



# JANSSEN IMMUNOLOGY

## FOR THE **PEACE** WITHIN

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



**Liam Grimmette**  
Communications & Internal  
Events Specialist

## 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.

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

Jaime Oliver, MD  
*Janssen Therapeutic Area Lead, Immunology, Europe, Middle East & Africa, Cilag GmbH International.*

### 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

**57–70 million** people in Europe<sup>1</sup> 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  
78 million<sup>3,4</sup>

Psoriasis  
up to  
125 million<sup>2</sup>

Psoriatic arthritis  
~40 million<sup>2,10</sup>

Ulcerative colitis  
~12.8 million<sup>5-9</sup>

Crohn's disease  
~6.2 million<sup>5-9</sup>

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

Cardiovascular  
disorders<sup>11-14</sup>



Metabolic  
disorders<sup>14-17</sup>



Psychological  
disorders<sup>14,18-20</sup>



## 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.<sup>19-23</sup>



People with **psoriatic arthritis** and **Crohn's disease** can suffer from **pain** and **discomfort**, which can **complicate daily activities** and **lower performance at work**.<sup>24,25</sup>

## 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**.<sup>26,27</sup>



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**.<sup>28</sup>



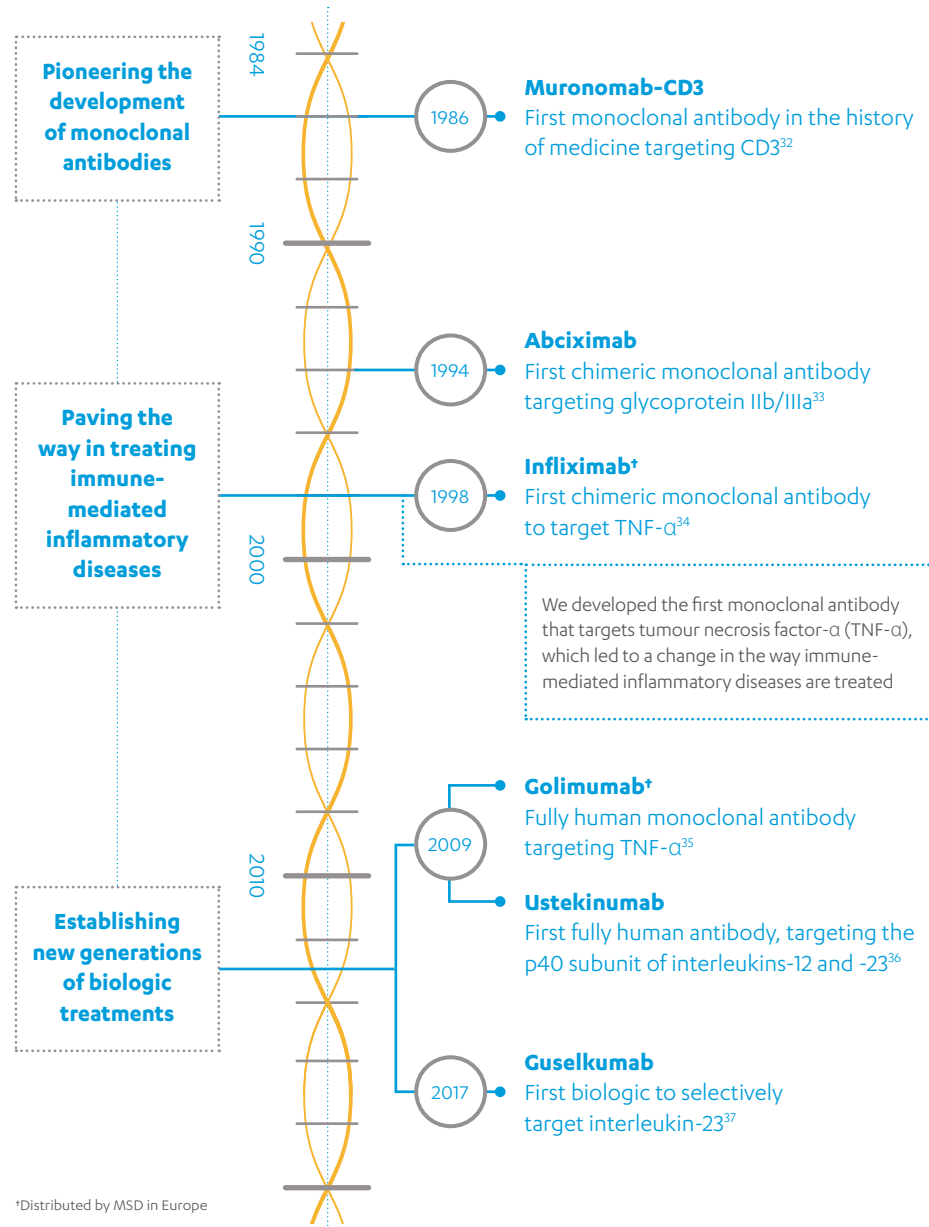
People with a **visible symptom** caused by an **immune-mediated inflammatory disease** can experience **social stigma** and have to develop **coping mechanisms** to avoid unpleasant situations.<sup>29-31</sup>



