

JANSSEN IMMUNOLOGY

FOR THE

PEACE

WITHIN

We're creating a future where
immune-mediated inflammatory disease
is a thing of the past



Janssen Immunology

At Janssen, we have always been pioneers in innovative science, finding new and more effective ways to transform and intercept the course of immune-mediated inflammatory diseases.

Our treatments have changed the lives of millions of people around the world, across a broad spectrum of immune-mediated conditions. Recognising the remaining challenges, we will keep discovering and developing new and better medicines so that one day people will be able to live in a world where immune-mediated inflammatory disease is a thing of the past.

“Even though we have made great progress in the last decade for the treatment of immune-mediated inflammatory diseases, our mission continues to push the bar to address durable remission and allow patients with these debilitating diseases to lead normal lives.”

Ludovic de Beaucoudrey, Ph.D.
*Janssen Therapeutic Area Lead, Immunology, Europe, Middle East & Africa,
Janssen-Cilag*

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-mediated inflammatory diseases.

Our mission is clear, and we will not rest until we achieve a world where immune-mediated inflammatory disease is a thing of the past.

The prevalence and severity of chronic immune-mediated inflammatory diseases is not always recognised or taken seriously

Immune-mediated inflammatory diseases

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

70 million people in Europe¹ and this number is rising

That's approximately 1 in 10 people



Global prevalence estimates of common immune-mediated inflammatory diseases:

Rheumatoid arthritis
up to 13 million³

Psoriasis
up to 125 million²

Psoriatic arthritis
~40 million^{2,5}

Inflammatory bowel diseases
6.8 million⁴

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

Cardiovascular disorders⁵⁻⁹



Metabolic disorders^{10,12}



Psychological disorders^{7, 13-15}



Immune-mediated inflammatory diseases are chronic conditions

Immune-mediated inflammatory diseases are debilitating, chronic, life-shortening and sometimes even fatal. Pain, fatigue and inability to perform everyday tasks are the most apparent symptoms, and many people also suffer from severe comorbidities. These diseases can develop at any age, and have a significant impact on quality of life.¹⁴⁻¹⁸



People with **psoriatic arthritis** and **Crohn's disease** can suffer from **pain** and **discomfort**, which can **complicate daily activities** and **lower performance at work**.^{19,20}

The impact of living with immune-mediated inflammatory disease

Immune-mediated inflammatory diseases are often misunderstood and sometimes referred to as 'invisible diseases'. Although people living with these chronic diseases often show no visible signs of their illness, when they do occur they can cause significant embarrassment. The exact effects of an immune-mediated inflammatory disease vary according to the specific diagnosis, but there are some aspects common among people affected.

Living with an **immune-mediated inflammatory disease** has a similar impact on **quality of life** as seen in **cancer**, **heart disease** and **hypertension**.^{21,22}



