



## Janssen Oncology: **Driving Toward the Elimination of Cancer**

Cancer breakthroughs take time - that's why we work at such a furious pace.

janssen  Oncology

PHARMACEUTICAL COMPANIES OF 



“The patients are waiting.”

— Dr. Paul Janssen

## Three Decades of Delivering Innovation in Oncology

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- Multiple health authority achievements -- Breakthrough Therapy Designations and Priority Reviews from the U.S. Food & Drug Administration (FDA) and other regulators; PRIME Designation from the European Medicines Agency (EMA)
- A distinguished and robust portfolio of novel therapies addressing significant unmet needs in the treatment of patients diagnosed with cancer
- A relentless commitment to improve patients' lives by advancing oncology science and treatments through an open innovation, collaborative approach

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# Our Commitment to Patients

At Janssen Oncology, we have a singular focus – the elimination of cancer. We are inspired by the tremendous progress and emerging new ideas to fight cancer, and we are driven by the enormous global unmet medical need in oncology. Cancer remains the second leading cause of death globally.<sup>i</sup> In 2018 alone, more than 18 million people were diagnosed with cancer worldwide and 9.6 million died of the disease.<sup>ii</sup>

**As champions of science, we are dedicated to enriching our deep understanding of cancer’s complex nature. We are intensely focused on specific cancers and on cutting-edge science, such as immune therapy, with the goal of making cancer a preventable, manageable and curable condition.**

Our unwavering commitment to patients diagnosed with cancer spans more than 30 years of leadership. That legacy is reflected in our successful track record for shepherding innovative science through the drug discovery and development process – and ultimately to commercialization of medical breakthroughs that have become standards of care in cancer treatment. As part of the Janssen Pharmaceutical Companies of Johnson & Johnson,

one of the world’s most innovative and expansive healthcare companies, we are able to marshal tremendous global resources, capabilities and research alliances to develop first-in-class treatments for hematologic malignancies, prostate cancer and solid tumors.

No one company can solve the challenges of cancer, so we seek to collaborate with the finest scientific minds from across academia, clinical practice and industry to bring transformational therapies to people who previously had few or no options.

Through this overview, we hope to share with you how we honor the legacy of our company’s namesake, Dr. Paul Janssen, by working with a sense of urgency and dedication to help millions of people who are waiting and hoping for new cancer treatments and cures.



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# Pursuing the Best Science

With unrelenting drive, Janssen Oncology is applying the most compelling science to bring forward transformational solutions to prevent, intercept, and cure cancer. Our goal is to evolve the next wave of cancer therapies into comprehensive regimens that combine several approaches tailored to patients' individual needs.

## Our Cutting-edge Research Platforms

### Small molecules

Targeted therapies such as those that inhibit specific processes necessary for tumor proliferation or migration.

### T cell redirection

Recombinant proteins bridge T cells and tumor cells, redirecting T cells to better target tumors.

### Antibodies

Monoclonal antibodies are identical immunoglobulins generated from a single B cell clone. These antibodies recognize binding sites on a single antigen, such as CD38, a surface protein that is highly expressed across multiple myeloma cells. Bispecific antibodies target antigens and T cells; bi- and tri-specifics target multiple antigens.

### Chimeric antigen receptor-T cell (CAR-T) therapy

T cells from patients or healthy donors are genetically engineered to include these receptors, which specifically direct the T cells to recognize and kill cancer cells.

### Oncolytic viruses

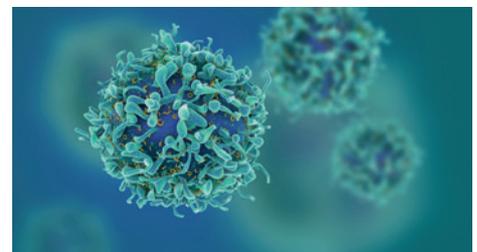
Enable the simultaneous delivery of multiple immune-modulating agents.

### Vaccines

Trigger T cell responses against cancer cells.

## Leading Cancer Interception

One of the innovative ways we are seeking to eliminate cancer is through cancer interception. Our researchers are going beyond early detection to determine why some healthy cells turn cancerous in order to develop treatments that interrupt that process. Janssen has earned worldwide recognition for its innovation and leadership in this area. The theory behind interception is that finding pre-malignant cells will allow us to target them before they become more aggressive and resistant to treatment.



