

Japan Immunosuppressant Drugs Market By Drug Class (Calcineurin Inhibitors, Antiproliferative Agents, MTOR Inhibitor, Steroids, and Others), By Application (Autoimmune Diseases, Organ Transplant, and Others), By Distribution Channel (Hospital Pharmacies, Retail Pharmacies, and Online Pharmacies), By Region, Competition, Forecast & Opportunities, 2020-2030F

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### **Report description:**

Japan Immunosuppressant Drugs Market was valued at USD 304.31 Million in 2024 and is expected to reach USD 419.18 Million by 2030 with a CAGR of 5.44% during the forecast period. The Japan Immunosuppressant Drugs Market is driven by several key factors. The rising prevalence of autoimmune diseases, organ transplants, and certain cancers necessitates effective immunosuppressive treatments. Japan's aging population further contributes to the demand, as older individuals are more likely to require organ transplants and face autoimmune disorders. Advances in immunosuppressive drug formulations and the introduction of targeted therapies improve treatment efficacy and patient outcomes, fueling market growth. Increased awareness and improved diagnostics for autoimmune conditions lead to earlier and more frequent use of immunosuppressants. Regulatory support and healthcare investments in Japan also enhance access to advanced therapies, driving the market forward. These combined factors ensure a growing and dynamic landscape for immunosuppressant drugs in Japan. Key Market Drivers

### Rising Prevalence of Autoimmune Diseases

The increasing incidence of autoimmune diseases in Japan is a major driver of the demand for immunosuppressant drugs, reflecting a growing healthcare challenge that requires effective management solutions. Autoimmune diseases, such as rheumatoid arthritis, lupus, and multiple sclerosis, occur when the body's immune system erroneously targets and attacks its own tissues. This misguided immune response leads to chronic inflammation, tissue damage, and a range of debilitating symptoms that necessitate long-term treatment with immunosuppressive medications. The rise in autoimmune conditions can be attributed

to a complex interplay of factors, including genetic predispositions, environmental exposures, and lifestyle changes. According to a study in "High incidence of autoimmune disease in Japanese patients with ocular adnexal reactive lymphoid hyperplasia", the authors examined the incidence of autoimmune disease among 88 patients with primary ocular adnexal lymphoid proliferations. Southern blot analysis was employed to assess B-cell clonality in reactive lymphoid hyperplasia (RLH) linked to autoimmune disease. Histopathological findings revealed that 15 (17%) patients had RLH, 62 (70%) had mucosa-associated lymphoid tissue lymphoma (MALToma), and 11 (13%) had primary lymphomas. Among these, autoimmune disease was found in seven (47%) of the 15 patients with RLH, two (3%) of the 62 patients with MALToma, and none (0%) of the 11 patients with primary lymphoma. B-cell clonality was observed in one (14%) of the seven RLH patients with autoimmune disease.

Japan has seen a notable increase in the prevalence of autoimmune diseases, driven by both genetic factors and modern lifestyle changes. Genetic predispositions play a crucial role, as certain genetic markers can increase susceptibility to autoimmune disorders. Environmental influences such as exposure to pollutants, infections, and dietary factors contribute to the development and exacerbation of these conditions. Lifestyle changes, including increased stress levels and sedentary behavior, have also been linked to a higher incidence of autoimmune diseases. The growing number of patients diagnosed with autoimmune disorders underscores the urgent need for effective immunosuppressive therapies. These conditions often require ongoing management to control symptoms, reduce inflammation, and prevent further tissue damage. Immunosuppressant drugs are critical in this regard, as they help modulate the immune response, thereby reducing the severity of symptoms and improving the quality of life for patients. The demand for these medications has consequently risen, as healthcare providers and patients seek effective treatments to manage chronic autoimmune conditions.