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**.²³



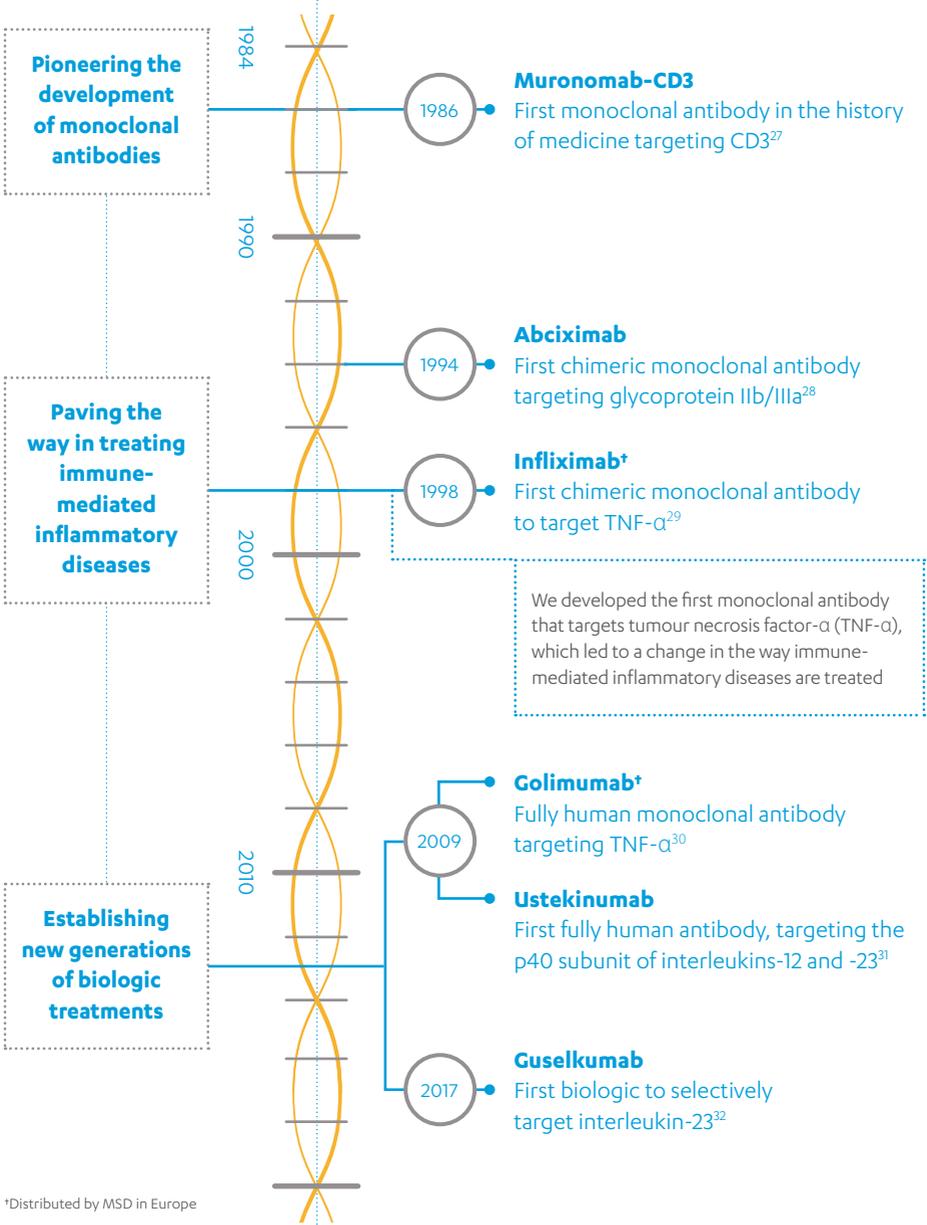
People with a **visible symptom** caused by an **immune-mediated inflammatory disease** can experience **social stigma** and have to develop **coping mechanisms** to avoid unpleasant situations.²⁴⁻²⁶



Yet as their diseases are not readily recognised, people often suffer silently before eventually receiving treatment

Janssen's pioneering breakthroughs change lives

Since the advent of targeted biologic therapy over 30 years ago, we have continued to advance our knowledge of the inflammatory process, being first to develop treatments that intercept new pathways which can help improve patients' lives.



*Distributed by MSD in Europe

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

Whilst treatments today have made a big difference to the lives of many patients, there remains a significant need for medicines that work better, faster and for longer.

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.

Our current areas of active research in immunology:

🕒 Dermatology

(Atopic dermatitis, Hidradentis suppurativa, Plaque psoriasis, Pustular psoriasis)

🕒 Gastroenterology

(Ulcerative colitis, Crohn's disease)

🕒 Rheumatology

(Psoriatic arthritis, Systemic lupus erythematosus, Lupus nephritis, Sjogren's syndrome, Scleroderma)

Our aim is to provide more effective treatments for a wider range of people across a broader spectrum of immune-mediated inflammatory diseases

We aim to provide effective therapeutic options for people with earlier and mild stages of immune-mediated inflammatory disease, all the way to those with severe forms of the disease and those who have run out of treatment options.

Our aim is to restore balance to the immune system with a portfolio of innovative treatments that either engage the brakes or block the accelerators of the immune system. In the future, we aim to use these therapeutic approaches simultaneously to provide patients with even better outcomes.

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

Clinical trial 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. The data has been used in publications. We support and advocate for greater transparency of clinical trial information within the pharmaceutical industry, and are working with experts to increase transparency and implement best practices in clinical trial data disclosure.

New data advances

Psoriasis Longitudinal Assessment and Registry (PSOLAR) study

At Janssen, we recognise the value of real world evidence in the treatment decision-making process. The PSOLAR study is the largest single-industry sponsored, international, disease-based, longitudinal registry focused on psoriasis patients. PSOLAR assesses the long-term 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.