We're currently exploring biological precursors that allow us to measure abnormalities before a person has clinical symptoms of cancer. For example, we are pursuing and pioneering research in smoldering myeloma and colorectal cancer, as we look to identify other diseases for interception strategies.

## Immune Therapy

One of the most significant advancements in treating cancer has been the advent of Immuno-Oncology (I-O), harnessing the body's immune system to fight cancer. Identifying how to leverage a patient's immune system through addressing immune exhaustion, evasion, and resistance is a key capability and part of our focus on both patients with advanced cancer and cancer interception. This focus has led Janssen Oncology to form a dedicated, multi-functional team entirely focused on Immune Therapy research to explore new ways we can harness the immune system against cancer. This approach includes chimeric antigen receptor-T cell (CAR-T) therapy, T cell redirection, vaccines and more.

## A Novel Oncolytic Virus Platform

The acquisition of BeneVir Biopharma, Inc., a small research-based company in Maryland, gives Janssen Oncology a best-in-class technology called T-Stealth™ Oncolytic Virus Platform that allows oncolytic viruses to be tailored to avoid destruction by the body's immune system. Viruses stimulate the immune system, which eliminates them as foreign bodies. By avoiding this process, the new technology platform allows the therapeutic virus to spread further and persist longer in tumors, thus inducing an improved anti-tumor immune response.

The platform also enables the simultaneous delivery of multiple immune-modulating agents. These engineered viruses are intended to infect and directly destroy cancer cells, mobilize the immune system to hunt down and destroy solid tumor cells throughout the body, and enhance the effectiveness of other immunotherapies.



## The Potential of Diagnostics and Biomarkers

- We see enormous potential in the use of companion diagnostics to help identify patients who are most likely to respond to a therapy, to achieve the best outcomes with one of our therapies or to experience an adverse event. As part of this effort, we are developing predictive biomarkers to guide targeted, personalized treatment options for different cancers.
- There is also strong scientific support that the earlier cancer is diagnosed and potentially treated, the more favorable the potential outcome. We are advancing digital tools to measure signs and symptoms of disease so that cancer can be diagnosed and intercepted at the earliest phases of malignancy to improve chances of a more favorable outcome.

## Our Areas of Focus

Janssen Oncology's research, development and collaborative efforts are focused in areas where our deep expertise, understanding of disease biology and scientific innovation can be concentrated on specific tumor types with the greatest need for new treatment options.

## Hematologic Malignancies (Blood Cancers)

**There has been significant progress in the treatment of people diagnosed with blood cancers over the past 40 years. Our leadership has advanced transformative therapies for hematologic malignancies, and we are committed to continuing to lead in the evolution of our understanding and treatment of these diseases, including targeting pediatric tumors in hematologic malignancies.**

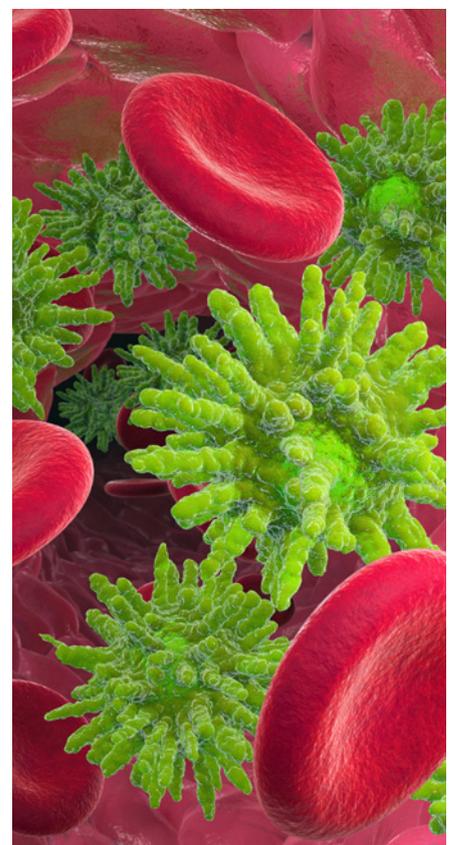
To that end, we are developing comprehensive regimens in B cell malignancies, myeloid malignancies and multiple myeloma. We also are working on ways to enhance the ability of the immune system to kill cancer cells.