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:

- |   |  |  |
|---|--|--|
|  <b>Dermatology</b><br>(Atopic dermatitis, Hidradentis suppurativa, Plaque psoriasis, Pustular psoriasis) |  <b>Gastroenterology</b><br>(Ulcerative colitis, Crohn's disease) |  <b>Rheumatology</b><br>(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](http://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.

**12,000** enrolled patients<sup>38</sup>  **16** countries<sup>38</sup>  **13** years of data collection<sup>38</sup> 

#### 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 is 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 will also explore the impact of PsA from the patients' perspective by using several patient reporting outcome tools.

**~1,000** enrolled patients<sup>39</sup>  **8** countries across Europe<sup>39</sup>  **3** years of data collection<sup>39</sup> 

## 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](http://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 have developed Care4Today® IBD: a platform that connects HCPs and patients, offering physicians greater insight into their patients' clinical evolution, engaging patients and aiming to improve health outcomes.

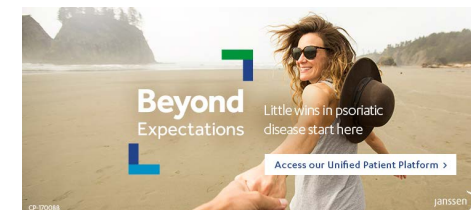


Care4Today® IBD was developed with input and support from EFCCA, the European Crohn's and Colitis Organisation (ECCO) and leading experts in gastroenterology, and is currently being piloted in selected countries across Europe.

## 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.

### 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 oncology, haematology, immunology, neuroscience, gastroenterology, cardiovascular and metabolic therapy areas.

Janssen  
Medical Cloud™

### OPT-In

OPT-In (the Optimize 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.<sup>40</sup>



### Improving the standard of care in psoriasis

Together with a group of multidisciplinary 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).<sup>41</sup>

The Psoriasis Mandate inspired over

**19,000** people affected by psoriasis

across **44** European countries to call for improved standards in psoriasis care



