H1 2019 financial results and corporate business update

- Cash and cash equivalents of €37.1 million on June 30, 2019
- Successful €8.2 million capital increase enabling the Company to extend its cash runway to Q3 2020, beyond the ongoing lanifibranor and odiparcil clinical studies results
- H1 revenues at €1.3 million
- Completion of patient recruitment in the Phase IIb clinical study evaluating lanifibranor in NASH and confirmation of the results publication in H1 2020
- Completion of patient recruitment in the Phase IIa clinical study evaluating odiparcil in MPS VI and confirmation of the results publication by the end of the year
- Continuation of the clinical development of ABBV-157 in moderate to severe psoriasis and next milestone payment expected in H1 2020

Daix (France), September 25, 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 interim financial results for the six months ended June 30, 2019, and provided an update on its business activities.

Frédéric Cren, Chairman, Chief Executive Officer and cofounder of Inventiva, stated: *"We have made significant progress in our most advanced programs dedicated to non-alcoholic steatohepatitis (NASH) and mucopolysaccharidosis type VI (MPS), especially with the completion of patient recruitment in the Phase IIb and Phase IIa studies respectively. The FDA's decision to lift the clinical hold for lanifibranor, which generally applies to this type of drugs, also represents a key milestone enabling us to initiate long-term clinical studies ahead of its potential commercialization. In addition, we have reinforced the protection of lanifibranor in the areas of NASH and fibrotic diseases in two key markets, Europe and the United States, through new patents demonstrating our innovative R&D approach. The launch of a new clinical study with ABB-157 in patients with moderate to severe psoriasis by our partner AbbVie is also excellent news for this program in which Inventiva remains eligible to receive milestone payments as well as sales royalties. The success of our latest capital increase, which strengthens our investor base in the United States and Europe, and the various progress achieved across our product portfolio allows us to focus on executing our strategy with confidence and serenity."*

Key financial results

Key financial results for the first half of 2019

(in thousands of euros, except share and per share amounts)	June 30, 2019	June 30, 2018 *restated* [1]
Revenue	**1,333**	**1,403**
Other income	2,198	2,754
Research and development expenses	(19,646)	(15,926)
Marketing – business development expenses	(135)	(107)
General and administrative expenses	(3,132)	(3 056)
Other operating income (expenses)	(1,274)	(1,140)
Operating profit (loss)	**(20,656)**	**(16,074)**
Financial income	153	56
Financial expenses	(42)	(172)
Financial income (loss)	**111**	**(116)**
Income tax	-	9
Net loss for the period	**(20,545)**	**(16,181)**
Basic / diluted loss per share (euros/share)	**(0.93)**	**(0.86)**
Weighted average number of outstanding shares used for computing basic/diluted loss per share	22,160,448	18,860,276

[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 detailed explanation in the press release published on February 13, 2019).

Revenues for the first half of 2019 reached €1.3 million compared to €1.4 million in the first half of 2018.

R&D expenses amounted to €19.6 million in the first half of 2019, up 23% compared to the first half of 2018. This increase is mainly due to expenses related to clinical studies conducted as part of research and development projects for the treatment of NASH with lanifibranor and MPS VI with odiparcil as well as to the termination of the clinical study with lanifibranor in systemic sclerosis (SSc). **General and administrative expenses** amounted to €3.1 million, stable compared to the same period in 2018.

Operating income amounted to -€20.7 million (compared to -€16.1 million in the first half of 2018) while **net income** stood at -€20.5 million (compared to -€16.2 million in the first half of 2018).

Over the first six months of 2019, **cash consumption** reached €19.7 million. In the first half of 2018, the Company recorded a positive cash flow of €16.9 million, of which €32.3 million related to the successful capital increase on April 17, 2018. In the first half of 2019, cash consumption related to operating activities amounted to €18.7 million compared to €15.3 million in the first half of 2018. This increase in cash consumption related to operating activities is mainly due to higher research and development expenses over the period, reflected in the increase in operating expenses of €3.8 million (+20% compared to 2018).

As a result, **cash and cash equivalents** stood at €37.1 million on June 30, 2019 compared to €56.7 million on December 31, 2018. Considering the capital increase of September 20, 2019, the current level of cash should

enable the Company to finance its activities on the basis of existing programs until the end of the third quarter of 2020, beyond the results of the ongoing clinical studies with lanifibranor and odiparcil.

The financial statements of the first half of 2019 were approved by the Board of Directors on September 24, 2019. 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: www.inventivapharma.com.

Financial information after the closing of the accounts

Last week, Inventiva completed a capital increase of €8.2 million subscribed by New Enterprise Associates, a leading American investor in the biotechnology sector, and by BVF Partners L.P. and Novo Holdings A/S , two existing shareholders of the Company. The gross proceeds from the transaction will be used primarily for research and development activities, including the development of Inventiva's lead product candidates, lanifibranor and odiparcil. This capital increase also ensures continued planned activities of the Company until the end of 3rd quarter 2020, beyond the results of the Phase IIb NATIVE clinical study evaluating lanifibranor for the treatment of NASH.