### Multiple Myeloma

Until recently, progress in treating multiple myeloma had focused on extending survival through stem cell transplants and targeted therapies. We developed a globally approved therapy that reduces the risk of disease progression and increases time in remission for patients who previously had few options. We are leveraging our extensive understanding of hematologic malignancies to research and develop immune-based therapies that uniquely target multiple myeloma.

### Amyloidosis

Amyloidosis is a rare and serious disease in which amyloid protein builds up in tissues or organs and eventually can lead to organ failure. Our work focuses on better



understanding the disease and on whether standard of care plus a new, subcutaneous version of an existing therapy for other hematologic malignancies will benefit patients.

## B cell Malignancies

We collaborated to pioneer the development of a globally approved, first-in-class treatment for certain B cell malignancies, including chronic lymphocytic leukemia, previously treated mantle cell lymphoma, Waldenstrom's macroglobulinemia and previously treated marginal zone lymphoma. Using our full array of strategic research approaches, we are continuing to innovate to advance care and provide new treatment options for these malignancies, as well as for diffuse large B cell lymphoma and follicular lymphoma.

## Myeloid Malignancies

Acute myeloid leukemia (AML) is a disease of the bone marrow that can quickly spread to the blood. Our focus is to better understand existing

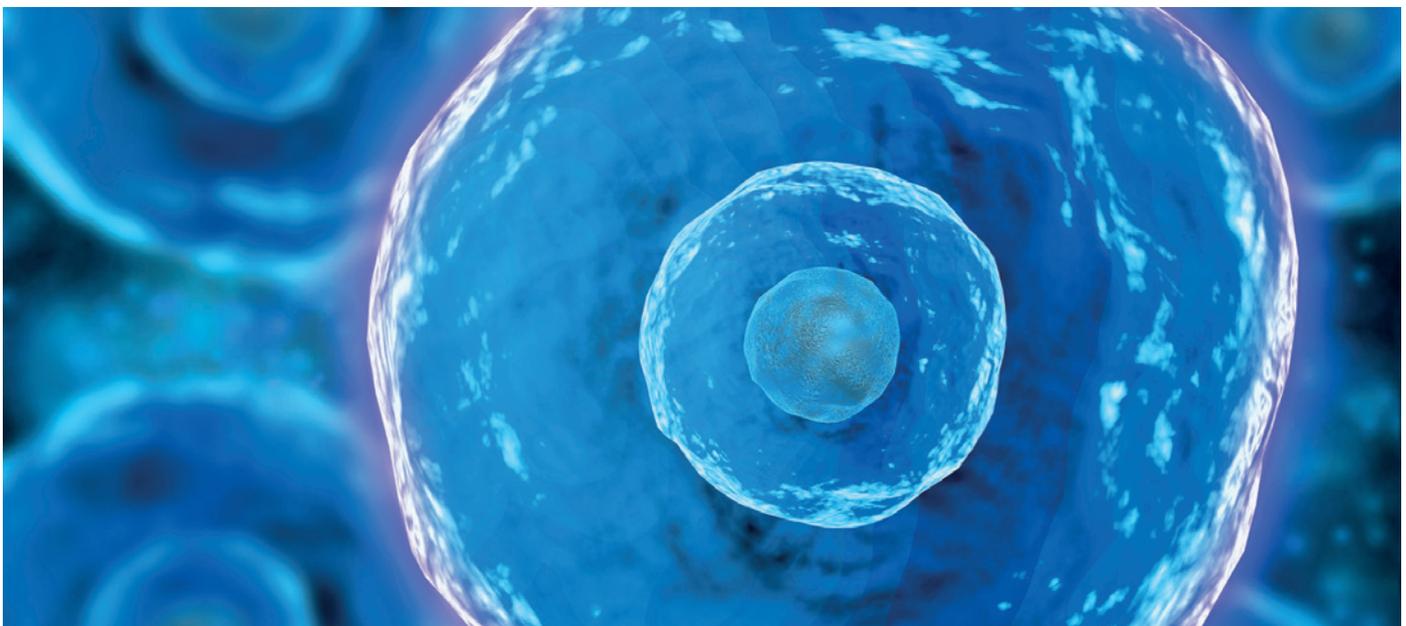


therapies and certain bone marrow factors that make patients resistant to standard treatment and to research new ways to overcome resistance.

