



Janssen in Immunology

Janssen Pharmaceutica NV



Immunology

Rheumatology | Gastroenterology | Dermatology

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Janssen in immunology

Innovation is in our nature – we strive to continually deliver pioneering solutions in immunology through dedicated research and collaboration.

We are proud to have one of the strongest treatment portfolios for some of the most common immune and inflammatory diseases across rheumatology, gastroenterology and dermatology.



“Our mission is to address unmet medical needs in immune and inflammatory diseases, and allow patients with these debilitating diseases to lead normal lives”

Frederic Lavie MD, PhD, EMEA Therapeutic Area Leader, Immunology, Cardiovascular & Metabolics

Supporting Janssen’s vision

For 75 years, we have helped improve health around the world as part of our long standing commitment to patients. Today, the Janssen Immunology team are working together with our partners in academia and biotechnology to continue developing new, tailored therapeutic options that aim to provide the right treatment for the right person in every part of the world.

Janssen’s commitment to immunology

Collectively we aim to provide new hope and good health for people and their families living with immune and inflammatory diseases by utilising our expertise in this area and understanding of the inflammatory cascade. As we build upon existing discoveries and share our knowledge with internal and external partners, we will continue to help transform the field of immunology. Our collaborations with external partners help us to enable earlier diagnosis and develop successful treatments through cutting-edge research and advanced technologies.

Janssen's investment in immunology

Janssen invests in an extensive presence and multiple partnerships across the Europe, Middle East and Africa (EMEA) region to support progress in immunology.

Janssen EMEA has:

Activities in
more than
100
countries



Local offices in
more than
30
countries

More than
14,000
employees



Research & development investments of more than

€1.5 billion annually

8  
research &
development
centres

10  
manufacturing sites for
worldwide distribution
of medicines and vaccines

Continued cross-disciplinary research in the field of immunology is vital for ongoing innovation in this therapy area to improve the lives of patients, families and carers affected by immune and inflammatory diseases.

Immune and inflammatory diseases

such as rheumatoid arthritis, Crohn's disease, asthma and psoriasis, affect an estimated

56–70 million people in Europe¹



Global prevalence estimates of common immune and inflammatory diseases:

217 million people suffer from psoriasis²

72 million people suffer from psoriatic arthritis²

72 million people suffer from rheumatoid arthritis³

65 million people suffer from ankylosing spondylitis⁴

1.2 million people suffer from Crohn's disease⁵

1.8 million people suffer from ulcerative colitis⁵

348 million people suffer from COPD (chronic obstructive pulmonary disease)⁶

311 million people suffer from asthma⁷

People who are diagnosed with an immune and inflammatory disease are prone to develop the following co-morbidities:

Cardiovascular
disorders^{8–14}

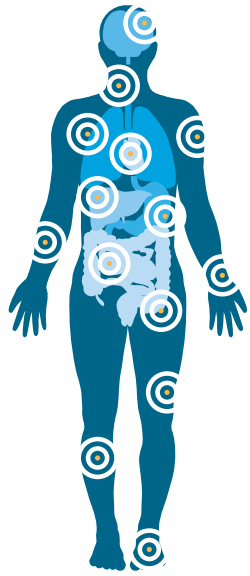


Metabolic
disorders^{8,9,12–14}



Psychological
disorders^{9,10,13}





Immune and inflammatory diseases are lifelong conditions¹⁵

All immune and inflammatory diseases are triggered by the immune system attacking an organ or tissue in the body. Depending on where the immune system attacks, different immune and inflammatory diseases will manifest. These diseases can develop at any age, and have a significant impact on quality of life.^{2,4,9,15-21}

The impact of living with an immune and inflammatory disease

Living with an immune and inflammatory disease has a similar impact on quality of life as seen in other diseases, including cancer, heart disease, and hypertension.²¹ The exact effects of an immune and inflammatory disease vary according to the specific diagnosis, but there are some aspects common to people affected by immune and inflammatory diseases.

People with psoriatic arthritis and Crohn's disease can suffer from pain and discomfort, which can complicate daily activities and lower performance at work.^{22,23}



Many people with an immune and inflammatory disease worry about future disease episodes, as well as being able to fulfil their role as a parent, maintaining an active social life and spending time with friends, family and their partner.



The impact of continuous disease episodes can extend beyond the person with an immune and inflammatory disease and affect the lives of their partners, children, family and carers.



People with a visible immune and inflammatory disease, like psoriasis, or those who have to take their medication in public, like people with asthma, can experience social stigma and develop coping strategies to avoid unpleasant situations.^{21,24}

This can have a serious psychological impact on the individual as seen in patients with COPD.²³



Janssen's established track record of bringing innovative treatments for chronic illnesses to patients makes us a leader in the discovery, research and development of immunotherapies.

The foundations built from our pioneering work in developing monoclonal antibodies allow us to expand our portfolio to include novel, oral, small molecules, new biologic platforms and inhaled therapies.

Innovation is at the heart of our work

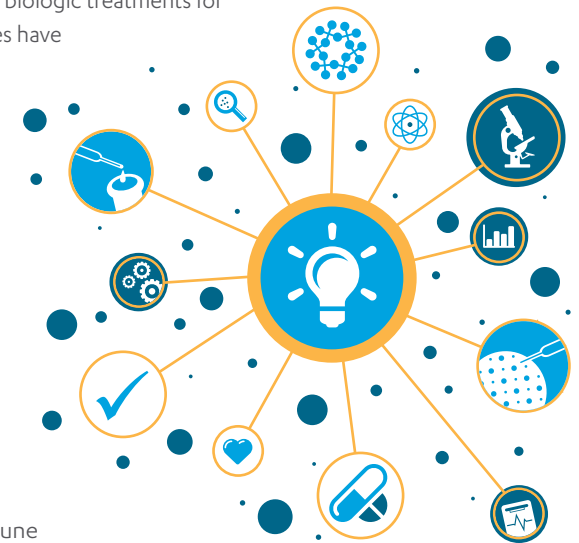
We paved the way in treating immune and inflammatory diseases through establishing monoclonal antibodies that target anti-tumour necrosis factor- α (TNF- α). TNF- α therapies have become a standard of treatment for certain immune and inflammatory diseases.