16,000 patients enrolled³³  **23** countries³³  **15** years of data collection³³ 

PsABIO – Evaluating treatment retention and safety of psoriatic arthritis biologic treatments

There is a substantial requirement for longer-term real world data on biological treatment usage in patients with psoriatic arthritis (PsA) to confirm findings from randomised clinical trials.

PsABIO was a large European single-industry sponsored study focused on evaluating treatment retention, safety, quality of life as well as health economic outcomes in PsA patients. This observational study also explored the impact of PsA from the patients' perspective by using several patient reporting outcome tools.

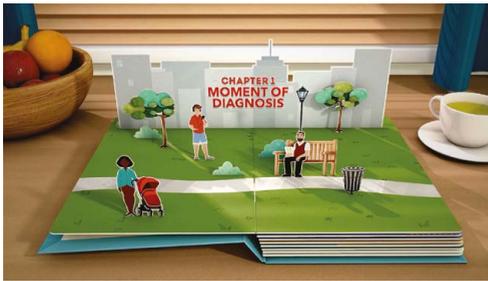
~1,000 patients enrolled³⁴  **8** countries³⁴  **5** years of data collection³⁴ 

Patient advocacy and multi-disciplinary collaboration

Our commitment to immune-mediated inflammatory diseases goes beyond our medicines. We actively support patients through our collaborations with PAGs. We are bringing together the brightest minds including doctors, nurses, patients and patient groups, scientists and policy makers to ensure that people with immune-mediated inflammatory diseases can benefit from the best treatments when they need them.

My IBD Journey animation series

We are 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 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 animations are available in a number of languages.

Care4Today® IBD

As part of Janssen's long term commitment in IBD, we developed Care4Today® IBD; an innovative digital solution including a smartphone app and web portal, that enables collaboration between healthcare professionals (HCPs) and patients to deliver improved outcomes.



Care4Today® IBD 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 Europe.

Beyond Expectations

Beyond Expectations is a platform developed to help patients with psoriatic disease. It provides patient stories, advice and support, as well as credible scientifically supported information to help and encourage patients to move forward with their lives.

Through finding inspiration on how to live their lives, we want patients to see that any progress is something to be proud of and that their condition does not define them. The platform also provides tools for patients to further explore treatment options and make the most of the limited time in their consultations.



We believe that with the right tools there are no limits to what patients can achieve. Every day can and should be filled with triumphs, big or small.

Visitors can learn more about psoriasis, psoriatic arthritis, and the link between these two, at the Beyond Expectations website [GoBeyondExpectations.com](https://www.GoBeyondExpectations.com)

Janssen Medical Cloud™

The Janssen Medical Cloud provides a platform for collaboration between Janssen and HCPs. It hosts resources on a range of diseases including dermatology, gastroenterology, rheumatology, neurology, psychiatry, infectious diseases, pulmonary arterial hypertension and oncology.

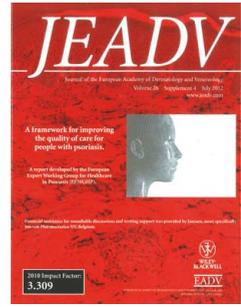
Janssen
Medical Cloud™

OPT-In

OPT-In (the Optimized Patient Treatment Initiative) is a unique tool developed by Janssen which brings together published, unbiased, evidence-based data to determine the most effective treatment sequencing strategy for seven of the most common immune-mediated inflammatory diseases. Soon to be available for three countries in Europe, OPT-In will be able to estimate the most effective treatment sequence based on all nationally reimbursed therapies – including biosimilars – for each respective disease, with the specific aim of limiting the frequency at which patients need to switch treatments. It then compares it to current practice and assesses the impact from both a patient outcome and budget impact perspective. Switching patients from one treatment to another has a detrimental impact on patients physically and mentally and costs money to health systems. OPT-In has the two-fold benefit of supporting the sustainability of healthcare systems and delivering a ‘right treatment, right time, right patient’ approach.

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



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

Activities in
more than
150
countries



Local offices in
more than
30
countries

More than
14,000
employees



Research & development investments of *more than*
\$1.5 billion *annually*

We invest heavily in continuously helping doctors and care-providers, bringing them together across the different therapeutic areas to share their expertise and best practices.

We will not rest until we achieve a world where immune-mediated inflammatory disease is a thing of the past.

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