

## NECESSITY PROJECT OFFICIALLY STARTED

### OVERVIEW

Primary Sjögren's syndrome (pSS) is a systemic autoimmune disease (AID) characterized by lymphocyte infiltration of salivary and lacrimal glands that leads to progressive xerostomia and xerophthalmia. Fatigue and limb pain are also common symptoms. Systemic and extra-glandular manifestation may develop in one third of patients, and includes arthritis, fever, vasculitis, peripheral neuropathy, synovitis, kidney involvement and interstitial lung disease. Moreover, pSS patients have a 10 to 20-fold higher risk of developing B-cell lymphomas, conferring shorter lifetime expectancy to these patients.

In the past two decades, eleven new targeted-immunomodulatory treatments have been marketed for rheumatoid arthritis; however, only one drug has been licensed for other systemic autoimmune diseases (AIDs), belimumab, in systemic lupus erythematosus (SLE). Several factors may have hampered the development of successful drugs. AIDs are multiorgan diseases and considerably heterogeneous among individuals, both in terms of clinical manifestations and biological disturbances. As a consequence, it is challenging to set-up accurate clinical end-points sensitive to change and feasible in clinical trials.

### OBJECTIVES OF NECESSITY

NECESSITY project aims to overcome these challenges with three objectives to enhance the development of new medicines for pSS:

- To develop and assess sensitive clinical endpoints to evaluate response to drug treatments in patients with pSS;
- To identify and evaluate discriminative biomarkers for stratification of pSS patients;
- To design and perform a multi-arm multi-stage clinical trial to validate the newly defined pSS endpoints and the identified biomarkers.

#### NECESSITY at a glance Full project title:

**NEw Clinical Endpoints** in primary Sjögren's Syndrome: an **I**nterventional **T**rial based on stratif**Y**ing patients

**Start date:** 01/01/2019

**Duration:** 72 months

**Total cost:** €15.4 million

**Project Coordinator:**  
INSERM

**Project Leader:**  
Novartis Pharma AG

### KICK-OFF MEETING - PARIS

The kick-off meeting for the NECESSITY project took place in Paris on 16-17 January 2019. The project consortium was represented by twenty-one academic partners and four EFPIA member companies representing nine European countries: United Kingdom, France, Italy, Switzerland, Netherlands, Spain, Sweden, Greece and Norway.



### IMPACT

The NECESSITY project, by bringing the relevant stakeholders together including the academia, pharmaceutical industry, health authorities, payors and patient groups, is expected to generate impactful novel tools and capabilities for the confirmation of new endpoints and design of new pSS clinical trials to ultimately facilitate new drug development for patients with pSS.

In the field of autoimmunity, given the frequency of pSS and the absence of any treatment available, finding an efficient treatment for patients is a key unmet medical need which will be more easily achieved by combining Horizon 2020 and private sector funds in a public-private partnership

Laboratory assays and bioinformatics methodology implemented in this project will be transferable to other autoimmune diseases. The conceptual approach that we will take in the translational part of the project aims at identifying biomarkers able to address both autoimmune activation and organ damage will be also relevant to other autoimmune conditions characterised by organ involvement. Similarly, our new original stratification and umbrella trial will be applicable to other complex auto-immune diseases such as systemic lupus erythematosus and systemic sclerosis.

## PROJECT PARTNERS

### UNIVERSITIES, RESEARCH ORGANISATIONS, PUBLIC BODIES, NON-PROFIT GROUPS

- Institut National de la Santé et de la Recherche Médicale, Paris, France (Project Coordinator)
- The University of Birmingham, Birmingham, UK
- Karolinska Institutet, Stockholm, Sweden
- Newcastle University, Newcastle upon Tyne, UK
- Les Hôpitaux Universitaires de Strasbourg, Strasbourg, France
- Universitair Medisch Centrum Utrecht, Utrecht, The Netherlands
- Université de Bretagne Occidentale, Brest, France
- Fundación Pública Andaluza Progreso y Salud, Sevilla, Spain
- Ethniko Kai Kapodistriako Panepistimio Athinon, Athens, Greece
- Université Paris Descartes, Paris, France
- Assistance Publique – Hôpitaux de Paris, Paris, France
- European Clinical Research Infrastructure Network, Paris, France
- Universitetet i Bergen, Bergen, Norway
- Association Française du Gougerot Sjögren, Paris, France
- Queen Mary University of London, London, UK
- Università degli Studi di Udine, Udine, Italy
- Institut Pasteur, Paris, France
- Helse Stavanger HF, Stavanger, Norway
- Het Academisch Ziekenhuis Groningen, Groningen, The Netherlands
- Fundació Clinic per a la Recerca Biomèdica, Barcelona, Spain

### EFPIA MEMBER COMPANIES

- Novartis Pharma AG, Basel, Switzerland (Project Leader)
- GlaxoSmithKline, Brentford, UK
- Institut de Recherches Internationales Servier, Suresnes, France
- Bristol Myers Squibb Company CORP, New York, USA

### SMALL AND MEDIUM-SIZED ENTERPRISES (SMES)

- Innovation Acta S.r.l, Roma, Italy

#### FINANCING

IMI2 JU funding	€ 8.2 million
EFPIA in kind contribution	€ 7.2 million
<b>Total project cost</b>	<b>€ 15.4 million</b>

#### CONTACTS

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