



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-mediated inflammatory diseases across dermatology, gastroenterology and rheumatology.



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

José Antonio Burón Vidal, Vice President, EMEA Medical Affair.

Supporting Janssen's vision

For over 80 years, we have helped improve health around the world as part of our long-standing dedication to creating medicines that meet the unmet needs of millions of people. Today, Janssen is working with its partners in academia and biotechnology to continue developing new, tailored therapies that aim to provide the right treatment for the right person, in every part of the world.

Janssen's commitment to immunology

Every day, millions of people around the world are challenged by debilitating diseases that are the result of an imbalance in the immune system. At Janssen, we are focusing our scientific expertise on restoring immune balance and advancing the discovery and development of new medicines that will redefine the way we approach immune diseases. Our mission is clear, and we will not rest until we achieve a world free from immune diseases.

Janssen's investment in the Europe, Middle East and Africa (EMEA) region:

Activities in more than



Local offices in more than

More than

employees





Research & development investments of more than

E1.5 billion annually

research & development centres

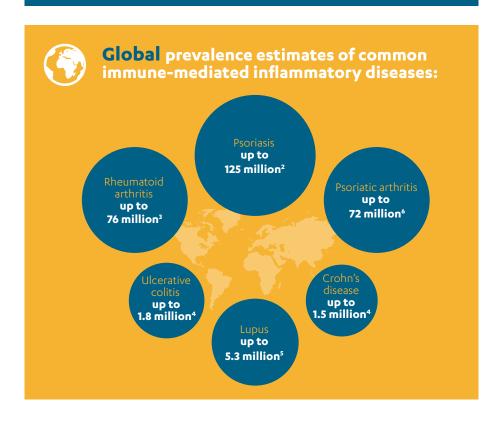




Immune-mediated inflammatory diseases

such as inflammatory bowel disease (IBD), rheumatoid arthritis and psoriasis are estimated to affect up to

57-70 million people in Europe



People who are diagnosed with an immune-mediated inflammatory disease are prone to develop the following comorbidities:









Psychological disorders10,14-16



Immune-mediated inflammatory diseases are chronic conditions

All immune-mediated diseases are triggered by the immune system attacking an organ or tissue in the body. Depending on where the immune system attacks, different immune-mediated inflammatory diseases will manifest. These diseases can develop at any age, and have a significant impact on quality of life. 5.6,15-19

The impact of living with an immune-mediated inflammatory disease

Immune-mediated inflammatory diseases are often misunderstood and sometimes referred to as 'invisible diseases' – people living with these chronic diseases sometimes show no outward signs of their illness and may be embarrassed by their symptoms. The exact effects of an immune-mediated inflammatory disease vary according to the specific diagnosis, but there are some aspects common among people affected.



People with **psoriatic arthritis** and **Crohn's disease** can suffer from **pain** and **discomfort**, which can **complicate daily activities** and **lower performance at work**.^{20,21}

Living with an **immune-mediated inflammatory disease** has a similar impact on **quality of life** as seen in **cancer, heart disease** and **hypertension**.^{22,23}



The impact of continuous disease episodes can extend beyond the person living with the disease and affect the lives of their family members and carers. 24

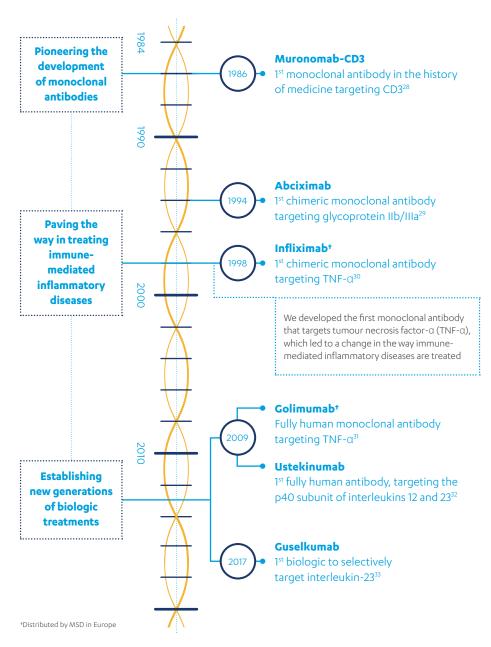




People with a **visible symptom** caused by an **immune-mediated inflammatory disease** can experience **social stigma** and have to develop **coping mechanisms** to avoid unpleasant situations. ^{24–27}

Innovation is at the heart of our research

For over two decades, we have been a world leader in the development of monoclonal antibodies.



The fine art of biologic treatments

Biologic treatments have provided transformational disease-modifying medicines that have been used to treat millions of people worldwide. Manufacturing biologic treatments is a long, complex process that involves a series of stages that must be validated and approved by relevant regulatory authorities. This process is generally unique to each biologic treatment.

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.



Janssen pushing frontiers

We have pioneered the research and development of innovative therapies to address the needs of people living with immune-mediated inflammatory diseases.