This breakthrough led us to research interleukins, proteins released by immune cells to control inflammatory responses. As a result, the new-generation of biologic treatments for immune and inflammatory diseases have been developed – monoclonal antibodies that target interleukins. Now even more treatment options are available for patients and physicians.

The fine art of biologic treatments

Biologic treatments have provided transformational disease-modifying medicines, and have been used to treat millions of patients worldwide across a broad spectrum of immune and inflammatory diseases. We helped pioneer the development of monoclonal antibody treatments, with three first-in-class therapies in our biologic treatment portfolio.

The manufacturing of biologic treatments is a long process which involves a series of stages that must be validated and approved by relevant regulatory authorities. This process is generally individual to a specific biologic treatment and may take many years to complete.



Biologic treatments are manufactured in a staged process:

1. Upstream processing:

First a cell line expression system is developed from which the biologic treatment is produced, ideally in high quantities and in a purifiable active form.



2. Downstream processing:

The biologic treatment is then purified and a series of analytical characterisation tests are carried out to check the purity of the biologic.



Biosimilars are medicines that are 'similar' but not identical to an already approved biologic treatment; they should not be confused with generic medicine. As the equivalence to the original biologic treatment cannot be fully established, the safety and efficacy of a biosimilar cannot be fully based on clinical studies of the reference medicine. Within Europe the European Medicines Agency evaluates biosimilar medicines for authorisation purposes but does not include recommendations on whether a biosimilar should be used interchangeably with its referenced medicine.²⁵

Janssen is pushing the frontiers of immunology research and development to develop the best possible medicines for people with immune and inflammatory diseases.

We are using our expertise and capabilities in inflammation research and biologic treatments to pursue the next-generation of therapeutic solutions for immune and inflammatory diseases.

In addition to investing in extensive clinical trial programmes for dermatology, gastroenterology and rheumatology, we are also focusing our research on:

Janssen's current areas of active research in immunology:

- Psoriasis
- Psoriatic arthritis
- Crohn's disease
- Axial spondyloarthritis (ankylosing spondylitis)
- Rheumatoid arthritis
- Ulcerative colitis
- COPD (chronic obstructive pulmonary disease)
- Asthma

Small molecule compounds

We are focused on advancing small molecule research in immune and inflammatory diseases and pulmonary diseases, including asthma and COPD.

Biomarkers

We are investing in the discovery of biomarkers to help predict patient responses to certain treatments and ensure that each patient receives the right treatment for them.

Translational research

Placing translational research at the core of our research and development strategy will help us achieve a more efficient progression from pre-clinical to clinical stages for our treatments.

Our focus on understanding research at a molecular level is key to the discovery of new targets that drive the inflammatory and autoimmune processes.

This knowledge will help us to unlock new approaches to understanding and treating diseases.

Collaboration and partnership are fundamental for informing our research and delivering solutions that make a real difference for patients.

Clinical trials transparency

We entered a novel agreement with the Yale School of Medicine, called the Yale Open Data Access (YODA) project, to extend our commitment to sharing clinical trial data to enhance public health and advance science and medicine. We support and advocate greater transparency of clinical trial information by the pharmaceutical industry, and are working with experts to increase transparency and implement best practices in clinical trial data disclosure.

Patient advocacy

Patient advocacy and access to care are critical components of ensuring the reach of our medicines to appropriate patient populations. This is why we work in close collaboration with patient organisations and other stakeholders, to understand their experiences and insights in each disease. We can then provide the tailored information and medical education that they need to help them support patients with immune and inflammatory diseases.

Two examples of our ongoing initiatives with patient advocacy groups are:

Improving standard of care in psoriasis

Together with a group of multi-disciplinary stakeholders involved in psoriasis care, we supported the formation of the European Expert Working Group for Healthcare in Psoriasis (EEWGHP). The EEWGHP produced the Psoriasis White Paper, a framework for improving early access to high-quality care for people with psoriasis in Europe, through raised awareness and consistent management. The Psoriasis White Paper was supported by The Psoriasis Mandate, an e-petition highlighting the five key rights for patients with psoriasis. The Psoriasis White Paper and results of the Psoriasis Mandate have since been presented to the European Parliament by the European umbrella organisation for psoriasis movements (EUROPSO).

The EEWGHP consists of **9** members across **5** European countries

The Psoriasis Mandate totalled over **19,000** individual signatures across **44** European countries

10 national patient organisations signed the Psoriasis Mandate on behalf of their members



EUROPSO and the Psoriasis International Network also pledged their support

European Patient Advocacy Engagement Workshops

The annual European Patient Advocacy Engagement Workshop is a patient advocacy group-driven initiative, supported by an educational grant from Janssen. The workshop is designed to enhance each participating organisation's communications capabilities through interactive educational sessions and by sharing best practice. The programme is targeted at Pan-European organisations who work to support national member groups.

The European Patient Advocacy Engagement Workshop has been running for



Over **25**

patient advocacy groups have attended the Workshop from a diverse range of therapy areas including neurology, immunology, oncology, infectious disease and vaccines, and cardiovascular and metabolic disease

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Dorethey is a joyful, self-taught artist living with arthritis,
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