

11 September 2024

Press release

TWINSS: the efficacy and safety of subcutaneous iscalimab in Sjögren's disease

Teams from the rheumatology department at the Hôpital Bicêtre AP-HP, Université Paris-Saclay, Inserm and the University of Birmingham have taken part in a clinical trial to study the efficacy and safety of subcutaneous iscalimab in Sjögren's disease. The results of the primary endpoint at week 24, co-authored by Professors Xavier Mariette and Benjamin A Fisher, were published on 31 July 2024 in [The Lancet](#).

Sjögren's disease is a rare chronic autoimmune disorder for which no targeted therapy has yet been approved. Patients with this disease mainly complain of chronic dry eyes and mouth, joint pain and fatigue, and may present numerous complications in different organs, including the risk of lymphoma, a cancer of the lymph nodes.

The Phase II TWINSS trial, promoted by Novartis, was conducted by an international team of researchers in 23 different countries, and included 273 patients in two cohorts. It assessed the safety and efficacy of multiple doses of iscalimab, a monoclonal antibody¹ that recognises the CD40 molecule, essential for B lymphocyte activation.

In the first cohort, patients (173) with both moderate and high systemic activity and significant symptoms were randomised between placebo and iscalimab 150 mg, 300 mg and 600 mg. In the second cohort, patients (100) with weak systemic activity but significant symptoms were randomised between placebo and iscalimab 600 mg.

In total, serious adverse events were reported in eight patients (6%) in the iscalimab-treated groups and in one patient (2%) in the placebo-treated group up to week 24. In the first cohort, systemic disease activity improved with all three drug doses, significantly compared to placebo for the 150 mg and 600 mg doses. In the second cohort, a trend towards improvement in disease symptoms was observed with iscalimab compared to placebo. Both stimulated and unstimulated salivary flow improved with iscalimab.

This study shows the importance of the CD40/CD40 ligand pathway in Sjögren's disease.

1. *Antibodies produced by cells in culture to treat specific diseases*

References: Benjamin A Fisher, Xavier Mariette, Athena Papas, Thomas Grader-Beck, Hendrika Bootsma, Wan-Fai Ng, P L A van Daele, Stephanie Finzel, Ghaith Noaiseh, Sergio Elgueta, Josef Hermann, Sara S McCoy, Esen Akpek, Arthur Bookman, Monika Sopala, Michela Montecchi-Palmer, Wen-Lin Luo, Cornelia Scheurer, Wolfgang Hueber - [The Lancet](#)

The [University of Birmingham](#) is ranked amongst the world's top 100 institutions. Its work brings people from across the world to Birmingham, including researchers, educators and more than 40,000 students from over 150 countries. England's first civic university, the University of Birmingham is proud to be rooted in one of the most dynamic and diverse cities in the country. A member of the Russell Group and a founding member of the Universitas 21 global network of research universities, the University of Birmingham has been changing the way the world works for more than a century. The University of Birmingham is a founding member of [Birmingham Health Partners](#) (BHP), a strategic alliance which transcends organisational boundaries to rapidly translate healthcare research findings into new diagnostics, drugs and devices for patients. Birmingham Health Partners is a strategic alliance between seven organisations who collaborate to bring healthcare innovations through to clinical application: University of Birmingham, University Hospitals Birmingham NHS Foundation Trust, Birmingham Women's and Children's Hospitals NHS Foundation Trust, Aston University, The Royal Orthopaedic Hospital NHS Foundation Trust, Sandwell and West Birmingham Hospitals NHS Trust, West Midlands Academic Health Science Network, Birmingham and Solihull Mental Health NHS Foundation Trust.

About AP-HP: Europe's leading university hospital centre (CHU), AP-HP and its 38 hospitals are organised into six university hospital groups (AP-HP. Centre - Université Paris Cité; AP-HP. Sorbonne University; AP-HP. Centre - Université Paris Cité; AP-HP. Université Paris-Saclay; AP-HP. Henri-Mondor University Hospitals and AP-HP. Hôpitaux Universitaires Paris Seine-Saint-Denis) and are organised around five different universities in the Paris region. Closely linked to major research organisations, AP-HP is home to eight world-class university hospital institutes (ICM, ICAN, IMAGINE, FOReSIGHT, PROMETHEUS, InovAND, reConnect, THEMA) and France's largest healthcare data warehouse (EDS). AP-HP is a major player in applied research and innovation in healthcare, and holds a portfolio of 810 active patents. Its clinician-researchers author over 11,000 scientific publications every year, and nearly 4,400 research projects are currently underway, all sponsors included. In 2020, AP-HP was awarded the Institut Carnot label, which acknowledges the quality of its research partnerships: the Carnot@AP-HP provides industrial players with applied and clinical research solutions in the healthcare field. In 2015, AP-HP also created the AP-HP Foundation, which works directly with caregivers to support the organisation of care, hospital staff and research within HP-HP.

<http://www.aphp.fr>



Press contact:

AP-HP Press Office: service.presse@aphp.fr

About Université Paris-Saclay: Université Paris-Saclay was born from the shared ambition of French universities, grandes écoles and national research organisations. As a leading university in Europe and the world, it covers the fields of science and engineering, life sciences and health, and humanities and social sciences. The university's science policy closely intertwines research and innovation, incorporating both basic and applied science to tackle major societal challenges. Université Paris-Saclay offers a varied range of undergraduate to doctorate level degrees, including programmes with its grandes écoles, all of which are focused on achieving student success and employability. The university prepares students for an ever-changing world where the ability to think critically, remain agile and renew one's skills are crucial. Université Paris-Saclay also offers a comprehensive range of lifelong learning courses. Located to the south of Paris, the university extends across a vast and rich local area. Its location strengthens both its international visibility and its close ties with its socio-economic partners (major companies, SMEs, start-ups, local authorities, charities). www.universite-paris-saclay.fr/en/



Press contact: service.presse@universite-paris-saclay.fr