

Janssen Oncology

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Janssen Oncology—leading the way in transformational innovation

With a focus on detecting, intercepting, treating, and ultimately curing cancer, Janssen Oncology is advancing science and solutions in hematologic malignancies and solid tumors through an innovative strategic partnering approach.

Janssen Research & Development, LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson and one of the world's leaders in oncology, is focused on harnessing the most compelling science with the aim of intercepting, preventing, treating, and ultimately curing cancer. Working toward this bold vision of eliminating cancer, its oncology group is executing on a strategy that capitalizes on the company's global resources, scientific expertise, research capabilities, and alliances. With a focus on hematologic malignancies, prostate cancer, lung cancer, bladder cancer, and colorectal cancer, Janssen continually seeks to expand its portfolio of cancer solutions through strategic partnerships across industry and academia.

"At Janssen, we are focused on specific tumor types with great unmet needs where we believe our advanced understanding of disease biology and our scientific expertise can deliver innovative treatments for patients," said Peter Lebowitz, global head of oncology at Janssen Research & Development. "Based on our belief that collaboration is essential to drive change and innovation, we are dedicated to collaborating with strategic partners across the globe who share our vision to make cancer a preventable and curable disease."

Over the past ten years, Janssen has advanced ten new oncology drugs through regulatory approval, including several first-in-class medicines (Fig. 1). Among these are the first fully human bispecific antibody for lung cancer, the first Bruton's tyrosine kinase (BTK) inhibitor for B cell malignancies, the first monoclonal antibody approved for multiple myeloma, and the first CYP17 inhibitor for prostate cancer. The company's current portfolio includes a diverse array of modalities—small molecules, multi-specific antibodies, T cell-based therapies, oncolytic viruses, vaccines, and induced pluripotent stem cells—complemented by novel drug-delivery technologies and data science platforms.

Setting the stage

Janssen has built its portfolio through a process of open and continuous innovation. This is true when it comes to designing drug development programs, pushing understanding of the biology of disease, or collaborating with partners to bring new cancer medicines to market by leveraging the company's extensive global resources (Fig. 2).

Traditionally, cancer research and drug development have focused on improving detection and refining treatment to ameliorate disease. Janssen

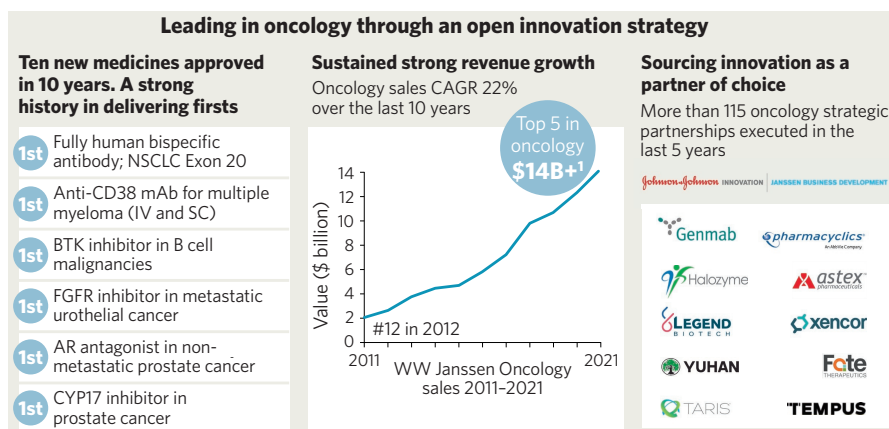


Fig. 1 | Leading in oncology through an open innovation strategy. Over the past ten years, Janssen has advanced a portfolio of firsts in oncology that has solidified the company's position as a leader and partner of choice in the field. AR, androgen receptor; BTK, Bruton's tyrosine kinase; FGFR, fibroblast growth factor receptor; mAb, monoclonal antibody; NSCLC, non-small cell lung cancer.

has expanded this view by pushing the horizons for intervention further upstream and focusing on cancer interception to stop healthy cells from turning cancerous in the first place. Its team of scientists is pioneering both the identification of cellular and molecular signals leading to cancerous states and the development of treatments aimed at stopping these processes. The group continues to be a leader in cancer interception with programs in myeloma and colorectal cancer and exploratory programs in other cancers.

A second front in which the company is uniquely positioned is interventional oncology, the integrated development of drugs, and devices to create novel therapeutic solutions. In particular, interventional oncology offers an opportunity to optimize drug delivery both physically—by delivering drugs directly to the right place—and temporally—by affording sustained dosage over days, weeks or months. Johnson & Johnson is advancing this aspect of its innovation pipeline by bringing together expertise in pharmaceuticals and medical devices, and through an extensive external partner network. Technologies in development include versatile intra-vesicular drug-delivery or robotic devices (for example, bronchoscopy) to facilitate detection, diagnosis, and treatment.

