidate for entry into Phase I/II
- Launch of Phase I clinical trial of ABBV-157, the clinical drug candidate resulting from the partnership with AbbVie, for the treatment of moderate to severe psoriasis
- Solid cash position at €56.7 million, following the capital increase in April 2018

Daix (France), February 27, 2019 – 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 2018.

Frédéric Cren, Chairman and CEO of Inventiva, stated: "*This year was marked by the results of the Phase IIb FASST clinical trial evaluating lanifibranor in the treatment of diffuse cutaneous systemic sclerosis (dcSSc), which did not meet its primary endpoint. We will be presenting interim safety information from the subset of NASH patients who have already completed the Phase IIb NATIVE clinical study during tonight's webcast. These results, which confirm the benign safety profile of lanifibranor, suggest that the once-daily dosing schedule in the NATIVE study is preferable to the twice-daily dosing schedule of the FASST study. Following our decision to discontinue the program for the treatment of systemic sclerosis (SSc), we are focusing all our efforts on the development of lanifibranor for the treatment of NASH, odiparcil for the treatment of mucopolysaccharidoses (MPS) and YAP-TEAD in the field of oncology. The favorable safety profile of lanifibranor as demonstrated by the FASST clinical study and two DSMBs in the NATIVE clinical study is very encouraging particularly in view of the latter's results, which are expected for the first half of 2020. In 2018, we also launched another Phase II clinical trial in the Unites States with lanifibranor for the treatment of non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes, a population where lanifibranor may prove particularly competitive and differentiating. The results of this study are also expected in the first half of 2020 and, if positive, would be supportive to our discussions with regulatory authorities.*

Regarding odiparcil, we have successfully completed the first stage of the Phase IIa clinical study for the treatment of MPS VI with the confirmation of odiparcil's favorable safety profile by the first DSMB of the study. The results of this study are expected in the second half of 2019.

We have also made progress in our YAP-TEAD oncology program with very promising results demonstrating the activity of our lead molecules in a xenograft mice model and a patient derived xenograft ('PDX') mice model and the launch of preliminary toxicology studies to select a clinical drug candidate for the Phase I/II clinical study.

Finally, we are very satisfied with the progress achieved in our partnership with AbbVie, which has decided to enter into Phase I with ABBV-157, the clinical drug candidate resulting from this partnership, for the treatment of moderate to severe psoriasis.

Inventiva has a highly creative research and development platform and the necessary financial resources to advance its promising and diversified development projects. We look forward to the clinical results of lanifibranor, odiparcil and ABBV-157, as well as the identification of a clinical candidate for our YAP-TEAD program."

Key financial results

Inventiva's key financial figures for its 2018 full-year results are as follows:

As of December 31, 2018, the Company's cash and cash equivalents amounted to €56.7 million, versus €59.1 million at December 31, 2017.

- **Net cash** used for the **Company's operating activities** in 2018 amounted to €34.2 million, versus €17.0 million in 2017. This increase is primarily explained by increased expenses in 2018 linked to clinical development activities and, to a lesser extent, by the non-recurring €2.5 million milestone payment from Boehringer Ingelheim which had been received in 2017 as well as the timing of the annual reimbursements of the Company's research tax credit (€3.7 million of the 2016 research tax credit received in 2017 while the €4.3 million 2017 research tax credit not yet received in 2018).

- **Net cash from investing activities** over the period amounted to - €0.4 million, compared to €6.1 million over the same period in 2017, essentially due to the maturity in April 2017 of the quarterly payments received from Abbott, in connection with the asset purchase agreement entered into at the Company's inception.

- Finally, **net cash from financing activities** in 2018 amounted to €32.3 million in 2018, compared to €44.9 million in 2017, which included the €35.5 million of proceeds from the capital increase by means of a private placement which was carried out in April 2018 whereas, over the same period in 2017, Inventiva had raised €48.5 million in its Initial Public Offering on the regulated market of Euronext Paris in 2017.

Inventiva's full-year revenues for 2018 amounted to €3.2 million, in line with expectations and to a decrease of 33% versus the €4.8 million recognized in 2017 *(after application of the new revenue recognition standard, IFRS 15).*

- This decrease is mainly attributable to ABBV-157's entry into Phase I, a clinical program resulting from the collaboration between the Company and AbbVie for the treatment of moderate to severe psoriasis. Upon entrance into Phase I, the Company's research activities, and resulting compensation for research-based services related to this program, concluded. The development of ABBV-157 is funded by AbbVie. Inventiva remains eligible for milestone payments as well as royalties on potential sales resulting from this development.