Key milestones

Lanifibranor in non-alcoholic steatohepatitis (NASH)

- **Lifting of the target class clinical hold applying to PPAR agonists for lanifibranor by the U.S. Food and Drug Administration (FDA), confirming its differentiating and favorable safety profile**

  In May 2019, the FDA in the United States has lifted the clinical hold in place on the peroxisome proliferator-activated receptor (PPAR) target class for lanifibranor. This decision enables Inventiva to conduct clinical trials equal to or longer than six months evaluating lanifibranor for the treatment of NASH and confirms the benign safety profile of lanifibranor. It represents an important milestone for Inventiva as it removes a key obstacle that prevented the Company from initiating long-term Phase III clinical trials necessary to obtain marketing approval for lanifibranor for the treatment of NASH.

- **Approval of a new patent in the United States strengthening the protection of lanifibranor**

  On August 20, 2019, the United States Patent and Trademark Office (USPTO) granted a new patent that protects the use of lanifibranor for the treatment of fibrotic diseases until June 2035. This new patent further strenghens Inventiva's patent portfolio for lanifibranor in the United States, which already comprised a New Chemical Entity (NCE) patent and a patent protecting the use of lanifibranor in several diseases including NASH.

- **Approval of a new European patent strengthening the protection of lanifibranor**

  On August 28, 2019, the European Patent Office (EPO) granted a new patent protecting the use of lanifibranor in 38 European countries for the treatment of several fibrotic diseases, including NASH, until June 2035. This new patent strengthens and extends the term of protection of lanifibranor in Europe, which was already established with the NCE patent expiring in August 2031.

- **Completion of patient recruitment for the Phase IIb NATIVE clinical study evaluating lanifibranor in NASH**

  On September 4, 2019, Inventiva announced the successful completion of patient recruitment for its Phase IIb NATIVE (NAsh Trial To Evaluate IVA337 Efficacy) clinical trial evaluating lanifibranor for the treatment of NASH. A total of 247 patients have been randomized in the trial, exceeding the initial target of 225 patients following an acceleration of inclusions over the last months. Patients were mainly recruited in sites located in

Australia, Canada, Europe and the United States. By early September, 146 patients had already successfully completed the six-month study, confirming that the treatment is well tolerated. Having reached this key recruitment milestone, the publication of the study's headline results is expected for the first half of 2020.

- **Recommendation by the second, third and fourth Data Safety Monitoring Boards (DSMB) to continue the Phase IIb NATIVE clinical study without changing the protocol**

  The second, third and fourth DSMBs of the Phase IIb NATIVE clinical study met in October 2018, March and September 2019 respectively. No safety issues were reported at the various meetings and, after the analysis of all safety data, the three DSMBs recommended, as did the first, to continue the study without changing the protocol, thus confirming the good safety profile of lanifibranor.

- **Phase II clinical study evaluating lanifibranor in the treatment of non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes**

  The study conducted at the University of Florida at Gainesville with lanifibranor in the treatment of non-alcoholic fatty liver disease (NAFLD) in patients with type 2 diabetes continues. Following the delay in patient recruitment, Professor Cusi, the principal investigator of the study, now believes that he will be able to publish the complete results of the study in the second half of 2020 and aims to provide interim data in the first half of 2020. This delay in the University of Florida study does not affect the Company's clinical development plan for lanifibranor in NASH.

Odiparcil in mucopolysaccharidoses (MPS)

- **Grant by the FDA of Rare Pediatric Disease Designation to odiparcil for the treatment of MPS VI**

  In early March 2019, the FDA granted Rare Pediatric Disease Designation (RPDD) to odiparcil for the treatment of MPS VI. This status confirms the eligibility of odiparcil to receive a Priority Review Voucher to be used for another New Drug Application (NDA) or Biologics License Application (BLA). Inventiva will obtain this voucher upon marketing approval of odiparcil by the FDA. These vouchers can reduce the FDA review time from twelve to six months and can be used by the sponsor, or sold or transferred to a third party.

- **Completion of patient recruitment for the Phase IIa iMProveS clinical study**

  In early June 2019, Inventiva announced the successful completion of patient recruitment for its Phase IIa iMProveS clinical study evaluating odiparcil for the treatment of MPS VI. Given the recent progress achieved in the study, headline results for all treatment arms are now expected by the end of the year. Inventiva had initially planned to publish the study results in two steps: the results of the double-blind placebo-controlled arms by the end of the year followed by the results of the open label cohort in the first quarter of 2020.

- **Launch of a new biomarker study in children and adults with MPS VI**

  In early September 2019, the Company announced the recruitment of the first patients in a new biomarker study in children and adults with MPS VI. Conducted in the United States, the study will investigate leukocyte glycosaminoglycan (leukoGAGs) levels in three children and skin glycosaminoglycan (skinGAGs) levels in three adults with MPS VI before and post enzyme replacement therapy (ERT), and in six age-matched control subjects not affected by MPS VI. Results of this study are expected in the first half of 2020.