### Increasing Awareness and Early Diagnosis

Enhanced awareness and early diagnosis of autoimmune diseases and transplant needs are pivotal factors driving the growth of the Japan Immunosuppressant Drugs Market. Increased public health campaigns, educational initiatives, and outreach efforts have significantly improved understanding and recognition of autoimmune disorders and the critical role of immunosuppressive therapies. This heightened awareness has led to earlier detection and intervention, which are crucial for effective disease management. Public health campaigns and educational programs have played a significant role in elevating awareness about autoimmune diseases and the necessity for early diagnosis. By disseminating information about the symptoms, risk factors, and treatment options for conditions like rheumatoid arthritis, lupus, and multiple sclerosis, these initiatives have empowered both patients and healthcare providers. Improved knowledge enables individuals to seek medical attention sooner, leading to earlier diagnosis and intervention. For autoimmune diseases, early diagnosis is critical as it allows for the prompt initiation of immunosuppressive therapies, which can substantially improve treatment outcomes and enhance the quality of life for patients. Educational efforts targeted at healthcare providers have resulted in more accurate and comprehensive management of autoimmune diseases and transplant patients. Training programs, conferences, and workshops have equipped medical professionals with the latest knowledge and techniques for diagnosing and treating these conditions. This increased competency in healthcare providers ensures that patients receive appropriate and effective immunosuppressive treatments tailored to their specific needs. Consequently, there is a more precise approach to disease management, which translates into better patient outcomes and drives demand for immunosuppressant drugs. Advancements in diagnostic technologies have further contributed to the growth of the Japan Immunosuppressant Drugs Market by facilitating earlier and more accurate detection of autoimmune diseases and transplant needs. Innovations in diagnostic tools, such as advanced biomarkers, imaging techniques, and genetic testing, have made it possible to identify these conditions at an earlier stage. Early detection is instrumental in preventing disease progression and initiating timely treatment, which is essential for managing chronic autoimmune disorders and ensuring successful transplant outcomes.

### **Rising Incidence of Cancer**

The increasing incidence of cancer in Japan significantly drives the demand for immunosuppressant drugs, particularly in the context of managing cancer-related complications and post-treatment care. As cancer rates rise, the need for effective immunosuppressive therapies has become more pronounced, highlighting the crucial role these drugs play in oncology. Cancer treatments, such as stem cell and bone marrow transplants, often necessitate the use of immunosuppressants. These therapies are designed to prevent the rejection of transplanted tissues and manage adverse effects that arise from aggressive cancer treatments. Immunosuppressants help mitigate the immune response that can target and destroy transplanted cells or tissues,

thereby increasing the likelihood of a successful transplant and improving overall treatment outcomes. This requirement for immunosuppressive therapy in oncology settings drives a substantial demand for these drugs.

The prevalence of cancer in Japan has been steadily increasing, driven by an aging population and lifestyle factors. As more individuals are diagnosed with various forms of cancer, there is a growing need for comprehensive treatment strategies that include immunosuppressive therapies. The complexity of cancer management often means that patients require a combination of treatments, including surgery, radiation therapy, chemotherapy, and immunosuppressive drugs. The rising cancer incidence therefore contributes to the expanding market for immunosuppressants.

Advances in oncology and hematology have led to a more frequent use of immunosuppressive therapies. Modern cancer treatments are increasingly sophisticated and may involve stem cell transplants or targeted therapies that require careful management of the patient's immune system. For instance, stem cell transplants are used to treat certain types of cancers, such as leukemia and lymphoma, and involve the administration of high-dose chemotherapy followed by stem cell infusion. The immune system's ability to accept these transplanted cells and prevent graft-versus-host disease (GVHD) is critical, and immunosuppressants are essential to achieving this balance. Similarly, bone marrow transplants and other advanced therapies also rely on immunosuppressive drugs to ensure that the transplant is successful and to minimize complications. Collaborative Research and Development

Collaborative research and development efforts between pharmaceutical companies, research institutions, and healthcare providers are pivotal in driving the growth of the Japan Immunosuppressant Drugs Market. These strategic partnerships play a crucial role in the advancement of new therapies, enhancing clinical research, and fostering innovation within the field of immunosuppressive treatments. Pharmaceutical companies, as key players in drug development, bring significant resources, expertise, and technological capabilities to the table. They are instrumental in the research and development (R&D) of new immunosuppressant drugs. By working with academic institutions and healthcare providers, these companies can leverage cutting-edge research and clinical insights to identify novel drug targets and develop innovative therapies. Their involvement ensures that new drugs are not only scientifically validated but also have practical applications in real-world settings. Research institutions, such as universities and specialized medical research centers, contribute valuable scientific knowledge and advanced research techniques. These institutions are often at the forefront of discovering new biological pathways, understanding disease mechanisms, and developing potential drug candidates. Collaborative projects between these institutions and pharmaceutical companies can lead to breakthroughs in immunosuppressive therapies. For instance, joint research efforts might focus on understanding the molecular basis of immune system regulation, which can lead to the development of more targeted and effective immunosuppressants. Healthcare providers play a critical role in translating research findings into clinical practice. Their involvement in collaborative research initiatives helps ensure that new therapies are relevant to patient needs and can be integrated into existing treatment protocols. Providers offer real-world insights into patient experiences, treatment outcomes, and the practical challenges of implementing new therapies. This feedback is invaluable for refining drug formulations, optimizing dosages, and improving overall treatment efficacy.