And on the partnering front, Janssen has been equally innovative. Its differentiated approach is based on 'aiming higher and thinking broader' to build full approach platforms and technologies in

key disease areas. Janssen looks for partnerships where the sum is greater than the parts—a synergistic focus that benefits both parties. As part of Johnson & Johnson, Janssen can leverage an array of resources to tailor each collaboration to the specific needs of the program and the partners. These resources include the Janssen Business Development group and, under the umbrella of Johnson & Johnson Innovation, the company's incubators JLABS and JPODS, innovation centers located in Shanghai, Boston, South San Francisco, and London, and JJDC, its strategic venture capital arm. The company's end-to-end capabilities are integrated and strategically leveraged to effectively accelerate partnerships while managing the complexities of the global drug discovery and development process.

A focus on disease

Janssen's vision is built around a simple notion—cure cancers with great unmet needs. The company's approach is not asset-, target-, modality-, platform-, or even partnership model-centric. Instead, all strategic decisions are centered around developing the most comprehensive solutions to conquer specific types of cancer.

"Our strategy addresses the entire disease continuum, from pre-cancerous to advanced stages, and seeks to harness the necessary approaches to detect, intercept, prevent, treat, and eradicate specific cancers," said Lebowitz. "Driven by this strategy,

we are now advancing a wide range of therapies and developing comprehensive regimens to address select hematological cancers and solid tumors.”

• **Multiple myeloma.** Multiple myeloma (MM) is a complex disease that requires complementary therapeutics to achieve durable remission. Rooted in a deep understanding of the biology of MM, Janssen is advancing a portfolio of therapies, including monoclonal antibodies, chimeric antigen receptor (CAR) T cells, and bispecific T cell engagers, with an eye toward early intervention. A focal point of the MM program is to develop approaches that in combination may yield synergistic curative effects. Specifically, the company's CAR-T cell therapies and bispecific T cell engagers are expected to complement current standard of care therapy by providing opportunities to tailor treatment to a patient's disease, response to therapy, and preferences.

• **Going deeper in MM science.** Together with Legend Biotech, Janssen is developing a CAR-T cell therapy in MM. Janssen views this single asset collaboration as a foundational component of potential future integrated solutions within its larger hematologic malignancy program. The CAR-T cell therapy is undergoing regulatory reviews in multiple countries.

• **B cell malignancies.** B cell malignancies comprise a heterogeneous group of cancers that originate at different stages of the B cell differentiation process and thus require treatments that can address different disease presentations. Janssen pioneered the co-development of a globally approved, first-in-class treatment for certain B cell malignancies, including chronic lymphocytic leukemia, previously treated mantle cell lymphoma, Waldenström's macroglobulinemia and previously treated marginal zone lymphoma. Ongoing programs include immunotherapies that target novel antigens in combination regimens for the above malignancies and several additional indications, including several types of lymphoma.

• **Myeloid malignancies.** Myeloid malignancies are clonal hematopoietic disorders caused by different genetic and epigenetic changes in hematopoietic stem cells and functional changes in bone marrow. Janssen is pursuing programs in acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). In AML, a disease of the bone marrow that can quickly spread to the blood, the company is developing new ways to overcome the emergence of intrinsic and/or acquired resistance to standard of care treatments, a major hurdle to the therapeutic management of AML. In MDS, a disorder in which the bone marrow does not produce enough healthy blood cells, Janssen developed the first erythropoiesis-stimulating agent approved to treat MDS-associated anemia in lower-risk MDS patients. Ongoing comprehensive development programs for AML and MDS include novel targets and bispecific approaches.

• **Prostate cancer.** Worldwide, prostate cancer is the second most common cancer in men. Since the approval in 2011 of the company's first-in-class CYP17 inhibitor for the treatment of metastatic castration-resistant prostate cancer (CRPC), Janssen has continued to develop a comprehensive program of prostate cancer therapies that includes an androgen-receptor inhibitor, a poly-ADP ribose polymerase (PARP) inhibitor,

