



## Major health stakeholders in France launch the PACIFIC Consortium to redefine heart failure with preserved ejection fraction (HFpEF)

**Paris (France) - January 21, 2019** - Sanofi, Servier, Medicen Paris-Region, BpiFrance, the “Secrétariat Général Pour l’Investissement”, “l’Assistance Publique– Hôpitaux de Paris”, Inserm, Bioserenity, Casis, Fealinx and Firalis announced the launch of the PACIFIC consortium (Physiopathology, Classification, Innovation in Heart Failure) to redefine heart failure with preserved ejection fraction (HFpEF).

Cardiovascular diseases are by far the leading cause of death in the world and amongst these pathologies, heart failure affecting nearly one million people in France<sup>1</sup> is constantly increasing. Half of patients with heart failure present with a preserved ejection fraction (HFpEF), a complex syndrome that is misunderstood, highly heterogeneous and often associated with multiple co-morbidities.

The disease is a source of repeated hospitalizations, with major consequences on the quality of life and has a significant impact on health expenditures. The prognosis for this pathology remains unfavorable: one out of two patients dies within five years of onset<sup>2</sup>.

The diagnosis of this disease is difficult because there is no specific diagnostic test. To date, no treatment in heart failure with preserved ejection fraction has been shown to reduce mortality or the number of hospitalizations. HFpEF remains the highest unmet medical need in cardiology.

### **A new transdisciplinary and structuring approach to the disease**

The PACIFIC consortium aims to redefine heart failure with preserved ejection fraction through a comprehensive approach that combines state of the art science and disruptive technologies. The main objective is to improve patient care and healthcare circuits in HFpEF.

PACIFIC is a 5-year project (“Projet de Recherche et Développement Structurant pour la Compétitivité” -PSPC). Operated by Bpifrance, the PSPC's mission is to organize or stimulate the development of new industrial sectors through collaborations between private and academic partners on ambitious projects.

PACIFIC originates from a call for projects in 2017, initiated by two pharmaceutical companies Sanofi and Servier, together with Medicen, the Paris Region competitiveness cluster.

- (1) De Peretti, et al. Prevalence and functional status of ischemic heart disease and heart failure in the adult population in France: contributions from “disability-health” declarative surveys, *BEH* 2014; (9-10): 172-81
- (2) *Nature Review in Cardiology*. 2017; 14: 591-602 / Dunlay Shannon et al.

The main objective of PACIFIC is to redefine HFpEF in order to:

- Better understand patient heterogeneity (phenotypes) by setting up a prospective clinical study to collect more comprehensive data.
- Stratify the HFpEF patient population into more homogeneous subgroups.
- Apply the latest innovations in the field of artificial intelligence (unsupervised and supervised machine learning) to HFpEF, to allow a thorough data analysis and development of precision medicine.
- Develop specific diagnostic tools.
- Structure an innovation network in France around HFpEF.

### A project serving patient care circuits

Most recent advances in science and technology will be applied in the PACIFIC project. This will allow a simple and rapid diagnosis for personalized care and improved healthcare circuits.

This progress will be possible thanks to the development and validation of new algorithms allowing patient stratification. In addition, the advancement in HFpEF knowledge and the experience acquired throughout this project could pave the way for the development of future personalized treatments for each subpopulation with HFpEF.

### An innovative and unique project bringing together key partners in the French health ecosystem

Funded by public and private funds and coordinated by the Assistance Publique - Hôpitaux de Paris (AP-HP), as the promoter of the clinical study, the PACIFIC consortium led by Sanofi brings together state of the art clinical expertise and research:

- **Sanofi and Servier** will contribute by their expertise in data management, biological analysis and biostatistics to develop in the medium-term new therapeutic solutions.

- **The five cardiology hospitals and clinical investigation centers of AP-HP** –Hôpital Européen Georges Pompidou (HEGP), Bichat, Henri-Mondor, Lariboisière and Pitié-Salpêtrière will recruit patients under the coordination of Professor Jean-Sébastien Hulot, HEGP.