Myelodysplastic syndromes (MDS) are disorders in which the bone marrow does not produce enough healthy blood cells, leading to anemia and the need for blood transfusions. We developed the first erythropoiesis-stimulating agents approved to treat anemia in patients with MDS and reduce the number

of transfusions to improve quality of life in lower-risk MDS patients.

We are committed to bringing forth new treatment options for patients with AML and MDS and have advanced a comprehensive development program that includes novel bispecific approaches as well as a promising antibody targeting an immune checkpoint involved in hematological malignancies. Preclinical work is underway on other promising compounds.

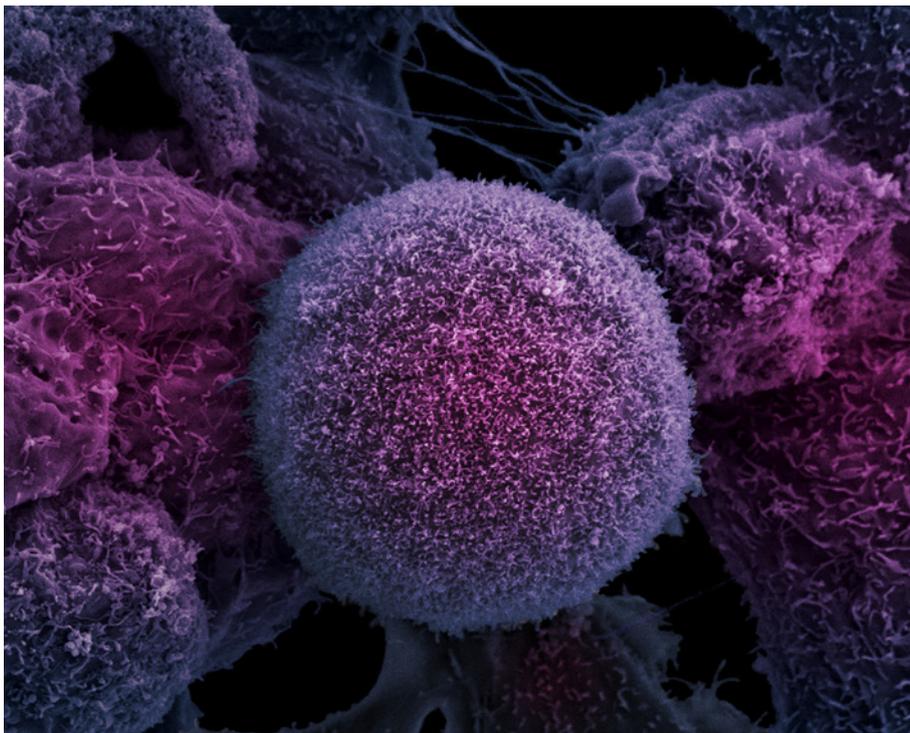


# Prostate Cancer

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**Janssen has built a legacy of innovation in the treatment of prostate cancer beginning with the development of a novel agent for patients with metastatic castration-resistant prostate cancer and, more recently, for patients with high-risk metastatic castration-sensitive prostate cancer. We are driven by the fact that, for patients with advanced disease and for those at high-risk of developing castration-resistant prostate cancer, this is a deadly illness.**

Through over a decade of work, we have progressed our understanding of the biology underpinning various types of prostate cancer, progressing research from groundbreaking innovations in late-stage treatments to intervening earlier in the disease. Our work to advance next-generation treatments has resulted in a first-in-class therapy for patients with non-metastatic castration-resistant prostate cancer.



Our development programs also include intervening earlier before patients become castration-resistant and to one day stop prostate cancer from spreading entirely by focusing on high-risk localized disease.

We continue to innovate leveraging novel endpoints to bring new transformational therapies to patients. Our approach includes evaluating the benefits of combining therapies in our portfolio, as well as bringing novel compounds into clinical development with the goal of extending life and helping patients enjoy the highest possible quality of life.

