

A new report from the Drug Discovery series...

Immunomodulators

Therapeutic Needs, Pipelines & Prospects



Pre-publication Offer...



Report overview

The modulation of immune system activity is a required pharmacological intervention for many medical conditions. Immunosuppression is integral to the treatment of autoimmune diseases and allergies, and the inhibition and prevention of immune responses also constitutes a prominent treatment aim for transplant recipients. Conversely, immune system stimulation is adopted for a number of infections and cancers. With traditional immunomodulatory drugs continuing to exhibit limited efficacy and adverse side effects, the drive to develop new, improved, and specifically targeted immunotherapies has been gaining momentum.

'Immunomodulators: Therapeutic Needs, Pipelines & Prospects' is a new report published by Business Insights that examines the current market for immunomodulatory therapies and highlights the commercial imperatives in the development of improved products. The strategies and technologies used in immunomodulation are analysed and the major clinical applications of immunomodulators are reviewed to identify the leading drug classes and most promising agents currently in development. This report will also investigate patient metrics and provide market forecasts for immunomodulators to 2011.

Identify future growth areas and patenting trends to develop future strategies, and assess your organisation's competitive position within the immunomdulatory market using this new report...

Key findings...

- The market for immunomodulators was valued at \$43bn in 2006, and is expected to grow at a CAGR of 13% to reach \$80bn by 2011.
- Pipeline immunomodulators mainly consist of biopharmaceuticals such as recombinant proteins, vaccines and monoclonal antibodies, but also include several small molecules.
- In **inflammatory and autoimmune disorders**, immunomodulators in clinical development are predominantly aimed at **GCPR's**, **leukocyte surface antigens**, **cytokines** and **kinases**.
- Clinical trials for infectious diseases are focused upon prophylatic vaccines. However, the treatment of HIV and HCV infections has also warranted the development of therapeutic vaccines.
- Immunostimulation marks a dynamic change in cancer treatments. Two prophylactic cancer vaccines have been approved and several therapeutic vaccines are in clinical and preclinical development.
- **Co-stimulation blockers** promise to become the new standard of **post-transplantation immunosuppression**.

Extract: Pre-clinical Immunomodulators by Indication

Rank	Туре	Drugs	%
1	Infection	265	41.9
	+Influenza	43	6.8
	+HIV/AIDS	37	5.9
	+Hepatitis B	15	2.4
	+Anthrax	15	2.4
	+Streptococcal	13	2.1
	+Malaria	11	1.7
	+Staphylococcal	10	1.6

Business Insights

"As is the case with immunomodulators in clinical trials, the most active areas in infectious disease continue to be in Influenza, HIV, and hepatitis viral infections. The initiation of many preclinical programs targeting Streptococcal and Staphylococcal bacteria, as well as the parasite malaria, has in all likelihood been driven by a recent dramatic rise in levels of microbial resistance to antibiotics. The leading cancer indications are breast and prostate cancers..."

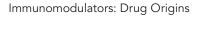
Immunomodulators

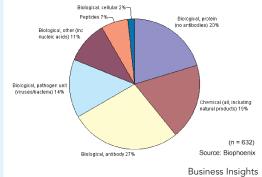
Therapeutic needs, Pipelines & Prospects



Key questions answered...

- How is the immunomodulator market structured?
- What were the leading immunomodulator drug classes in 2006?
- Which immunomodulator drug classes will dominate the market in 2010?
- What types of immunomodulators are in clinical development for:
 - Inflammatory and Autoimmune disorders?
 - Infectious Diseases?
 - Cancer?
- Who are the pharmaceutical and biotechnology companies that are set to become the future market leaders?
- Which companies were the most influential signees of immunomodulatory US patents?





"Only 19% of the immunomodulators in pre-clinical development are small molecule chemical compounds; most are biologicals (led by antibodies and other proteins), reflecting the paradigm shift ongoing in the pharmaceutical industry towards disease-modifying therapy...."

Key issues examined in this report...