- **Unit 979/7587 "Wave physics for medicine"** (Inserm unit - CNRS-ESPCI), **Unit U970 "Paris Cardiovascular Research Center - PARCC"** (Inserm Unit - Université Paris-Descartes) and the **unit 1146 "Laboratory of Biomedical Imaging - LIB"** (Inserm unit - CNRS - Sorbonne University) will bring their expertise in the field of biomedical ultrasound and cardiovascular imaging analysis.

- Four SMEs will develop innovative technologies and analysis softwares: **Bioserenity** (connected textiles for remote patient monitoring), **Casis** (AI image analysis software), **Fealinx** (development of AI algorithms), and **Firalis** (soluble and molecular diagnostic biomarkers).

This collaboration is possible thanks to the support of Medicen-Paris-Région, a competitiveness cluster for innovative health technologies, with national and international scope.

**Dr. Philip Janiak, Director of Research, Cardiovascular and Metabolism Sanofi,** says: *"This unprecedented consortium brings together the best public and private experts in France to lead an innovative international project in cardiology addressing a major public health issue. Sanofi, the leader in the health and biomedical research sector in France, will lead this project along with Servier, Medicen Paris Region and Assistance Publique - Hôpitaux de Paris."*

**Dr. Benoît Tyl, Director of Translational and Cardiovascular Clinical Research at Servier,** says: *"Servier has been a major player for more than 20 years in the field of cardiology, one of its priority research areas. This new project is part of the Servier philosophy that combines its know-how with that of partners with complementary knowledge and technologies, whether public, including academia, or private, to offer new therapeutic solutions that bring hope for patients."*

**Paul-François Fournier, Executive Director Innovation at Bpifrance,** says:

*"We are very pleased to support this research project, which brings together leading French private and public entities, large companies and SMEs. It is a perfect illustration of the ability of our various innovation ecosystems to mobilize together for ambitious projects focused on medical progress."*

**Christian Lajoux, President of Medicen, Paris Region,** says: *"Medicen is delighted with the progress of the Pacific project. This project illustrates the capability of "ensemblier" and facilitator of the competitiveness cluster in the service of excellence and competitiveness of the Ile-de-France and national ecosystem, one of the most successful in the world."*

**Prof. Jean-Sébastien Hulot, from the CIC1418 clinical investigation center at the AP-HP Hôpital Européen Georges Pompidou,** says: *"The AP-HP will be the promoter and sole recruiting center for patients in the framework of the PACIFIC research project. At its five cardiology centers that are expert in the management of heart failure, coordinated by the AP-HP Hôpital Européen Georges Pompidou, we will identify patients, set up clinical investigations and collect data relevant to the study. The AP-HP will thus dedicate its expertise as a key player in clinical research, in addition to its state-of-the-art equipment (imaging and biology platform, etc.) toward this true public health challenge."*

**Jean-Joseph Christophe, President of CASIS,** says: *"At CASIS we are very excited about meeting the challenges in heart imaging analysis for a better understanding of heart failure. We are also delighted with the opportunity to participate in this very ambitious, large-scale project."*

**Marc Frouin, President of Bioserenity France,** says: *"For the deployment of digital health service in France, BFM would say that we have everything needed to succeed. It is incredible to be able to co-work with a group of experts who are each the best in their category. For BioSerenity and its 150 young employees, this project corresponds to our goal of helping millions of patients by providing them with a solution for better management of their diseases."*

**Pr. Hüseyin FIRAT, CEO of Firalis,** says: *"Firalis is very pleased to contribute to the Pacific project. Through its proprietary targeted sequencing tools such as FiMICS and BIOPRED, and innovative platforms such as QMAP, Firalis will develop new biomarker-based precision medicine tools for HFpEF patients' care."*

**Bruno Virieux, Managing Director of Fealinx,** says: *"It is through the augmented intelligence, combining the human intelligence of the consortium actors and the artificial intelligence technologies brought by Fealinx, that a better understanding of preserved ejection fraction heart failure will be possible!"*