# Solid Tumor Targeted Therapy

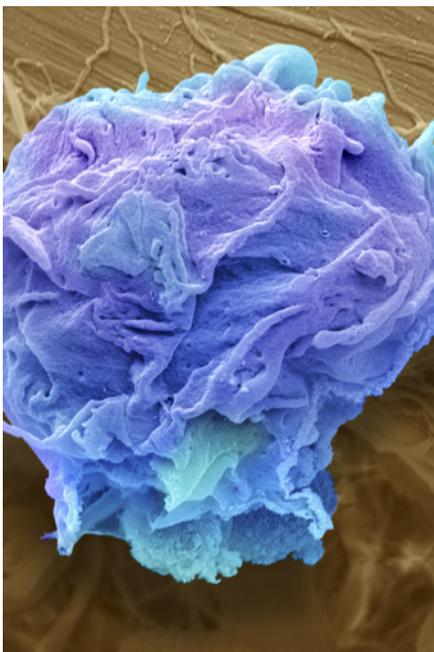
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## Lung Cancer

We are committed to leading a paradigm shift in the treatment of lung cancer, targeting the complex nature of the disease by interfering with multiple disease mechanisms.

**Our strategy involves three distinct therapeutic approaches to lung cancer: targeted therapy with small and large molecules, bispecifics designed to affect two different targets, and vaccine-based therapy.**

Our focus includes research and development efforts on non-small cell lung cancer (squamous and adenocarcinoma) as well as small cell lung cancer.



## Urothelial Cancer (Bladder Cancer)

Despite available therapies, there is a high unmet need based on the prevalence of poor outcomes.

**We are focusing on better understanding the drivers of urothelial cancer so that we can leverage targeted therapies alone and in combination to improve outcomes.**

## Colorectal Cancer

**In colorectal cancer, we are exploring stem cell properties, including how they self-renew, and the related hypothesis that tumors are proliferated by a type of cancer stem cell.**

We are also pursuing ways to prevent and arrest the development of malignancies of the colon and rectum by diagnosing and treating precursor lesions.

We focus our efforts where the need is great, the science is compelling, and there is the greatest opportunity to help people live longer, healthier lives.

## Hematologic Malignancies (Blood Cancers)

### Multiple Myeloma<sup>iii</sup>

- Second most common blood cancer
- Nearly 160,000 new cases diagnosed worldwide every year

### Amyloidosis<sup>iv</sup>

- An estimated 4000 new cases annually in the US
- Actual incidence may be higher due to under-diagnosis
- Can lead to life-threatening organ failure

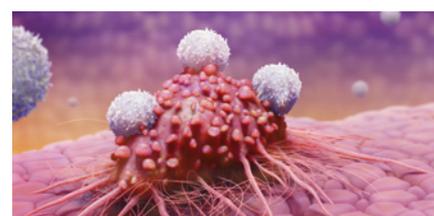
### B Cell Malignancies

- Chronic lymphocytic leukemia – most common form of leukemia in western world<sup>v</sup>
- Mantle cell lymphoma – a rare, aggressive lymphoma with average survival rate of 6-7 years<sup>vi</sup>

- Waldenstrom’s macroglobulinemia – a rare, slow-growing type of non-Hodgkin lymphoma (NHL) that occurs in less than 2% of patients with NHL<sup>vii</sup>
- Marginal zone lymphoma – slow-growing lymphoma that accounts for 8% of NHL patients<sup>viii</sup>
- Diffuse large B cell lymphoma – fast-growing type of NHL, accounting for up to 40% of all cases worldwide<sup>ix</sup>
- Follicular lymphoma – slow-growing form of NHL, accounting for 20-30% of all cases<sup>x</sup>

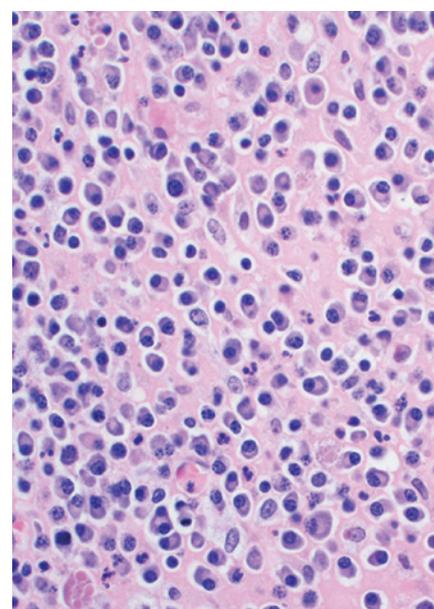
### Acute Myeloid Leukemia (AML)