As announced on February 13, 2019, Inventiva applies IFRS 15 – *Revenue from Contracts with Customers* since January 1, 2018. IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognized. It replaces IAS 18 *Revenue*, IAS 11 *Construction contracts* and related interpretations.

In its interim financial information as of and for the six months ended June 30, 2018, Inventiva applied IFRS 15 using the simplified transition method (with no practical expedient), resulting in a first-time application of the standard as of its effective date (i.e., from January 1, 2018). For its 2018 annual financial statements, the Company has modified its transition method and adopted IFRS 15 using the full retrospective transition method, enabling the Company to disclose restated comparatives for the 2017 financial year, in order to improve comparability and facilitate the presentation of Inventiva's activities year-on-year. In addition, as part of this change in the transition method, certain assumptions regarding the percentage of completion were refined.

As a result of these changes, revenues reported in all of the quarterly press releases for 2018 are impacted as follows:

In millions of euros	**2018** IFRS 15 – as adjusted[1]	**2018** IFRS 15 – as reported[1]	*Diff.*	**2017** Restated for IFRS 15[1]	**2017** IAS 18 – as reported	*Diff.*
Q1 – March 31 (3 months)	0.5	0.5	0.0	1.6	1.5	0.1
Q2 – June 30 (6 months)	1.4	1.3	0.1	2.9	2.7	0.2
Q3 – September 30 (9 months)	2.2	2.3	-0.1	4.2	6	-1.8
Q4 – December 31 (12 months)	3.2	n.a.	n.a.	4.8	6.5	-1.7

For the third and fourth quarters of 2017, the impact is primarily linked to the restatement, in accordance with IFRS 15, of the €2.5 million milestone payment from Boehringer Ingelheim received in 2017. In line with IAS 18, this payment was immediately recognized as revenues when it was received and, in line with IFRS 15, is now recognized according to the project's stage of completion, namely in an amount of €0.5 million in 2017, and €0.2[1] million in 2018.

These adjustments related to the first adoption of IFRS 15 do not impact the total revenue generated by the Company's contracts and the related cash flows, only the pattern of recognition of that revenue is changed, and the net result accordingly.

Other recurring operating revenues amounted to €4.9 million in 2018, versus €5.2 million in 2017, down by 6%. This increase was mainly composed of research tax credit and of non-dilutive subsidies. The decrease in the other operating revenues is mainly due to the decrease of these subsidies over the period.

R&D expenses amounted to €31.6 million in 2018, versus €26.7 million in 2017, up 18.3%. This trend marks the pursuit of significant efforts dedicated to projects in a clinical development phase including lanifibranor (NASH and SSc) and odiparcil (MPS), notably attributed to fees attributed to the outsourcing of clinical studies and the reinforcement of the internal development team. R&D expenses accounted for 83.5% of total recurring operating expenses in 2018. Clinical development made up around two-thirds of these R&D costs.

General and administrative expenses amounted to €6.0 million in 2018, compared to €5.1 million in 2017. The 19.4% increase was primarily attributable to the additional costs associated with its new status as a listed company on Euronext Paris for the full year 2018, following its IPO in mid-February 2017.

Other operating income and expenses amounted to - €3.4 million in 2018 compared to - €0.4 million in 2017. These non-recurring income and expenses for 2018 are related to the recognition of a provision for risk relating to the ongoing tax audit as well as the study and transaction costs relating to the fundraising activity .

Tax income (expense) stood at - €0.3 million in 2018, compared to €3.3 million in 2017. This evolution is linked almost entirely to the reversal of the deferred tax liability in 2017 arising from the treatment under IFRS of the exceptional grants from Abbott, the last of which was made during the first half of 2017.

[1] Unaudited figures except for December 31, 2018.