**Jean-Luc Moullet, Program Director, General Secretariat for Investment,** says: *"The PACIFIC project is emblematic of the winning projects of the Investments for the Future Program. It responds to a strong medical challenge of diagnosis and treatment design for the 13 million people affected by preserved ejection fraction heart failure. It is highly collaborative, associating start-ups, hospitals and public research laboratories as well as large pharmaceutical companies. It addresses various technological challenges in the fields of cardiac imaging, molecular biomarkers and stratification or diagnostic algorithms. Finally, it also is ambitious in terms of business development and employment. The General Secretariat for Investment is therefore pleased to have been able to support this project with € 7.3 m, with more than half in the form of reimbursable advances."*

#### **About AP-HP**

AP-HP, Greater Paris University Hospitals, is a first-in-class European and world-renowned university hospital. AP-HP is deeply structured around the 7 Universities of Paris and well integrated in the Paris and Ile-de-France metropolitan area. It collaborates closely with the entire French institutional research ecosystem (CNRS, INSERM, CEA, INRA, Institut Pasteur, etc.) thanks to the presence of joint research units distributed among its 10 hospital clusters. AP-HP also hosts 3 world-class Hospital-University-Institutes. A major player in applied research and health innovation, Greater Paris University Hospitals have created a network of support structures for the organization of research and for clinical investigation with: 14 clinical research units, 17 centers for clinical investigation, 4 centers for clinical research and 2 centers for early stage trials, 12 platforms for biological sample collections, 2 sites of state-of-the-art research on cancer, and 1 health data warehouse collecting healthcare data from the 8 million patients admitted each year. AP-HP researchers annually sign nearly 10,000 scientific publications and more than 4,450 research projects are currently under development, with academic or industrial promotion, at the national, European and international levels. With a portfolio of more than 500 patents, databases and unique biological materials, AP-HP promotes outstanding research by biologists and clinical researchers in its 39 hospitals. Nearly half of the patented innovations are licensed to companies around the world and led to the creation of about 60 startups.

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#### **About Inserm**

Founded in 1964, the French National Institute of Health and Medical research (Inserm) is a public science and technology institute, jointly supervised by the French Ministry of National Education, Higher Education and Research and the Ministry of Social Affairs, Health and women's Rights. Inserm is the only French public research institute to focus entirely on human health and positions itself on the pathway from research laboratory to the bed of the patient. The mission of its scientists is to study all diseases, from the most common to the rarest. With an initial budget of 912 million in 2019, Inserm supports more than 300 laboratories across France. In total, the teams include nearly 14,000 researchers, engineers, technicians, post-doctoral students etc.

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### About Servier

Servier is an international pharmaceutical company governed by a non-profit foundation, with its headquarters in France (Suresnes). With a strong international presence in 149 countries and a turnover of 4.152 billion euros in 2017, Servier employs 21,700 people worldwide. Entirely independent, the Group reinvests 25% of its turnover (princeps drugs) in research and development and uses all its profits for development. Corporate growth is driven by Servier's constant search for innovation in five areas of excellence: cardiovascular, immune-inflammatory and neurodegenerative diseases, cancer and diabetes, as well as by its activities in high-quality generic drugs. Servier also offers eHealth solutions beyond drug development.

More information: [www.servier.com](http://www.servier.com)

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### About Strategic Investment Program

The French Secretary general for investment (SGPI) is in charge, under the direct authority of the Prime Minister, to ensure the consistency of the State's innovation investment policy.

Since 2010, the Secretary general is in charge of implementing the "French Strategic Investment Program" of 57B€ (PIA). It's also supervising the "Major Investment plan 2018-2022" (57B€), decided by President Macron in September 2017:

- Major Investment Plan: launched in September 2017 for a five-year period. 57 billion euros, to support firms and face the new challenges in modernizing our economy;
- France's Strategic Investment Program: since 2010, 57 billion euros to provide our economy with long-term growth prospects through the financing of innovative projects.