- Resistant to several standard therapies; patients often relapse with poor prognosis
- 5-year overall survival rate of only 24%<sup>xi</sup>



### Myelodysplastic Syndromes (MDS)

- High-risk MDS is very similar to AML
- Approximately 60-80% of patients experience symptomatic anemia, significantly reducing quality of life<sup>xii</sup>
- Often requires repeated blood transfusions



# Prostate Cancer

- Second most common cancer in men worldwide<sup>xiii</sup>

## Localized Prostate Cancer (LPC)<sup>xiv</sup>

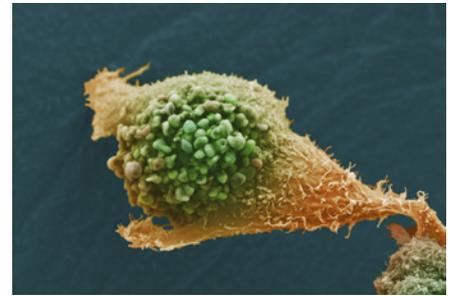
- 91% of prostate cancers discovered at localized stage when cancer is only inside the prostate gland
- High unmet need in LPC, as some men with high-risk disease experience early metastasis even after aggressive local treatments<sup>xv</sup>
- 5-year high-risk LPC PSA relapse-free survival rates range from 55-71%, indicating potential for metastatic relapse<sup>xvi</sup>

## Metastatic Castration-Sensitive Prostate Cancer

- Also known as metastatic hormone-sensitive prostate cancer
- Typically responds to testosterone suppression therapy and chemotherapy
- Patients with newly identified metastatic disease, either at first diagnosis or following prior local therapy, have a poorer prognosis<sup>xvii</sup>

## Non-Metastatic Castration-Resistant Prostate Cancer

- No longer responds to medical or surgical treatments that lower testosterone but has not been discovered in other parts of the body<sup>xviii</sup>



- 90% will develop bone metastases, which can lead to pain, fractures and spinal cord compression<sup>xix</sup>
- Median overall survival is less than 5 years<sup>xx</sup>

## Metastatic Castration-Resistant Prostate Cancer

- Has spread to other parts of the body
- No longer responds to a medical or surgical treatment that lowers testosterone
- Median overall survival is less than 3 years in chemotherapy-naïve men<sup>xxi</sup>

# Solid Tumor Targeted Therapy

## Lung Cancer<sup>xxii</sup>

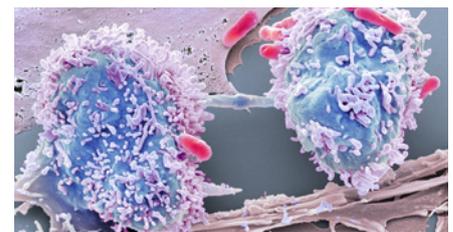
- Leading cause of cancer deaths worldwide
- Second most common cancer in both men and women
- Claims more lives than colon, breast and prostate cancers combined
- More than 2 million people worldwide diagnosed with lung cancer in 2018; about 85% of lung

cancers are non-small cell lung cancer (NSCLC)<sup>xxiii</sup>

- Overall survival rate is very low for NSCLC – 23%<sup>xxiv</sup>

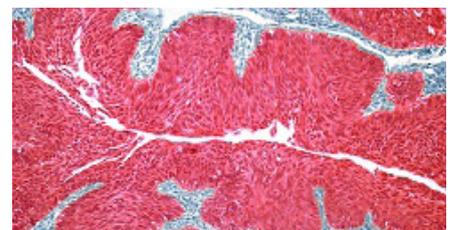
## Urothelial Cancer (Bladder Cancer)<sup>xxv</sup>

- 10th most common cancer worldwide
- An estimated 550,000 new cases diagnosed in 2018 alone



## Colorectal Cancer<sup>xxvi</sup>

- Third leading cause of cancer deaths worldwide
- 1.8 million cases in 2018



# Seeking the Best Collaborations to Find Cures

We seek medical breakthroughs wherever they occur. We leverage our internal expertise and embrace external science to bring forth truly transformational solutions.

**We are dedicated to collaborating with partners across the globe who share our vision to make cancer a preventable and curable disease by providing transformational therapeutic and diagnostic products and resources.**

Based on the belief that collaborations are essential to drive change and innovation, we seek strategic partnerships that bring new ideas and fresh approaches to understand, treat and intercept cancer.