Key Market Challenges

High Cost of Immunosuppressant Drugs

The high cost associated with immunosuppressant drugs is a significant challenge in the Japan market. Innovative immunosuppressive therapies, including biologics and newer small molecules, often come with substantial price tags due to their complex development processes and advanced manufacturing techniques. These costs can be prohibitive, particularly for patients with chronic conditions requiring long-term treatment. Despite Japan's advanced healthcare system and government subsidies, the financial burden on patients and the healthcare system remains considerable. High drug prices can limit patient access, especially for those with inadequate insurance coverage or high out-of-pocket expenses. The cost of newer drugs is compounded by the ongoing need for frequent monitoring and potential management of side effects, further straining healthcare budgets. Efforts to address these issues include the development of biosimilars, which aim to offer more affordable alternatives to branded immunosuppressants. However, biosimilars can also be expensive due to regulatory and production complexities. Thus, balancing cost with the need for effective treatment remains a critical challenge for the Japan Immunosuppressant Drugs Market. Regulatory and Approval Processes

The regulatory and approval processes for immunosuppressant drugs in Japan can be complex and time-consuming, posing

challenges for market entry and innovation. The Japanese regulatory framework requires rigorous clinical trials and extensive documentation to demonstrate the safety and efficacy of new drugs. This process can delay the availability of innovative therapies and increase the costs of drug development. The need for extensive data on long-term safety and effectiveness often extends the approval timeline. Navigating regulatory requirements, including those related to biosimilars and new drug formulations, adds another layer of complexity. While Japan has a robust regulatory system to ensure high standards of drug safety, the stringent requirements can sometimes hinder the timely introduction of new treatments and limit market competition. Pharmaceutical companies must invest significant resources to meet regulatory standards, which can impact the overall pace of innovation in the Japan Immunosuppressant Drugs Market.

### Key Market Trends

### Advancements in Drug Formulations

Innovations in immunosuppressant drug formulations are significantly influencing the growth of the Japan market by offering more effective and targeted treatments with enhanced safety profiles. The evolution of drug development has led to the creation of advanced immunosuppressive therapies, which are instrumental in managing autoimmune diseases and preventing organ rejection. These innovations not only improve clinical outcomes but also address specific patient needs and contribute to the market's expansion. Recent advancements have introduced novel biologics and small molecules, each designed to target specific aspects of immune system function. Biologics, including monoclonal antibodies and fusion proteins, offer precision in targeting immune cells involved in autoimmune diseases or transplant rejection. These therapies provide better efficacy by specifically modulating immune responses, thus improving disease management. For instance, monoclonal antibodies can selectively inhibit the activity of immune cells or cytokines that contribute to inflammation, leading to reduced disease symptoms and improved patient outcomes. In November 2023, Aurinia Pharmaceuticals Inc. announced that its collaboration partner, Otsuka Pharmaceutical Ltd., has submitted a new drug application (NDA) to the Japanese Ministry of Health, Labour, and Welfare. This submission is for the approval of voclosporin, a second-generation oral calcineurin inhibitor, for the treatment of lupus nephritis (LN) in Japan. LN is a severe kidney complication associated with the autoimmune disease systemic lupus erythematosus (SLE). In January 2021, the U.S. Food and Drug Administration (FDA) approved voclosporin, in combination with a background immunosuppressive regimen, for treating active LN in adult patients. It is currently marketed in the U.S. under the brand name LUPKYNIS.

