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LDI

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Specialty Drug News

Oncology Market Outlook

The American Society of Clinical Oncology had its annual meeting recently with about 40,000 attendees. Two top pharmaceutical analysts who specialize in oncology were asked to review the highlights of the conference and give an overview of the market. Here are their predictions:

- Total oncology market sales: 2007, \$59 billion. By 2012 sales will reach \$80 billion.
- Avastin, currently approved for colorectal cancer, non-small cell lung cancer and breast cancer will make an effort to extend their market to early-stage disease. In 2006 total sales reached \$2.4 billion. By 2011 sales are expected to reach \$2.4 billion to \$9.6 billion.
- Erbitux will try to grow its market share with an application for non-small cell lung cancer.
- Over the next five years, treat-

ments for lung cancer will be the fastest growing market.

- Breast cancer – now the largest market, is stable. Early detection methods have lead to earlier diagnosis and treatments with drugs like Herceptin, Avastin and

Avastin, currently approved for colorectal cancer, non-small cell lung cancer and breast cancer will make an effort to extend their market to early-stage disease.

Tykerb. The same holds true for colorectal cancer.

- Renal cancer medications will remain a fast-growing market.
- Leukemias and ovarian cancer drugs will see a big jump in sales as new treatments come to market.



Velcade
Approved for Initial Treatment of Patients with Multiple Myeloma



Pipeline Report:
Recent FDA Approvals



New Dosage Forms
in the Pipeline



Specialty Medication Listing

Velcade Approved for Initial Treatment of Patients with Multiple Myeloma

The Food and Drug Administration announced on June 23, 2008, that bortezomib for injection (Velcade, Millennium, Inc. and Johnson and Johnson Pharmaceutical Research and Development) has been approved for treatment of patients with multiple myeloma. The approval is for initial treatment of multiple myeloma. Velcade was previously approved in 2005 for treatment of multiple myeloma in patients who had received at least one prior therapy.

Specialty Medication Pipeline Update 2nd Quarter 2008

Recent FDA Approvals				
Drug Name	Indication	Route of Administration	Approval Date	Comments
Cimzia	Crohn's Disease	SC injection	4/22/08	
Xyntha	Hemophilia A	IV infusion	2/21/08	Launch expected in Sept 2008
Arcalyst	Treatment of cryopyrin-associated periodic syndromes (CAPS)	SC injection	2/27/08	Only medication approved for treatment of CAPS
Humira	Moderate to severe juvenile RA in patients 4 years and older	SC injection	2/21/08	Previously approved for RA, ankylosing spondylitis, Crohn's and plaque psoriasis
Orencia	Moderate to severe juvenile RA in patients 6 years and older	IV infusion	4/8/08	Previously approved for treatment of RA
Treanda	Treatment of chronic lymphocytic leukemia	IV infusion	3/20/08	Also currently under review for treatment of non-Hodgkin's lymphoma

Update on Phase III Trials			
Drug Name	Indication	Route of Administration	Comments
Kiacta	Treatment of Amyloid A amyloidosis	Oral	Orphan Drug designation. 2nd phase III trial to be conducted in 4QTR of 2008
Bosatria	Treatment of hypereosinophilic syndrome (HES)	IV infusion	Orphan Drug designation
Denufosol	Treatment of cystic fibrosis	Inhalation	Orphan drug with fast track status. Second phase III study initiated Feb 2008
Velaglu-cerase alfa	Treatment of type 1 Gaucher disease	IV infusion	