**12** regional and national patient organisations

signed the Psoriasis Mandate on behalf of their members



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

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



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.**

## References

- Cooper G, Bynum M and Somers E. Recent insights in the epidemiology of autoimmune diseases: Improved prevalence estimates and understanding of clustering of disease. *J Autoimmune* 2009;33:197–207.
- Griffiths C, van der Walt J, et al. The global state of psoriasis disease epidemiology: a workshop report. *Br J Dermatol* 2017;177(1):e4–e7.
- UNFPA. 2020. World Population Dashboard. Available at: <https://www.unfpa.org/data/world-population-dashboard>. Accessed October 2020.
- WHO. 2020. Chronic rheumatic conditions. Available at: <https://www.who.int/chp/topics/rheumatic/en/>. Accessed October 2020.
- Bernstein C, et al. World Gastroenterology Organisation Global Guidelines Inflammatory Bowel Disease: Update August 2015. *J Clin Gastroenterol* 2016;50(10):803–818.
- Dahlhamer J, et al. Prevalence of Inflammatory Bowel Disease Among Adults Aged ≥18 Years – United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;65(42):1166–1169.
- Kappelman M, et al. Recent trends in the prevalence of Crohn's disease and ulcerative colitis in a commercially insured US population. *Dig Dis Sci* 2013;58(2):519–525.
- Kotze P, et al. Progression of Inflammatory Bowel Diseases Throughout Latin America and the Caribbean: A Systematic Review. *Clin Gastroenterol Hepatol* 2020;18(2):304–312.
- United Nations. 2019. World Population Prospects. Available at: <https://population.un.org/wpp/>. Accessed October 2020.
- Ogdie A, et al. The Epidemiology Psoriatic Arthritis. *Rheum Dis Clin North Am* 2015;41(4):545–568.
- Nagy G, Németh N and Buzás EI. Mechanisms of vascular comorbidity in autoimmune diseases. *Curr Opin Rheumatol* 2018;30(2):197–206.
- Kabbany M, Joshi A and Mehta N. Cardiovascular diseases in chronic inflammatory disorders. American College of Cardiology. 2016. Available at: <https://www.acc.org/latest-in-cardiology/articles/2016/07/15/10/04/cardiovascular-diseases-in-chronic-inflammatory-disorders>. Accessed October 2020.
- Feng W, Chen G, et al. Inflammatory bowel disease and risk of ischemic heart disease: An updated meta-analysis of cohort studies. *J Am Heart Assoc: Cardiovascular and Cerebrovascular Disease* 2017;6(8):e005892.
- Shah K, Paris M, et al. Real-world burden of comorbidities in US patients with psoriatic arthritis. *RMD Open* 2017;3:e000588.
- Hallajzadeh J, Safiri S, et al. Metabolic syndrome and its components among rheumatoid arthritis patients: A comprehensive updated systematic review and meta-analysis. *PLoS ONE* 2017;12:e0170361.
- Kahraman R, Calhan T, et al. Are adipocytokines inflammatory or metabolic mediators in patients with inflammatory bowel disease? *Ther Clin Risk Manag* 2017;13:1295–1301.
- Batkaeva N, Korotaeva T and Batkaev E. AB0791 High prevalence of metabolic disorders and obesity in psoriatic arthritis compared to psoriasis alone: A retrospective dermatological clinic-based study. *Ann Rheum Dis* 2017;76:1334.
- Bernstein C, Hitchon C, et al. Increased burden of psychiatric disorders in inflammatory bowel disease. *Inflamm Bowel Dis* 2019;25(2):360–368.
- Bacconnier L, Rincheval N, et al. Psychological distress over time in early rheumatoid arthritis: results from a longitudinal study in an early arthritis cohort. *Rheumatology (Oxford)* 2015;54:520–527.
- Pompili M, Innamorati M, et al. Suicide risk and psychiatric comorbidity in patients with psoriasis. *J Int Med Res* 2016;44(1 suppl):61–67.
- Amador-Patarroyo M, Rodríguez-Rodríguez A, et al. How does age at onset influence the outcome of autoimmune diseases? *Autoimmune Dis* 2012;2012:251730.
- Habibi F, Habibi M, et al. Quality of life in inflammatory bowel disease patients: A cross-sectional study. *J Res Med Sci* 2017;22:104.