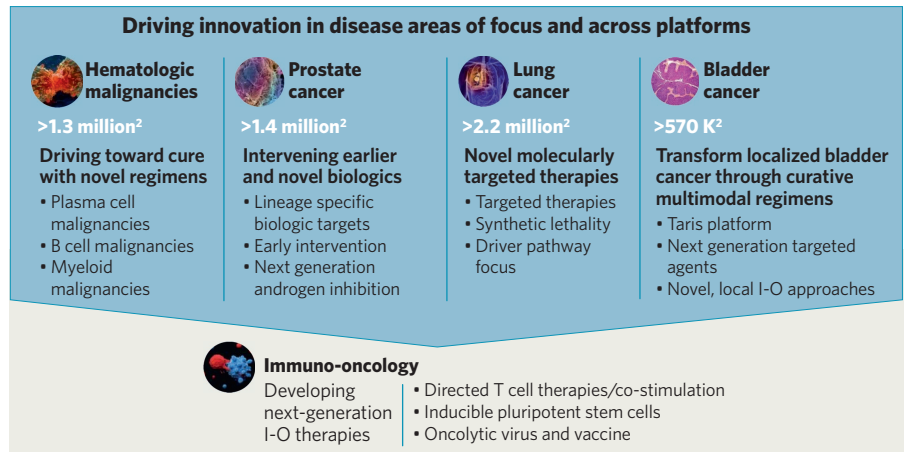


Fig. 2 | Driving innovation in disease areas of focus and across platforms. Janssen is advancing science with the goal of intercepting cancer and delivering cures. I-O, immuno-oncology.

several biologics, CAR-T cells, and antibody-drug conjugates, aiming to address the entire disease continuum from early, localized disease to late-stage metastatic prostate cancer. In addition to the different disease stages, Janssen's prostate cancer program addresses different types of the disease. The company's portfolio includes agents for non-metastatic CRPC and for metastatic castration-sensitive prostate cancer (CSPC), two first-in-class registration programs in high-risk localized prostate cancer combining hormonal therapy with radiation and radical prostatectomy, and biomarker-informed therapeutics for prostate cancers with underlying DNA repair defects.

• **Building toward the next generation in prostate cancer.** In collaboration with Xencor, Janssen is advancing next-generation bispecific antibodies designed to simultaneously bind to a prostate cancer-specific antigen and to a T cell-specific antigen. By physically bridging the distance between target tumor cells and effector immune cells, bispecific antibodies help engage T cells with the tumor and activate a powerful directed immune response. Bispecific antibodies represent a cornerstone of Janssen's immunotherapy strategy—indeed, the company has already expanded its partnership with Xencor to the area of B cell malignancies.

• **Bladder cancer.** Bladder cancers are highly treatable tumors albeit with high risk of recurrence that require long term monitoring. Building on the approval of its fibroblast growth factor receptor kinase inhibitor, Janssen is pursuing treatment strategies across all stages of the disease. In particular, the company is focused on advancing novel bladder-sparing technologies that could help improve the long-term outlook for patients.

• **Targeting disease locally.** Through its acquisition of Taris Biomedical, Janssen is progressing an innovative drug-eluting device that can deliver medication locally to the bladder. Janssen envisions this novel platform as a key for developing comprehensive and potentially transformative solutions not only for the treatment of early bladder cancer but also for prevention, and ultimately, interception of the disease.

• **Lung cancer.** Small-cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC), the two main types of lung cancer, are the leading cause of cancer mortality worldwide. On the back of the recent

approval of its first-in-class targeted treatment for patients with NSCLC with a specific genetic mutation, Janssen is continuing to develop a portfolio of lung cancer interventions that target the complex nature of the disease by interfering with multiple disease mechanisms. Specifically, the company is advancing targeted therapies with small and large molecules, multi-specific antibodies designed to affect multiple targets simultaneously, and vaccines, with a focus on both squamous and adenocarcinoma NSCLC and SCLC.

Understanding the biology of disease and creating regimens that drive towards cure are tenets of Janssen's oncology innovation strategy. Bridging the gap between both is data science, a constant effort to extract and apply the best knowledge and actionable insights from high dimensional data to guide the company's development programs from inception through commercialization. For Janssen, data science is key in areas such as novel target identification, including at the single cell level—the design of innovative immuno-oncology strategies, patient stratification to improve clinical study outcomes, enhancing therapeutic potential of new cell therapies, building effective neoantigen-targeting vaccines, personalized medicine—and is built into virtually all of Janssen's programs, as an enabler of guided treatment.

“Our robust and diverse pipeline is built around the synergy that emerges from approaching cancer from different angles simultaneously, and through open and continuous innovation,” said Lebowitz. “Our ultimate goal is to eliminate cancer by delivering transformational regimens to achieve cures and/or intercept disease, and we aim to do this through science, ingenuity, and heart to benefit patients everywhere.”

1. Investors section of the JNJ.com

2. World Health Organization, International Agency for Research on Cancer, Cancer Tomorrow data visualization, 2020.

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