R&D collaborations with AbbVie

- **Launch of a new clinical study with ABB-157 in moderate to severe psoriasis by AbbVie**

After having successfully completed a first Phase I study in 2019, AbbVie has initiated a new clinical study with ABBV-157, the drug candidate resulting from its collaboration with Inventiva for the treatment of moderate to severe psoriasis, to assess the compound's pharmacokinetics, safety and tolerance in healthy volunteers and in patients with chronic plaque psoriasis. Inventiva remains eligible to receive milestone payments based on the progress of the program as well as royalties on future sales. The next milestone payment is expected for the first half of 2020.

YAP-TEAD in the field of oncology

- **Presentation of new results for the treatment of malignant pleural mesothelioma (MPM) at the AACR (American Association for Cancer Research) special conference on the Hippo pathway**

  Last May, Inventiva presented new results from its YAP-TEAD program for the treatment of MPM at the AACR special conference dedicated to the Hippo pathway. Following the promising results of this study, Inventiva decided to expand its studies to other cancer indications as well as other combination strategies where standard of care agents are proven to be ineffective and where YAP is activated.

Other events

- **Evolution of the Board of Directors**

  Following the vote at the Ordinary and Extraordinary Shareholders' General Meeting of Inventiva held on May 27, 2019, Nawal Ouzren and Heinz Maeusli have been appointed as members of the Company's Board of Directors.

  As such, Mrs Nawal Ouzren and Mr Heinz Maeusli follow Mr Chris Newton, Mrs Nanna Lüneborg and Mr Jean-Louis Junien whose terms of office as Directors have officially ended. Mr Jean-Louis Junien now focuses on Inventiva's Scientific Advisory Board. In addition, during the Annual General Meeting, the director mandates of Frédéric Cren, Pierre Broqua, CELL + and Pienter-Jan BVBA have been renewed until the Combined General Meeting to approve the financial statements for the 2021 financial year.

- **Creation of Scientific Advisory Board (SAB)**

  In mid-June 2019, Inventiva announced the creation of its SAB to provide external scientific review and high-level advice to the Company's management with regards to its R&D activities and product portfolio. The SAB covers Inventiva's key areas of research and development with a particular focus on NASH, MPS and oncology. As such, it will support Inventiva's management regarding the preclinical and clinical aspects of the Company's development programs and its global scientific policy, including targets, fields of research, partnerships and market access.

  Since then, Andrew Shenker, MD, PhD in Medicine and Pharmacology, and Dr. Kenneth Cusi, Chief of the Division of Endocrinology, Diabetes and Metabolism in the Department of Medicine at the University of Florida, have joined the SAB. Inventiva will benefit from their complementary expertise in rare diseases and genetic therapies as well as in NASH.

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Next key milestones expected

- Results of the Phase IIa iMProveS clinical study in Europe evaluating odiparcil in MPS VI (by the end of 2019)
- Results of the Phase IIb NATIVE clinical study evaluating lanifibranor in NASH (H1 2020)

- Milestone payment for ABBV-157 by AbbVie, the drug candidate resulting from its collaboration with Inventiva for the treatment of moderate to severe psoriasis (H1 2020)

Upcoming investor conferences

- KBC Biotech Conference, Brussels, September 27, 2019
- Large & MidCap Event, Paris, October 14-15, 2019
- H.C. Wainwright NASH Conference, New York, October 21, 2019
- Gilbert Dupont NASH Day, Paris, October 29, 2019
- KOL and investors' meeting at the American Association for the Study of Liver Diseases (AASLD) conference, Boston, November 9, 2019
- Jefferies Healthcare Conference 2019, London, November 20-21, 2019

Conference call

A **conference call** in English will be held on **September 27, 2019** at **2:00pm (Paris time)**. To join the conference call, please use the code 3979458 after dialing one of the following numbers:

France: +33 1 70 73 27 27
Belgium: +32 10 39 12 06
Denmark: +45 32 72 75 18
Germany: +49 69 22 22 49 10
Netherlands: +31 20 71 57 366
Switzerland: +41 44 58 04 873
United Kingdom: +44 203 00 95 710
United States: +1 917-720-0178

The presentation accompanying this conference call will be available on Inventiva's website at the same time in the "Investors" – "Financial Results & Presentations" section. It can be followed live or in replay in the same section of the Company's website and at: https://edge.media-server.com/mmc/p/kg7mk7eb.

Next financial results publication

- **Q3 2019 Revenues and cash position:** Wednesday, November 13, 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 patients with the MPS VI subtype.

In parallel, Inventiva is in the process of selecting an oncology development candidate for its Hippo signalling pathway program. The Company has established two strategic partnerships with AbbVie and Boehringer Ingelheim in the areas of autoimmune diseases and idiopathic pulmonary fibrosis ("IPF") respectively. 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. 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 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 "Document de référence" filed with the Autorité des Marchés Financiers on April 12, 2019 under n° R.19-006 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.