- Becker H, Grigat D, et al. Living with inflammatory bowel disease: A Crohn's and Colitis Canada survey. *Can J Gastroenterol Hepatol* 2015;29(2):77–84.
- Löfvendahl S, Petersson I, et al. Incremental costs for psoriasis and psoriatic arthritis in a population-based cohort in southern Sweden: Is it all psoriasis-attributable morbidity? *J Rheumatol* 2016;43:640–647.
- Lönnfors S, Vermeire S, et al. IBD and health-related quality of life – discovering the true impact. *J Crohn's Colitis* 2014;8(10):1281–1286.
- Mease P. Assessing the impact of psoriatic arthritis on patient function and quality of life: lessons learned from other rheumatologic conditions. *Semin Arthritis Rheum* 2009;38:320–335.
- Walker J and Littlejohn G. Measuring quality of life in rheumatic conditions. *Clin Rheumatol* 2007;26:671–673.
- Eghlileb A, Davies E and Finlay A. Psoriasis has a major secondary impact on the lives of family members and partners. *Br J Dermatol* 2007;156:1245–1250.
- Narayanan S, Guyatt V, et al. Disease burden and patient reported outcomes among patients with moderate to severe psoriasis: An ethnography study. *Psoriasis (Auckl)* 2014;5:1–7.
- Dibley L, Norton C and Whitehead E. The experience of stigma in inflammatory bowel disease: An interpretive (hermeneutic) phenomenological study. *J Adv Nurs* 2018;74:838–851.
- Ograczyk A, Miniszewska J, et al. Itch, disease coping strategies and quality of life in psoriasis patients. *Postepy Dermatol Alergol* 2014;31:299–304.
- Liu JKH. The history of monoclonal antibody development – Progress, remaining challenges and future innovations. *Annals of Medicine and Surgery* 2014;3(4):113–116.
- Marks L. The birth pangs of monoclonal antibody therapeutics: The failure and legacy of Centoxin. *mAbs* 2012;4(3):403–412.
- Food and Drug Administration. Remicade prescribing information. 2013. Available at: [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2013/103772s5359lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103772s5359lbl.pdf). Accessed October 2020.
- European Medicines Agency. Simponi Summary of Product Characteristics. Last updated 2019. Available at: [https://www.ema.europa.eu/en/documents/product-information/simponi-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/simponi-epar-product-information_en.pdf). Accessed October 2020.
- European Medicines Agency. Stelara Summary of Product Characteristics. Last updated 2019. Available at: [https://www.ema.europa.eu/en/documents/product-information/stelara-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/stelara-epar-product-information_en.pdf). Accessed October 2020.
- European Medicines Agency. Tremfya Summary of Product Characteristics. Last updated 2018. Available at: [https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/tremfya-epar-product-information_en.pdf). Accessed October 2020.
- ClinicalTrials.gov. NCT00508547. Psoriasis Longitudinal Assessment and Registry (PSOLAR). Available at: <https://clinicaltrials.gov/ct2/show/study/NCT00508547>. Accessed October 2020.
- ClinicalTrials.gov. NCT02627768. A Study on Assessment of STELARA and Tumor Necrosis Factor Alpha Inhibitor Therapies in Participants With Psoriatic Arthritis (PsaBio). Available at: <https://clinicaltrials.gov/ct2/show/NCT02627768>. Accessed October 2020.
- Betteridge N, Boehncke W, Bundy C, et al. Promoting patient-centred care in psoriatic arthritis: A multidisciplinary European perspective on improving the patient experience. *J Eur Acad Dermatol Venereol* 2016;30(4):576–585.
- Augustin M, Alvaro-Gracia JM, et al. A framework for improving the quality of care for people with psoriasis. *J Eur Acad Dermatol Venereol* 2012; 26(4 Suppl):1–16.



**Rachel Palmer**  
Digital Marketing Lead,  
Dermatology



Janssen Pharmaceutica NV  
<https://www.janssen.com/emea/>

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

Copyright 2020

October 2020 CP-177154

Immunology

Dermatology | Gastroenterology | Rheumatology

janssen  Immunology

PHARMACEUTICAL COMPANIES OF *johnson-johnson*