Accordingly, Inventiva's **net loss** came to - €33.6 million in 2018, compared with a loss of - €19.1 million in 2017, after application of the new revenue recognition standard IFRS 15

The following table presents Inventiva's income statement, prepared in accordance with IFRS, for the 2018 financial year, with comparatives for the 2017 financial year:

(in thousands of euros, except share and per share amounts)	December 31, 2018	December 31, 2017 *restated*[(1)]
Revenue	**3,197**	**4,797**
Other income	4,853	5,161
Research and development expenses	(31,638)	(26,733)
Marketing – business development expenses	(225)	(353)
General and administrative expenses	(6,045)	(5,062)
Other operating income (expenses)	(3,395)	(449)
Operating profit (loss)	**(33,253)**	**(22,639)**
Financial income	142	317
Financial expenses	(253)	(39)
Financial income (loss)	**(111)**	**278**
Income tax	(253)	3,278
Net loss for the period	**(33,617)**	**(19,083)**

[(1)] Accounts restated in accordance with the first-time application of IFRS 15 – Revenue from Contracts with Customers using the full retrospective transition method (see comments included above and in the press release published February 13, 2019).

Principal advances in the R&D portfolio

Lanifibranor

- Results from two 2-year carcinogenicity studies confirming lanifibranor's favorable safety profile and presentation of the studies' results to the U.S. Food and Drug Administration ("FDA")
- Grant by the United States Patent and Trademark Office ("USPTO") of a new patent protecting the use of lanifibranor for the treatment of several fibrotic diseases and extending its protection in the United States until June 2035
- Approval by the FDA of the Investigational New Drug ("IND") application for lanifibranor allowing the initiation of its clinical development plan in the United States

Lanifibranor for the treatment of nonalcoholic steatohepatitis ("NASH")

- Launch of the Phase II clinical trial in the United States initiated by aninvestigator, Dr. Kenneth Cusi[2], for the treatment of non-alcoholic fatty liver disease ("NAFLD") in patients with type 2 diabetes
- Second positive conclusion from the Data and Safety Monitoring Board ("DSMB") for the Phase IIb NATIVE (*NASH Trial To Validate IVA337 Efficacy*) clinical study for the treatment of NASH
- Opening of new sites in the United States and Europe to accelerate patient recruitment in the Phase IIb NATIVE clinical study
- Screening of the first patient in the United States in the Phase IIb NATIVE clinical trial
- Creation of the panNASH™ initiative, a working group consisting of a committee of international independent experts, aiming to increase the visibility and to contribute to a better understanding of NASH, to share their expertise and to establish best practices for the treatment of the disease

Lanifibranor for the treatment of systemic sclerosis ("SSc")

- Second positive conclusion from the DSMB for the Phase IIb FASST (*For A Systemic Sclerosis Treatment*) clinical study for the treatment of SSc
- Results of the FASST clinical study:
  - The FASST clinical trial did not meet its primary endpoint of a mean absolute change from baseline to week 48, relative to placebo, in the modified Rodnan Skin Score ("mRSS"). While the study did not meet any of the secondary endpoints either, the overall assessment of disease activity by patients indicated a favourable trend for lanifibranor, with a mean absolute change in visual analogue scale[3] (p=0.08) relative to placebo, indicating a perceived benefit felt by patients. Within this fragile and poly- medicated population, lanifibranor was observed to be associated with a favourable safety profile: no adverse interactions with background immunosuppressive therapies were observed. The percentage of patients with at least one adverse event was similar across the three treatment groups.
  - Based on the FASST clinical trial results, Inventiva decided to discontinue lanifibranor's clinical development for the treatment of dcSSc in order to fully focus on the development of lanifibranor for the treatment of NASH, of odiparcil for the treatment of MPS, and of YAP-TEAD in the field of oncology.
  - The FASST clinical trial's head-line results and its confirmation of lanifibranor's favourable safety profile will be presented during today's webcast and conference call at 6:15pm (Paris time) – *see below for more information*.

Odiparcil for the treatment of MPS

- Positive recommendation from the first DSMB for the Phase IIa iMProveS (*improve MPS treatment*) clinical study for the treatment of MPS VI
- Opening of two additional sites to secure patient recruitment for the Phase IIa iMProveS clinical trial
- Positive results from the biomarker study in MPS VI patients measuring intracellular glycosaminoglycans ("GAG") levels in leukocytes as well as from preclinical toxicological studies in children

[2] Chief of the Division of Endocrinology, Diabetes & Metabolism in the Department of Medicine at the University of Florida, Gainesville
[3] The visual analog scale (VAS) corresponds to a global assessment of wellbeing by patients in the last month of treatment.