continued - Update on Phase III Trials

Drug Name	Indication	Route of Administration	Comments
Albuzeron	Chronic Hepatitis C	Injection	Phase III expected by spring 2009
Viramidine	Treatment of Chronic Hepatitis C	Oral	
Vicriviroc	Treatment of HIV	Oral	Two large phase III trials initiated Sept 2007
Nplate	Treatment of thrombocytopenia in adults with chronic immune thrombocytopenic purpura (ITP)	SC injection	Fast track orphan drug designation
Promacta	Short-term treatment of previously treated patients with ITP	Oral	Granted priority review by FDA in March 2008
Golimumab	Treatment of RA, psoriatic arthritis and ankylosing spondylitis	SC injection	
Ustekinumab	Chronic moderate to severe plaque psoriasis	SC injection	
ACZ885	Treatment of RA	SC injection	Orphan drug designation
Actemra	Treatment of RA	IV infusion	
Fingolimod	Multiple sclerosis	Oral	New Drug Application to FDA planned for end of 2009
Teriflunomide	Multiple sclerosis	Oral	Being studied in combination with interferon-beta and with Copaxone
Pasireotide	Cushing's disease and acromegaly	SC injection	
Zactima	Second line treatment of non-small cell lung cancer (NSCLC)	Oral	
Xyotax	Treatment of advanced NSCLC in women	IV infusion	Granted fast track status
Xerecept	Treatment of peritumoral brain edema	SC injection	Orphan drug designation
Lestaurtinib	Acute myeloid leukemia	Oral	Orphan drug designation
Provenge	Treatment of metastatic hormone-refractory prostate cancer	IV infusion	
Virulizin	First-line treatment of advanced pancreatic cancer in combination with Gemzar	IM injection	Orphan drug with fast track designation
Phenoxodiol	Treatment of hormone-refractory prostate cancer in Taxotere non-responders and recurrent chemo-resistant late-stage ovarian cancer	IV injection/Oral	FDA has granted fast track status
Saforis	Treatment of chemo-induced oral mucositis	Oral	FDA granted priority review status. FDA has also requested additional phase III efficacy trial.
Everolimus	Treatment of advanced renal cell carcinoma and neuroendocrine tumors	Oral	
Voraxaze	Adjunctive therapy for cancer patients who are at risk for MTX toxicity	IV injection	Available through an expanded access program

continued - Update on Phase III Trials

Drug Name	Indication	Route of Administration	Comments
Aflibercept	Third-line treatment of ovarian cancer	IV infusion	
Larotaxel	Second-line treatment of pancreatic cancer	IV infusion	
Denosumab	Treatment of postmenopausal osteoporosis and treatment induced bone loss	SC injection	All end points met in phase III trial.
Theelin	Treatment of pulmonary arterial hypertension	Oral	Orphan drug designation
Numax	Prevention of RSV in high-risk infants	IM injection	Expected to be more potent than Synagis. FDA response to Biologic License Application due in Nov 2008
Certican	Prevention of solid organ transplant rejection in combination with Neoral	Oral	Clinical trials ongoing

New Dosage Forms in the Pipeline

Drug Name	Indication	Current Route of Administration	Investigational Route of Administration	Comments
Cayston	Treatment of patients with cystic fibrosis who have pulmonary Pseudomonas aeruginosa	IV injection	Inhalation	Response from FDA to New Drug Application expected in Sept 2008
TBM100 (tobramycin)	Treatment of patients with cystic fibrosis who have pulmonary Pseudomonas aeruginosa	Solution for inhalation	Powder for inhalation	Expected to provide more rapid and convenient administration.
Mylinax	Treatment of relapsing MS	IV infusion	Oral	FDA granted fast track status. Study completion expected Nov 2008
Fludarabine	Treatment of relapsed B-cell CLL	IV infusion	Oral	Designated as orphan drug
Viveta	Treatment of pulmonary arterial hypertension	SC or IV infusion	Inhalation	Studied in combination with Tracleer or Revatio

New Indications in the Pipeline

Drug Name	Current Indication	Investigational Indication	Route of Administration	Comments
Viread	HIV treatment	Treatment of chronic hepatitis B	Oral	
Infergen	Treatment of HCV	Treatment of chronic HCV in combination with ribavirin and failure to respond to pegylated interferon plus ribavirin	SC injection	Clinical trials are ongoing.

New Indications in the Pipeline				
Drug Name	Current Indication	Investigational Indication	Route of Administration	Comments
Kineret	Treatment of RA	Treatment of polyarticular-course chronic juvenile RA	SC injection	Clinical trials are ongoing
Rituxan	Treatment of non-Hodgkins lymphoma and treatment of moderately to severely active RA in patients who have had an inadequate response to one or more anti-TNF inhibitors	Treatment of moderately to severely active RA in patients who have not received biologic medication for treatment of RA	IV infusion	Primary endpoint of the phase III trial was met in Jan 2008
Cimzia	Crohn's disease	Treatment of moderate to severe or active RA and psoriasis	SC injection	
Treanda	Treatment of CLL	Treatment of NHL in patients who failed Rituxan	IV infusion	
Tasigna	Treatment of chronic and accelerated phase Philadelphia chromosome positive chronic myelogenous leukemia	Treatment of gastrointestinal stromal tumor in patients to have failed both Gleevec and Sutent	Oral	
Sutent	Treatment of gastrointestinal stromal tumor and advanced renal cell carcinoma	Treatment of metastatic colorectal cancer	Oral	
PegIntron	Treatment of HCV infection	Adjuvant treatment of stage III melanoma	SC injection	Priority review status granted Jan 2008
Forteo	Treatment of men and postmenopausal women with osteoporosis who are at high risk for fracture	Treatment of glucocorticoid-induced osteoporosis	SC injection	
Reclast	Treatment of Paget's disease and Postmenopausal Osteoporosis	Treatment of Glucocorticoid Induced Osteoporosis	IV infusion	

