Inventiva Reports First-half 2018 Financial Results and Provides a Corporate Update

- Cash position at €75.9 million as of June 30, 2018
- Successful €32.5 million private placement on April 17, 2018 (net proceeds) strengthening the company's cash position
- Revenues of the first half-year at €1.5 million in line with forecasts

Daix (France) le 19 juillet 2018 – Inventiva S.A. (« Inventiva » or the « Company »), a biopharmaceutical company developing innovative therapies in nonalcoholic steatohepatitis (NASH), Systemic Sclerosis (SSc) and mucopolysaccharidosis (MPS), today published its cash position and revenues as of June 30, 2018.

H1 2018 Revenues and Cash position[1]

Due to a successful capital increase, Inventiva's cash position was reinforced in the first half of 2018 (April 13) with the issue of 5,572,500 new shares to European and American investors. Consequently, as of June 30, 2018, cash and cash equivalents amounted to 75.9 million euros compared to 59.0 million euros at 31 December 2017. The success of this capital increase allows Inventiva to finance its activities until mid-2020 beyond the lanifibranor Phase IIb results in NASH and SSc (NATIVE[2] and FASST[2] trials), phase II results in type 2 diabetic patients with non-alcoholic fatty liver disease (NAFLD) and Phase IIa and Phase Ib of odiparcil in MPS VI (iMProveS[2] and SAFE-KIDDS[2] studies).

Inventiva's revenues[1] for the first half of 2018 totaled €1.5 million compared to revenues of €2.7 million in H1 of 2017. As expected, this decrease of 45% is due to the evolution of the collaborations with AbbVie and Boehringer Ingelheim which, due to the progress made in their developments, have required fewer resources.

The first half of 2018 was equally marked by three important announcements.

Positive DSMB Reviews in both NASH and SSc Phase IIb Trials with Lanifibranor

The good safety of lanifibranor was confirmed once again by the positive results of two DSMBs (*Data Safety Monitoring Board*) for both NASH and SSc Phase IIb Trials. The FASST Data Safety Monitoring Board held its third and last meeting before the end of the trial of lanifibranor in SSc. Similarly to the conclusions of the first two DSMBs, the board recommended that the study continues without any modification to the protocol. Similarly the NATIVE DSMB met for the first time and after reviewing all safety data came to a similar conclusion and recommended to continue the study without any modification of the protocol. The positive outcomes of these two DSMBs confirm the good safety of lanifibranor, already demonstrated in long-term toxicological studies as well as in Phase I and Phase II clinical trials. Both studies are progressing as planned and topline results are anticipated in early 2019 for the FASST trial in SSc and second half of 2019 for the NATIVE trial in NASH.

[1] Non audited figure

[2] NATIVE: NASH Trial to Validate IVA337 Efficacy ; FASST: For A Systemic Sclerosis Treatment; iMProveS. Improve MPS treatment; SAFE-KIDDS: *A Phase Ib **SAFE**ty, pharmaco**KI**netics and pharmaco**D**ynamics, **D**ose escalating **S**tudy of odiparcil in pediatric population with MPS type VI*

FDA Approval of an Investigator Initiated IND Application to Conduct Phase II Study of Lanifibranor in Type 2 Diabetic Patients with Non-Alcoholic Fatty Liver Disease

The Company also received the approval for an Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to proceed with the Phase II study of lanifibranor in type 2 diabetic patients with nonalcoholic fatty liver disease (NAFLD). This approval allows Inventiva to proceed with the study, which will be conducted by Dr. Kenneth Cusi, Chief of the Division of Endocrinology, Diabetes & Metabolism in the Department of Medicine at the University of Florida, Gainesville. The trial is expected to enroll 64 patients treated for a 24-weeks period with a single daily dose of lanifibranor (800mg/day) or placebo and 10 subjects in a healthy, non-obese control group. The first patient is expected to be enrolled in the third quarter of 2018 and topline results are expected early 2020. The FDA approval is also a positive sign for the planned Company's IND applications in SSc and NASH.

