Cytokine Therapies and Inhibitors: A Vibrant Pipeline and Active Approved Market

By Mark C. Via

Cytokines have drawn immense interest from the pharmaceutical industry over the last two decades. Great effort has been devoted to finding ways to reproduce their effects—or to block their activity—in the quest to create novel drugs for cancer, infectious diseases, inflammatory and immune disorders, and myelosuppression. *Cytokine Therapies and Inhibitors: A Vibrant Pipeline and Active Approved Market*, a new Insight Pharma Report, takes a comprehensive look at the full range of cytokine therapies and inhibitors, from products in research and development to products already approved and marketed.
Overview

**Cytokine Therapies and Inhibitors: A Vibrant Pipeline and Active Approved Market** thoroughly evaluates the field of cytokines as it relates to drug development by providing:

- A description of cytokines and an explanation as to how they are classified
- In-depth coverage of approved and experimental cytokines and cytokine inhibitors, including late clinical research news on some of the most promising drugs in development
- Analysis of the interleukins, the interferons, the tumor necrosis factor superfamily, transforming growth factor-beta, the hematopoietic growth factors, and the chemokines, or chemotactic cytokines
- Discussion of efforts to develop improved versions of existing drugs
- Evaluation of the current and future markets for cytokine-based therapeutics

Recombinant forms of natural cytokines were among the early success stories of the biotech boom. Genetically engineered versions of interleukin-2, interferon α and β, erythropoietin, and the colony-stimulating factors have now been available for years and remain profitable products for their manufacturers.

In all, **Cytokine Therapies and Inhibitors: A Vibrant Pipeline and Active Approved Market** examines more than 200 drugs and research programs, ranging from cytokines to cytokine variants and agonists, from the approved interleukin-2 drug Proleukin from Chiron/Novartis, for treating renal cell carcinoma, to the interferon α drug candidate now in Phase II trials by Intarcia Therapeutics, for treating hepatitis C virus. For example, one drug discussed, Multikine from CEL-SCI, just received approval in January to go into a Phase III trial to show that it can increase survival times for head and neck cancer patients. The drug already has been shown to be non-toxic in Phase II trials that also showed improvements in survival. The report also evaluates cytokine inhibitors, from Amgen’s interleukin-1 receptor antagonist Kineret, approved for treatment of rheumatoid arthritis, to Abbott Laboratories’ interleukin-18 monoclonal antibody, now in Phase I research for autoimmune disorders.

The market for cytokine-based therapeutics holds great promise. Sales in 2005 for 13 of the 35 cytokine drugs already approved amounted to more than $1 billion each. Centocor/Johnson & Johnson’s Remicade alone racked up sales of almost $3.5 billion in 2005. Perhaps the biggest market of all is anemia, where recombinant erythropoietin drugs boasted sales of more than $10 billion in 2005.

**Cytokine Therapies and Inhibitors: A Vibrant Pipeline and Active Approved Market** is an indispensable report for individuals directly involved in the research and development, licensing, or marketing of cytokine-based therapies.

### About the Author

Mark C. Via, an editor at CTB International Publishing, has more than 13 years of experience writing and editing for pharmaceutical trade publications. He holds a BA in history from Williams College. Mr. Via has authored previous Cambridge Healthtech reports, including *Kinase Therapeutics: A Wealth of Targets Sparks a Highly Active Market* (www.InsightPharmaReports.com/all_reports/2006_64_Kinases/overview.html).

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1.1. What Are Cytokines? Terminology Recently Evolved

1.2. Classification of Cytokines

Interleukins
Interferons
Tumor Necessity Factors
Transforming Growth Factors
Colony-Stimulating Factors
Chemokines

Chapter 2: Cytokine Therapeutics: Administering Cytokines as Drugs

2.1. Interleukins
Interleukin-1
Aldesleukin
Denileukin Diftitox
BAY 50-7498
Multikine
ESM 270363/EMD 270366
TG 4010/TG 4001
IL-2 XL
IL-2/EPI
Liposomal IL-2
Sangamo BioSciences’ Technology
Others
Interleukin-3
Interleukin-4
PRX321
Interleukin-6
Interleukin-7
Interleukin-10
Interleukin-11
Opavelkin
PEGylated IL-11
Interleukin-12
EGEN-201
AS401
TDS/IL-12
CYT-4000
Interleukin-13
Cimtrexedin Besudotox
Uviden/Collidem
Globlastar-13
Interleukin-18
Ibocadexin
IL-18 Plasmids
Interleukin-21
IL-21
Interleukin-29
IL-29
2.2. Interferons
Interferon α
Intron A/Rebetron/PEG-Interon
Rovarx-A/Pegasys
Infegen
Alferon N/Alferon LDO
Multiferon
Albuferon

Chapter 3: Cytokine Inhibitors: Drugs that Block Cytokine Activity

3.1. Interleukin Inhibitors
Interleukin-1
Anakinra
IL-1 Trap
AMG 108
ACZ2855
Interleukin-2
Daclizumab
Basiliximab
MT204
Interleukin-4 and -13
Aerovant/Aeroderm/Aerolast
AMG 317
CATE 354
TXN-650
ISIS 369645
DOM10009/DOM0910
Zenyth Therapeutics/ Merck’s Compounds
Simia Therapeutics/ GlaxoSmithKline’s Compounds
Targetpeptides’ Compounds
Interleukin-5
Mepolizumab
BUFF305
YM-90709
Interleukin-6
Tocilizumab
C126
Interleukin-9
MEDI-528
Interleukin-12 and -23
CNTF 1275
ABT-874
STA-5326
Anti-IL-23 Aptimers
Interleukin-15
AMG 714
CRB-15
Other Interleukins
Centocor Research
ZymoGenetics/Seronex/Novo Nordisk Research
3.2. Interferon Inhibitors
Interferon α
MEDI-545/MEDI-546
Sargramostim
Molgramostim
Leucotropin
CTC-0214/CTC-0324
Sangamo BioSciences’ Technology
Macrophage Colony-Stimulating Factor
Minimostim
 Stem Cell Factor
Ancestim
Thrombopoeitin
AMG 531
Ertlomopag
Thromboβlus
e-Mpl Minibody
Aгонистs
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CXCR4

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4.2. Selected Markets

Cancer
HIV
Autoimmune Diseases
Rheumatoid Arthritis
Crohn’s Disease
Psoriasis
Lupus
Multiple Sclerosis
Asthma
Chronic Obstructive Pulmonary Disease
Infectious Diseases
HIV
 Hepatitis C Virus

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Prevailing cancer therapies are extremely limited in terms of safety, tolerability, and efficacy. The morbidity and mortality associated with cancer are fueling interest in novel therapeutic approaches. Foremost among these are therapies that enhance the ability of the body's own immune system to fight and destroy abnormal cancer cells. Anticancer vaccines and immune modulators, working in concert and as monotherapy, stole the show at ASCO last June, suggesting that, after years of failure in the clinic, their time has come. Cancer Immunotherapies and Vaccines: Pipeline Analysis and Competitive Dynamics, a new Insight Pharma Report, surveys and assesses recent developments in this highly promising avenue of cancer therapy.

Numerous biopharmaceutical companies are working to develop approaches that harness the body's own immune system to fight cancer. Several monoclonal antibodies have already reached the market. This approach is sometimes referred to as passive immunotherapy. Cancer Immunotherapies and Vaccines: Pipeline Analysis and Competitive Dynamics focuses primarily on active immunotherapies and vaccines—those that enhance the ability of the patient's own immune system to fight cancer.

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