For more information regarding LDI's Specialty Newsletter, please contact us:

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Specialty Medication Listing by Disease/Condition

AIDS/HIV

Daunoxome
Doxil
Intron A
Roferon-A
Serostim
Taxol
Fuzeon

Alpha1 - Proteinase Inhibitor Deficiency

Aralast
Prolastin
Zemaira

Antihemophilic Agents

Antihemophilic Factor
Advate
Alphanate
Bioclote
Helixate FS
Hemofil M
Humate P
Hyate C
Koate DVI
Kogenate FS
Monarc M
Monoclate P
Recombinate
ReFacto

Anti-nausea

Aloxi
Anzemet
Emend
Kytril
Zofran

Asthma

Xolair

Cancer/Related

Adriamycin
Adrucil
Alkeran
Aredia
Avastin
BiCNU
Blenoxane
Busulfex
Campath
Camptosar
Cerubidine
Cosmegen
Cytarabine
Cytoxan
Depocyt

Doxil
DTIC-Dome
Eligard
Ellence
Erbitux
Ethyol
Faslodex
Fludara
Gemzar
Gleevec
Herceptin
Hycamtin
Idamycin
IFEX
Intron A
Leucovorin
Leukine
Leustatin
Lupron Depot
Lupron Depot-Ped
Mesnex
Mustargen
Mutamycin
Mylotarg
Navelbine
Nexavar
Nipent
Novantrone
Oncaspar
Ontak
Paraplatin
Platinol AQ
Proleukin
Rituxan
Roferon-A
Sutent
Tarceva
Taxol
Taxotere
Temodar
Thyrogen
Toposar
Trelstar Depot
Trelstar LA
Trisenox
VePesid
Vinblastine
Vincasar
Vumon
Xeloda
Zanosar
Zoladex
Zometa

Contraceptives

Depo-Provera

Crohn's Disease

Remicade

Dystonia

Botox
Myobloc

Factor IX Concentrates

Alphanine SD
Benefix
Mononine
Profilnine SD
Proplex T
Bebulin VH

Gaucher's Disease

Ceredase
Cerezyme
Zavesca

Growth Hormone Deficiency

Genotropin
Humatrope
Norditropin
Nutropin
Nutropin AQ
Saizen

Hematologics

Arixtra
Aranesp
Epogen
Fragmin
Innohep
Lovenox
Neulasta
Neumega
Neupogen
Procrit

Hepatitis C

Copegus
Infergen
Intron A
Pegasys
Peg-Intron
Rebetron
Roferon-A

Hormone Deficiency

Delatestryl
Delestrogen
Depo-Estradiol
Depo-Testosterone

Hunter Syndrome

Elaprase

Primary Immunodeficiency

Carimune NF
Gamimune N
Gammagard S/D
Gammar-P
Gamunex
Iveegam EN
Panglobulin
Panglobulin NF
Polygam S/D
Venoglobulin-S

Miscellaneous

Alferon-N
Milrinone
Zincard

Multiple Sclerosis

Avonex
Betaseron
Copaxone
Novantrone
Rebif
Tysabri

Osteo/ Rheumatoid/ Psoriatic Arthritis

Enbrel
Humira
Hyalgan
Kineret
Orencia
Remicade
Supartz
Synvisc

Osteoporosis

Forteo
Miacalcin

Psoriasis

Amevive
Enbrel
Raptiva
Remicade

Respiratory Syncytial Virus

Synagis

Rh Hemolytic Disease

BayRho-D
Micro-Rhogam
Rhogam
WinRho-SDF