Small molecules, another class of innovative immunosuppressants, have been developed to interfere with intracellular signaling pathways crucial for immune activation. These drugs can precisely modulate immune responses at the cellular level, offering new treatment options for conditions resistant to traditional therapies. Small molecules often come with the advantage of oral administration, which enhances patient adherence compared to injectable formulations. Their development represents a significant leap forward in providing effective treatment options for chronic autoimmune conditions and transplant patients. Advancements in drug formulations have improved the pharmacokinetics of immunosuppressants, leading to better therapeutic outcomes and enhanced patient convenience. Improved pharmacokinetics means that the drugs are more effectively absorbed and utilized by the body, ensuring that they reach therapeutic levels more efficiently. This can result in more stable drug levels in the bloodstream, reducing the need for frequent dosing and minimizing fluctuations that might impact treatment efficacy. These enhancements are particularly important for patients requiring long-term immunosuppressive therapy, as they contribute to better disease management and fewer side effects.

### Growing Demand for Organ Transplantation

The expanding need for organ transplantation in Japan significantly drives the growth of the Japan Immunosuppressant Drugs Market. As medical technology and surgical techniques continue to advance, organ transplantation has become a viable and increasingly common treatment option for patients experiencing end-stage organ failure. This growing reliance on transplantation as a therapeutic strategy necessitates the use of effective immunosuppressive therapies to ensure the success of these procedures. Immunosuppressants are crucial for preventing organ rejection and maintaining the long-term viability of transplanted organs, making them an essential component of post-transplant care.

In Japan, the rising demand for organ transplants is fueled by several factors, including an aging population, increasing rates of chronic diseases such as diabetes and hypertension, and advancements in transplant surgical techniques. As the number of patients needing transplants grows, there is a corresponding increase in the requirement for immunosuppressant drugs to

manage and prevent complications associated with organ transplants. The effective management of transplant patients relies on these medications to suppress the recipient's immune system and prevent it from attacking the new organ. Japan's healthcare system has been actively investing in and expanding its transplant programs to address this rising need. Efforts have been made to improve access to organ donations and streamline the transplant process, thereby enhancing the overall success rates of these procedures. This focus on expanding transplant capabilities and improving patient outcomes directly drives the demand for immunosuppressant drugs. The more successful and frequent organ transplants become, the greater the need for effective immunosuppressive therapies to support these procedures. Advancements in immunosuppressive drug formulations play a pivotal role in supporting the growing demand for organ transplants. New formulations and targeted therapies have been developed to enhance transplant outcomes by providing more precise and effective immune system modulation. These innovations include the development of newer classes of immunosuppressants with improved efficacy and safety profiles, as well as advanced drug delivery systems that offer better patient compliance and convenience. Segmental Insights

# Drug Class Insights

Based on the Drug Class, Calcineurin Inhibitors are the dominant class of medications. These drugs, which include cyclosporine and tacrolimus, play a pivotal role in managing autoimmune diseases and post-transplant immunosuppression. Their dominance is attributed to their established efficacy, long history of use, and critical role in preventing organ rejection. Calcineurin inhibitors work by specifically targeting and inhibiting calcineurin, a protein phosphatase involved in the activation of T-cells, which are central to the immune response. By disrupting this process, calcineurin inhibitors effectively suppress the immune system's ability to attack transplanted organs or tissues, thereby reducing the risk of rejection and improving graft survival rates. This mechanism of action has made them the cornerstone of immunosuppressive therapy in transplantation.

In Japan, the high prevalence of organ transplants\_particularly kidney and liver transplants\_has significantly driven the demand for calcineurin inhibitors. The success of these drugs in enhancing graft survival has established their position as a first-line treatment. The long-standing clinical experience with these agents has provided a wealth of data supporting their safety and efficacy, contributing to their continued use and dominance in the market. While other classes of immunosuppressants, such as antiproliferative agents (e.g., mycophenolate mofetil), mTOR inhibitors (e.g., sirolimus), and steroids (e.g., prednisone), also play crucial roles in immunosuppressive therapy, calcineurin inhibitors maintain their leading position due to their essential role in the initial and maintenance phases of immunosuppressive therapy. Antiproliferative agents are often used in combination with calcineurin inhibitors to enhance efficacy and reduce the risk of side effects, but they do not replace the need for calcineurin inhibitors. Similarly, mTOR inhibitors and steroids are used adjunctively or in specific cases but have not surpassed calcineurin inhibitors in terms of overall market dominance.