- **Concerns over traditional immunomodulators.** Agents in development are set to enhance safety and specificity, and may also be administered over a more convenient time-course.
- **Opportunities in inflammation.** The inflammation pathway offers a range of promising targets for the development of new immunomodulator drugs.
- New approaches to vaccine development. Sub-unit and DNA vaccines have emerged to address the ineffectiveness of traditional vaccines in inducing cell-mediated immunity.
- **Biological response modifiers.** Widespread debate has been evoked over the capabilties of immune sytems in eliminating cancer cells. Cytokines, monoclonal antibodies and therapeutic vaccines are set to enhance this function.
- **Developments in immunosuppression therapy.** Co-stimulatory blockers are a class of immunomodulators under investigation for chronic maintenance therapy.

Pre-clinical Vaccines: Therapy types

Therapy Type	No.	%
Recombinant	109	47.2
vaccines		
Prophylactic,	79	34.2
non-recombinant		
vaccine		
Therapeutic	37	16
vaccine (Cancer)		
Other	6	2.6
Total	231	100

Business Insights

"Current therapeutic cancer vaccine candidates in clinical trials are commonly tested in patients with advanced cancer. However, it is increasingly acknowledged that they are unlikely to be very successful in the context of high tumor burden/load commonly encountered in late-stage cancer. In advanced cancer, due to the limited time window and practical constraints imposed by large tumor masses immediate tumor regression is desired..."

Immunomodulators

Therapeutic needs, Pipelines & Prospects



CHAPTER 1: MODULATING THE IMMUNE SYSTEM

- Overview of the human immune system
 - Innate (non-specific) immunity
 - Cytokines: the chemical messengers
 - Lipid mediators of inflammation
 - Phagocytic and natural killer cells
 - Complement system
 - Inflammatory and acute phase responses
 - Adaptive (specific) immunity
 - B and T lymphocytes
 - Antigen-presenting cells
- Biopharmaceuticals as immunomodulators
 - Delivery of biopharmaceuticals
 - Regulatory requirements (US)

CHAPTER 2: INFLAMMATORY AND AUTOIMMUNE DISORDERS

- The role of T cells in autoimmune diseases and allergies
- Current therapies
- Glucocorticoids
- Nonsteroidal anti-inflammatory drugs
- Nitric oxide (NO)-releasing NSAIDs
- Therapies targeting proinflammatory cytokines
- B cell-targeted therapeutics
- Current drug targets
 - GPCRs
 - Chemokine receptors
 - LTB4 receptor
 - S1P1 receptor
 - Leukocyte surface antigens
 - Cytokines and their receptors
 - IL-1 and receptors
 - Other ILs and receptors
 - TNF proteins and receptors
 - BlyS (BAFF) and APRIL
 - Interferons
 - Other cytokines
- Kinases
- Immunomodulators in clinical development (US)
- Rheumatoid arthritis
- Psoriasis
- Multiple sclerosis
- Inflammatory bowel disease
- Systemic lupus erythematosus
- Asthma and allergic rhinitis
- Chronic obstructive pulmonary disease
- Cardiovascular disease

CHAPTER 3: INFECTIOUS DISEASE

- Combination vaccines
- Viruses
- Influenza
- New vaccines
- HIV
- New vaccines
- Other immunotherapies
- Hepatitis viruses
- New vaccines
- Other immunotherapies
- Herpes simplex viruses
- New vaccines
- RSV
- New vaccines and immunotherapies
- Bacteria, fungi and parasites
- New vaccines

CHAPTER 4: CANCER

- Tumor immunity
- Treatment of cancer
- Overview of immunotherapies
 - Small molecule immunomodulators
 - Cytokines
 - Monoclonal antibodies
 - Recent trends
- Prophylactic vaccines
- Therapeutic vaccines
- Tumor antigens targeted by vaccines
- Antigen/adjuvant vaccines
- Whole cell vaccines
- Dendritic cell vaccines
- Idiotype vaccines
- Genetically-engineered vaccines
- Immunostimulatory sequences
- Adoptive T cell immunity