In addition, the SGPI leads a public investment evaluation mission and is supporting the implementation in France of the "Juncker Plan", European Investment Plan, led by the European Investment Bank.

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### About Bpifrance

Bpifrance is the French national investment bank: it finances businesses – at every stage of their development – through loans, guarantees, equity investments and export insurances. Bpifrance also provides extrafinancial services (training, consultancy..) to help entrepreneurs meet their challenges (innovation, export...).

For more information, please visit: [www.bpifrance.fr](http://www.bpifrance.fr) and [presse.bpifrance.fr](http://presse.bpifrance.fr) - Follow us on Twitter: @Bpifrance - @BpifrancePresse

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### About CASIS

CASIS – CARdiac Simulation & Imaging Software is a young medtech founded from the encounter between Alain LALANDE, researcher and clinician, inventor of cardiovascular imaging software QIR, and Jean-joseph CHRISTOPHE, specialized in blood flow study and with a sound experience in Artificial Intelligence in an INRIA laboratory. The strong motivation of Jean-Joseph CHRISTOPHE for valuing the results from academic research in clinical applications led him naturally to found CASIS. Within only thirty months, CASIS has developed and certified as medical device a complete solution for the analysis of cardiovascular MRI. CASIS acquired a global reach at a very early stage, with a reach in East Asia (Japan, Taiwan, China), in USA, in West Europe, in North Africa and Middle East. Through various academic collaborations in France and internationally, CASIS had been able to demonstrate to be a driving force in a scientific approach with industrial purpose. <https://www.casis.fr/>

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### About BioSerenity

BioSerenity is an innovative MedTech startup located inside the Brain and Spine Institute in La Pitié Salpêtrière Hospital, the largest European Hospital. With 150 employees, the company develops connected medical devices for the diagnosis and monitoring of chronic pathologies. The company operates in cardiology, neurology, sleep disorders, urology, and pregnancy monitoring. Bioserenity's solutions are used by over 100 hospitals and the company collaborates with four pharmaceutical companies on the development of companion diagnostic solutions. Bioserenity is very proud to be part of the PACIFIC project and is looking forward to a collaboration involving extremely talented doctors and leading pharmaceutical companies in Cardiology. As one of the workgroup leaders Bioserenity aims to leverage patient stratification results to develop a continuous monitoring solution for heart failure patients.

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### About FIRALIS S.A.

Firalis is a biotechnology company with a mission to improve disease outcome, therapeutic decisions and generate savings in healthcare industry. Through biomarker discovery, development and regulatory qualification, Firalis develops and markets biomarker based RUO (Research-use-only) and IVD (In-vitro- diagnostic) kits in the field of cardiovascular, inflammatory and autoimmune diseases with particular interest in rheumatoid arthritis. With a cutting-edge technology platform and a very high quality environment (ISO 9001, ISO 13845, ISO 17025 and NF S 96-900), Firalis provides a comprehensive range of biomarker services from research to clinical applications in key therapeutic areas. Additional information is available at [www.firalis.com](http://www.firalis.com)

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### About FEALINX

FEALINX, a Lyon-based digital services company, has been supporting its customers for 20 years in managing and valuing their data. In 2010, FEALINX has created an operational unit dedicated to medical world and biomedical research. Thus, following various research works in collaboration with academic teams, FEALINX has developed an enterprise software called SWOMed which allows to manipulate any type of data from acquisition to valorization. Expert in data science, Fealinx's biomedical team is actively involved in a joint ANR laboratory (Ginesislab) managed with researchers from the Neurofunctional Imaging Group in Bordeaux. This laboratory is focused on machine learning applied to medical imaging. Convinced that Artificial Intelligence technologies will be an essential component of biomedical research and tomorrow's medicine, Fealinx has created in 2018 a new subsidiary called ARTIFICIAL INSIGHT, conducted by Bruno VIRIEUX in order to coordinate all the health activities of the company.

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### About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions. With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

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