Our world-class immunology research and development capabilities attract innovative external partners, creating opportunities to advance new therapeutics, solutions and platforms to treat and intercept immune-mediated inflammatory diseases.



We are also focusing our research on:



Small molecule compounds

We are focused on advancing small molecule research in immune-mediated inflammatory diseases.



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.

Janssen's current areas of active research in immunology:

Psoriasis

- Ulcerative colitis
- Psoriatic arthritis
- Systemic lupus erythematosus
- Crohn's disease

Janssen continues to build an in-depth understanding of immune-mediated inflammatory diseases and disease triggers, advancing innovation in biomarkers, informatics and translational sciences in order to intervene earlier in the course of disease and deliver co-diagnostics and targeted therapeutic options to patients.

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

Clinical trials transparency

We entered into a unique agreement with the Yale School of Medicine, called the Yale Open Data Access (YODA) project (yoda.yale.edu), to extend our commitment to sharing clinical trial data, to enhance public health and advance science and medicine. We support and advocate for the 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.

Real world evidence generation

Psoriasis Longitudinal Assessment and Registry (PSOLAR) study

At Janssen, we recognise the value of Real World Evidence (RWE) in the treatment decisionmaking process. The PSOLAR study is the largest single-industry sponsored, international, disease-based, longitudinal registry focused on psoriasis patients. PSOLAR assesses the longterm safety and efficacy of biologic treatments for psoriasis, providing a valuable resource for examining safety events among patients eligible to receive treatment with systemic therapies.







Patient advocacy and multi-disciplinary collaboration

We work in close collaboration with patient organisations to understand their experiences and insights in each disease to deliver healthcare solutions beyond therapies.

My IBD Journey animation series

Janssen is working in partnership with the European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) (www.efcca.org) to develop a series of animations that convey, through emotive and engaging storytelling, the reality of living with inflammatory bowel disease (IBD) and the impact of the condition.





The animation series is based on typical experiences of people with either Crohn's disease or ulcerative colitis and provides advice and support on topics related to living well with IBD.

The first two animations in the series are available in a number of languages.

Care4Today® Crohn's

As part of Janssen's long-term commitment in IBD, we have developed Care4Today® Crohn's: a platform that connects HCPs and patients, offering physicians greater insight into their patients' clinical evolution, engaging patients and aiming to improve health outcomes.

care4today



Care4Today® Crohn's was developed with input and support from EFCCA, the European Crohn's and Colitis Organisation (ECCO) and leading experts in gastroenterology, and is currently being piloted in selected countries across the region.

Little Wins

People living with rheumatic diseases can struggle to carry out everyday activities due to the physical limitations caused by their symptoms – for example, how do you open a tight jam jar lid with swollen, painful fingers?* With experience, many will find simple, innovative ways to overcome challenges like this. Wouldn't it be great if these people could share their knowledge with others in a similar situation?





Little Wins is an initiative, supported and funded by Janssen, that provides an online platform for people living with rheumatic diseases to share 'little wins' that they've discovered that enable them to overcome some of the common physical challenges their disease throws at them. Supported by the Little Wins website (www.littlewins.net), this campaign shows that real, practical support can often come from the little ideas.

*wear rubber gloves, or wrap rubber bands round the lid #littlewins

Janssen Medical Cloud™

The Janssen Medical Cloud (www.janssenmedicalcloud.co.uk) provides a platform for collaboration between Janssen and healthcare professionals (HCPs) in order to address unmet needs, improve access to treatment, and generate real-world data to



help people live longer, healthier and happier lives. The Janssen Education Academy, hosted on the Janssen Medical Cloud, is a resource for HCPs with clinical experience treating patients with a range of diseases, including oncology, haematology, immunology, neuroscience, gastroenterology, cardiovascular and metabolic therapy areas. The academy combines educational lectures, congress coverage and expert opinions, while providing updates on key data to inform clinical practice.

Promoting patient-centred care in psoriatic arthritis

Despite research and published literature on psoriatic arthritis care from the healthcare community and industry partners, the patient perspective on diagnosis through to long-term management had not been comprehensively addressed. Janssen partnered with a multidisciplinary working group of dermatologists, rheumatologists, patient advocacy representatives and a health psychologist – to explore barriers to optimal care from the patient perspective and recommendations for improving care.

Their recommendations were published in the *Journal of the European Academy* of *Dermatology and Venereology (JEADV)* and have subsequently formed the basis of an EADV Continuing Medical Education (CME) module for dermatologists across Europe.³⁵

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. 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 been presented to the European Parliament by the European umbrella organisation for psoriasis movements (EUROPSO).

The Psoriasis Mandate inspired over

19,000 people affected by psoriasis

across
44 European to call for improved standards of psoriasis care

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



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. 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 diseases and
vaccines, and cardiovascular and metabolic disease

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Donna Williams, Enticement
An autistic artist, author and renowned autism advocate, Donna passed away from cancer in 2017.

Janssen Pharmaceutica NV www.janssen-emea.com

Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse

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