CHAPTER 5: TRANSPLANTATION

- Introduction to organ transplantation
 - Rejection mechanisms
 - Prevention of rejection
- Small molecule immunosuppressants
 - Calcineurin inhibitors
 - Anti-proliferatives
 - Glucocorticoids
 - mTOR inhibitors
 - Novel small molecule drugs



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- Induction therapy with T cell antibodies
 - Polyclonal antibodies
 - Monoclonal antibodies and fusion proteins
- Co-stimulatory blockers
- New approaches to prevention of GVHD

CHAPTER 6: MARKET CONSIDERATIONS AND FORECASTS

- Overview of the AIID Market
 - Rheumatoid arthritis
 - Multiple sclerosis
 - Inflammatory bowel disease
 - Systemic lupus erythematosus
 - Psoriasis
 - Asthma and allergic rhinitis
- Overview of the Viral Infectious Disease
 - Market
 - Influenza
 - HIV
 - Hepatitis viruses
 - Herpes simplex viruses
 - RSV
- Overview of the Cancer Market
 - Cytokines
 - Monoclonal antibodies
 - Prophylactic vaccines
 - Therapeutic vaccines
- Overview of the Transplantation Market
- Quantitative Market Analysis
 - The global immunomodulator market
 - Immunosuppression in AIID and
 - allergies
 - Vaccines for viral pathogens
 - Vaccines for cancer
 - Monoclonal antibodies for cancer
 - Recombinant interferons
 - Transplantation medicine
 - Geographical analysis

CHAPTER 7: TRENDS AND HJOPPORTUNITIES

- Preclinical immunomodulator programs
- Trends in vaccines
- Trends in monoclonal antibodies
- Future players in immunomodulation
- Immunomodulators Patent Survey

- Patenting Activity
- Leading assignees
- Patent citation analysis

LIST OF TABLES

- Indications by Category and Within-Category Count
- Recent Immunomodulator Deals
- Immunomodulators in US Clinical Development
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 - Psoriasis
 - Multiple Sclerosis
 - Crohn's Disease
 - Ulcerative Colitis
 - SLE
 - Asthma
 - Allergic Rhiniti
 - COPD
 - General Inflammation
 - Autoimmune Disorders
 - Influenza
 - HIV
 - Viral Hepatitis
 - Herpes simplex
 - Other Viruses
 - Bacteria
 - Fungi and Parasites
 - Breast cancer
 - Prostate cancer
 - Non-Small Cell Lung Cancer
 - Ovarian cancer
 - Malignant melanoma
 - Head and neck cancer
 - Pancreatic cancer
 - Renal cancer
 - Solid tumours
 - Lymphoma
 - Non-Hodgkin's Lymphoma
 - Multiple myeloma
 - General Cancer
 - Colorectal cancer
 - Chronic Lymphocytic
 - Leukaemia
- Glossary Immunomodulators in US Clinical Development

- Immunomodulators in US Clinical Development (Transplantation)
- Inflammatory Disease Prevalences and Incidences (2006)
- Inflammatory Disease Summary (2006)
- World AIDS Statistics (2006)
- World Annual Cancer Incidence by Site (2002)
- Trends in cancer incidence, 1975-2000
- World Cancer Statistics (2002)
- World Pharma Market by Therapeutic Category, 2006-2011
- World Pharma Market by Region, 2006-2011
- Immunomodulator Analysis by Therapy Type, 2006-2011
- Immunomodulator Analysis by Indication, 2006-2011
- World Immunomodulator Market by Region, 2006-2011
- Preclinical Immunomodulators by
 Indication

Indications

development

Originators

•

Preclinical Vaccines: Therapy Types,

• Monoclonal antibodies in preclinical

Preclinical Immunomodulators: Top

Preclinical Vaccines: Top Originators

Immunomodulator Patent Survey:

Summary of Patents by Segment

US Immunomodulator Patents: Filing and

US Immunomodulator Patents: Assignee

US Immunomodulator Patents: Top

US Immunomodulator Patents: Most

Business Insights

Frequently Cited Organizations

Category Definitions

Publication Activity,

1992-2007

- Allergy

- Vaccines

Summary

Assignees

- All Patents

- Autoimmunity

- Transplantation

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