### **Application Insights**

Based on Application, organ transplant is the dominant driver compared to autoimmune diseases. The need for immunosuppressants in organ transplantation has significantly shaped the market dynamics, overshadowing the role of autoimmune diseases. Organ transplantation in Japan has become a critical and increasingly common medical intervention for patients with end-stage organ failure. As advancements in medical technology and surgical techniques have improved the success rates of transplants, the demand for effective immunosuppressive therapies has grown correspondingly. Immunosuppressants are essential in preventing organ rejection, which remains a significant challenge in transplant medicine. They are administered to suppress the recipient's immune system, thereby reducing the risk of the immune system attacking the transplanted organ. This need for robust and effective immunosuppressive drugs has driven substantial market growth and innovation in this sector. The Japanese healthcare system has invested heavily in organ transplant programs and has made significant strides in improving organ donation rates and transplantation procedures. As a result, the volume of organ transplants performed annually has increased, creating a strong demand for immunosuppressants. Key types of transplants, such as kidney, liver, heart, and lung transplants, require prolonged and effective immunosuppressive therapy to ensure the long-term success of the transplanted organ and to minimize the risk of rejection. Calcineurin inhibitors, such as cyclosporine and tacrolimus, are the cornerstone of immunosuppressive therapy in transplantation. Their established efficacy in preventing acute rejection episodes and improving graft survival rates has made them the preferred choice among healthcare providers. These drugs are essential in both the induction phase immediately following the transplant and the maintenance phase to ensure ongoing immunosuppression. The

dominance of organ transplantation in driving the market for immunosuppressants is thus reflected in the significant focus on these drugs and their continued development.

# **Regional Insights**

In the Japan immunosuppressant drugs market, the Kanto region stands out as the dominant. This region, which includes major cities such as Tokyo and Yokohama, has emerged as the epicenter of healthcare and pharmaceutical advancements in Japan, significantly impacting the Japan Immunosuppressant Drugs Market. The Kanto region's dominance is largely attributed to its robust healthcare infrastructure, extensive network of medical facilities, and its status as a hub for pharmaceutical research and development. Tokyo, as the capital city, hosts numerous world-class hospitals, specialized medical centers, and research institutions that play a pivotal role in the management and treatment of conditions requiring immunosuppressants, such as organ transplants and autoimmune diseases. The presence of leading healthcare institutions and cutting-edge research facilities contributes to the high demand for immunosuppressant drugs, driving market growth in the region.

The Kanto region benefits from a high concentration of pharmaceutical companies and biotech firms engaged in the development, production, and distribution of immunosuppressant medications. These companies are at the forefront of innovation, developing new drug formulations and therapies to address the complex needs of patients requiring immunosuppressive treatments. The region's strong pharmaceutical industry base supports a dynamic market environment, fostering the introduction and adoption of advanced immunosuppressant therapies. The large and diverse population in the Kanto region also contributes to its dominance in the Japan Immunosuppressant Drugs Market. With a significant number of residents, there is a higher incidence of conditions such as autoimmune diseases and the need for organ transplants, which drives demand for immunosuppressive therapies. The concentration of healthcare resources and medical expertise in Kanto ensures that patients in this region have access to the latest treatments and therapies.

Key Market Players Astellas Pharma Inc. Sanofi K.K. Novartis Pharma K.K. Chugai Pharmaceutical Co., Ltd. GlaxoSmithKline K.K. Asahi Kasei Corp.

Otsuka Pharmaceutical Co., Ltd.

# Report Scope:

In this report, the Japan Immunosuppressant Drugs Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

□]Japan Immunosuppressant Drugs Market, By Drug Class:

- o Calcineurin Inhibitors
- o Antiproliferative Agents
- o MTOR Inhibitor
- o Steroids
- o Others

IIJapan Immunosuppressant Drugs Market, By Application:

- o Autoimmune Diseases
- o Organ Transplant
- o Others

Japan Immunosuppressant Drugs Market, By Distribution Channel:

- o Hospital Pharmacies
- o Retail Pharmacies
- o Online Pharmacies

□]apan Immunosuppressant Drugs Market, By Region:

o Hokkaido

- o Tohoku
- o Kanto
- o Chubu
- o Kansai
- o Chugoku
- o Shikoku
- o Kyushu

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Japan Immunosuppressant Drugs Market.

Available Customizations:

Japan Immunosuppressant Drugs Market report with the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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