Appointment of Dr Lucy Lu to the Board of Directors

Inventiva has reinforced its Board of Directors with the appointment, at the Annual General Meeting held on May 28, 2018, of Dr Lucy Lu, President and Chief Executive Officer of Avenue Therapeutics, as independent director representing Sofinnova Crossover I SLP. Dr Lucy Lu has a wide experience of over 15 years in the biotech and healthcare sector as an investment banker, sellside analyst and CFO/CEO of biotech companies listed in the United States. As such, she will bring additional expertise in finance and clinical development to Inventiva. Drawing on her experience and knowledge of the American market, Dr Lucy Lu will also advise and help the Company in its development in the United States.

Next key milestones

- Results of the two two-year carcinogenicity trials with lanifibranor
- Recruitment of the first patient for the Phase II study of lanifibranor in type 2 diabetic patients with nonalcoholic fatty liver disease led by Dr Cusi in the United States
- Opening of INDs (*Investigational New Drug*) with the FDA for the further development of lanifibranor in SSc and NASH in the United States
- End of the Phase IIb FASST trial in SSc with lanifibranor
- End of the enrolment in the phase IIb NATIVE trial with lanifibranor in NASH
- Launch of the Phase Ib SAFE-KIDDS study with odiparcil in children with MPS VI
- Award by the FDA of the *Rare Pediatric Disease Designation* in MPS VI
- Launch of Phase I with ABBV-157, the new orally available ROR-gamma inverse agonist clinical candidate discovered by the partnership with AbbVie

Next conferences

- 15th Annual International Symposium on MPS and Related Diseases, San Diego, 2-4 August 2018
- 256th ACS (American Chemical Society) National Meeting & Exposition, Boston, 19-23 August 2018
- H.C. Wainwright Healthcare Conference, New York, 4-6 September 2018
- 83rd Scientific Day for the AFEF (*Association Française pour l'Etude du Foie*), Lyon, 3-6 October 2018
- 18ème Large & Midcap Event®, Paris, 8-9 October 2018
- 2018 ACR/ARHP (*American College of Rheumatology / Association of Rheumatology Professionals*) Annual Meeting, Chicago, 19-24 October 2018
- 24th Annual BIO-Europe®, Copenhague, 5-7 November 2018

- The Liver Meeting® 2018 by AASLD (*American Association for the Study of Liver Diseases*), San Francisco, 9-13 November 2018
- 9th Jefferies Healthcare Conference, London, 14-15 November 2018

Next financial announcement :

- Publication of the financial results for the first half of 2018 (after trading) on September 27, 2018

About Inventiva: www.inventivapharma.com

Inventiva is a biopharmaceutical company specialized in the development of drugs interacting with nuclear receptors, transcription factors and epigenetic modulators. Inventiva's research engine opens up novel breakthrough therapies against fibrotic diseases, cancers and orphan diseases with substantial unmet medical needs.

Lanifibranor, its lead product, is an anti-fibrotic treatment acting on the three alpha, gamma and delta PPARs (peroxisome proliferator-activated receptors), which play key roles in controlling the fibrotic process. Its anti-fibrotic action targets two initial indications with substantial unmet medical need: NASH, a severe and increasingly prevalent liver disease already affecting over 30 million people in the United States, and SSC, a disease with a very high mortality rate and for which there is no approved treatment to date.

Inventiva is also developing a second clinical program with odiparcil (IVA 336) for the treatment of patients with mucopolysaccaridosis type VI (or Maroteaux-Lamy syndrome), a rare and severe gene disease affecting children. Odiparcil has also the potential to address other MPS types, characterized by the accumulation of chondroitin or dermatan sulfate (MPS I or Hurler/Sheie syndrome, MPS II or Hunter syndrome, MPS IVa or Morqio syndrome and MPS VII or Sly syndrome). Inventiva is also developing a portfolio of early research projects in the field of oncology.

Inventiva benefits from partnerships with world-leading research entities such as the Institut Curie in the field of oncology. Two strategic partnerships have also been established with world-class major pharmaceutical companies AbbVie and Boehringer Ingelheim in the fields of autoimmune diseases (specifically in psoriasis) and fibrosis respectively. These partnerships provide milestone payments to Inventiva upon the achievement of pre-clinical, clinical, regulatory and commercial milestones, in addition to royalties on the products resulting from the partnerships.

Inventiva employs over 100 highly qualified employees and owns state-of-the-art R&D facilities near Dijon, acquired from the international pharmaceutical group Abbott. The Company owns, a proprietary chemical library of over 240,000 molecules as well as integrated biology, chemistry, ADME and pharmacology platforms.

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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.