Janssen Oncology is committed to ensuring the success of our collaborations. Our Johnson & Johnson Innovation and Janssen

Business Development teams bring scientific, funding and commercialization expertise to engage at all levels of research and development and the product life cycle process. Our flexible structure enables us to be agile and work effectively with a variety of partners to create the best business model for each collaboration. We work globally and regionally to foster promising early-stage opportunities and establish collaborations in which each partner brings unique strengths and experiences to the table so that together we can achieve more than either could alone.

## The Resources and Expertise to Deliver New Advances in Cancer

We have decades of experience in successfully bringing transformational cancer medicines to market, from research in the lab to our state-of-the-art development and commercialization capabilities. As part of the Janssen Pharmaceutical Companies of Johnson & Johnson, our team of world-class experts in oncology research and development has access to tremendous global resources. Our end-to-end capabilities are integrated and strategically aligned to effectively manage the complexities of the global drug discovery and development process. These include the ability to work with partners to rapidly advance ideas, to take local market and regulatory realities into consideration and to help reduce the cycle time from laboratory to patient. We have teams intensely focused on specific cancers with fully dedicated groups for each compound. Complementing them are global centers of excellence in biomarkers, companion diagnostics, biologics, and global marketing. These are further enhanced by local expertise in regulatory and medical affairs.



## Johnson & Johnson INNOVATION

Johnson & Johnson Innovation brings together business development, venture investment, incubation and research and development resources from across the company to advance science and technology at all stages of innovation.

This innovation network identifies the right partnerships and deal structures and allows innovators to leverage the many resources of Johnson & Johnson. We believe that the right kind of support for new ideas is critical to driving innovation and achieving our goals to transform world health.



### **JLABS and JPODS**

Help companies get up and running by providing a number of company incubation options.

### **Johnson & Johnson Innovation Centers**

Teams located in the life sciences hot spots of Shanghai, Boston, California and London identify opportunities from academics and early-stage companies who want to accelerate novel programs through collaborations. Each center houses science and technology experts and has broad deal-making capabilities.

### **Johnson & Johnson Innovation – JJDC, Inc. (JJDC)**

Invests in emerging life sciences companies developing healthcare solutions in areas of strategic interest to the Johnson & Johnson Family of Companies. Investments range from seed funding and Series A investments in the earliest-stage startups to Series B investments and beyond in more mature companies, each deal customized to fit the opportunity.

### **Johnson & Johnson Innovation | Janssen Business Development**

A decentralized approach combines an entrepreneurial drive for growth and proximity to customers with the resources, know-how and investment capital of a well-respected Fortune 500 company. This approach creates a strong sense of ownership and accountability with the goal of bringing the full strengths of Johnson & Johnson to bear to create long and valuable relationships.

## Our Team – Leading the Fight Against Cancer



I am grateful to be part of the Janssen Oncology team that works with such intentional focus and relentless effort to discover and develop the next generation of paradigm-changing treatments; therapies that will not only change the way oncologists practice, but will hopefully one day lead to cures.



**Jeff Infante, MD**  
Vice President, Oncology  
Early Development



**At Janssen Oncology, we share a deep passion for scientific innovation and for bringing together the best expertise worldwide to make promising treatments available to patients who are waiting for them.**

Our global research and development program is driven by world-class experts in oncology, with diverse experience in clinical medicine, academia and drug discovery and development. Every member of our team is deeply committed to changing the trajectory of health for people with cancer.

The Janssen Oncology team is breaking new ground and charting unexplored territory every day, developing innovative approaches to intercept cancer and move toward cures. Our unique teamwork-driven approach to discovery and innovation is leading to transformational breakthroughs in the fight against cancer.

We cherish unique perspectives because enormous problem-solving potential is unleashed when diverse minds work together. Consequently, cross-functional teamwork plays a vital role in oncology research.

Our Credo guides our decision making and challenges us to put the needs and well-being of the people we serve first. At Janssen Oncology, we lead with integrity to think critically and take innovative approaches to combating cancer.

**If you want to make groundbreaking contributions to cancer research, treatment and prevention, see how you can join us in the fight against cancer at <https://jobs.jnj.com/>**



### **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

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# Contact Us

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