YAP-TEAD in the field of oncology

- Positive results demonstrating the activity of YAP-TEAD inhibitors identified and patented by Inventiva in a xenograft mice model and a patient derived xenograft ("PDX") mice model with an activity either as a monotherapy or in combination with reference treatments
- Initiation of preliminary toxicological studies to select the clinical drug candidate for the program ahead of its entry into Phase I/II

Partnerships with AbbVie and Boehringer-Ingelheim

- Significant progress achieved in the partnership with AbbVie with the entry into Phase I of ABBV-157, the clinical drug candidate resulting from the partnership, for the treatment of moderate to severe psoriasis
  - Following the entry of ABBV-157 into Phase I by AbbVie and the identification of a back-up candidate, Inventiva's work to discover new orally available reverse ROR agonists is now complete.
  - Inventiva remains eligible for clinical, regulatory and commercial milestone payments and royalties on ROR reverse agonists discovered during the collaboration.

Other significant milestones

- Capital increase of €35.5 million from European and American investors
- Appointment of Dr Lucy Lu as the permanent representative of Sofinnova Crossover I SLP on the Board of Directors
- Appointment of Dr. Marie-Paule Richard as Chief Medical Officer and Head of Development to take over the functions previously held by Dr. Jean-Louis Abitbol, who will retire at the end of April 2019

Next key milestones expected

- End of the recruitment for the Phase IIb NATIVE clinical study evaluating lanifibranor for the treatment of NASH
- End of the recruitment for the Phase II clinical study evaluating lanifibranor for the treatment of NAFLD in patients with type 2 diabetes
- End of the recruitment for the Phase IIa iMProveS clinical study evaluating odiparcil for the treatment of MPS VI
- Designation of MPS VI as "rare pediatric disease" as part of the odiparcil program by the FDA
- Launch of a biomarker study in patients with MPS VI
- Launch of the Phase I/II clinical study evaluating odiparcil for the treatment of children with MPS VI
- Results of the Phase IIa iMProveS clinical study
- Selection of the clinical candidate in the YAP-TEAD oncology program
- Results of the Phase I clinical studies of ABBV-157

Next investor conferences

- Cowen Annual Healthcare Conference, Boston, March 11-13, 2019
- KBC Healthcare Conference, New York, March 27, 2019
- ROTH Battle of the NASH Thrones Spring Investor Conference, New York, March 28, 2019
- H.C. Wainwright Global Life Sciences Conference, Paris, April 7-9, 2019
- SmallCap Event, Paris, April 16-17, 2019
- Annual SunTrust Robinson Humphrey (STRH) Life Sciences Summit, New York, May 7-8, 2019
- BioEquity Europe, Barcelona, May 20-21, 2019

- Jefferies Healthcare Conference, New York, June 4-7, 2019
- European MidCap Event, Paris, June 18-19, 2019
- BMO 4th annual healthcare conference, New York, June 25, 2019

Conference call

A **conference call in English** will be held **today at 6:15pm (Paris time)**. To join the conference call, please use the code 2271029 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
UK : +44 (0) 203 009 5710
USA : +1 917-720-0178

The presentation accompanying this conference call will be available on Inventiva's website from 6:15pm (Paris time) onwards in the "Investors" – "Financial results" section and can be followed live at the same time at: https://edge.media-server.com/m6/p/bd3zaabj

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

Next financial announcement

- **Revenues and cash position for the first quarter of 2019** : Wednesday May 15, 2019 (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. The Company is currently investigating odiparcil in a Phase IIa clinical trial for the treatment of adult patients with the MPS VI subtype.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signaling pathway program and is advancing pre-clinical programs for the treatment of autoimmune diseases and idiopathic pulmonary fibrosis ("IPF") in collaboration with AbbVie and Boehringer Ingelheim International respectively.

AbbVie is investigating ABBV-157, a clinical development candidate resulting from its collaboration with Inventiva, in a Phase I clinical trial for the treatment of moderate to severe psoriasis. Both collaborations entitle 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 partnerships.

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. It also owns an extensive library of approximately 240,000 pharmacologically relevant molecules, 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 "Document de référence" filed with the Autorité des Marchés Financiers on April 13, 2018 under n° R.18-013 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.