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# LDI

Volume 14 | May 2008

# Specialty Drug News

## 2008 Medications to Watch

### 1. Respiratory syncytial virus (RSV)

#### Numax® (motavizumab)

Respiratory syncytial virus (RSV) infection causes respiratory tract illness in people of all ages, and is a serious public health problem around the world. In fact, RSV infection is the main cause of lower respiratory tract infections among infants and children, leading to the hospitalization of approximately 125,000 infants with severe infections each year.

Beyond symptom control, no effective treatments have been developed for RSV infection, so prevention is key. Synagis® (palivizumab), manufactured by MedImmune, is the only FDA-approved medication available for the prevention

of RSV infection in high-risk infants. RespiGam™ (RSV immune globulin intravenous) was also approved for this indication, but was discontinued at the end of 2003 due to Synagis entering the marketplace. Synagis is a monoclonal antibody that prevents RSV from infecting respiratory cells.

Numax® is a third generation anti-RSV product developed by MedImmune and AstraZeneca.

Similar to Synagis, Numax is a monoclonal antibody administered through an intramuscular injection; however, it is expected to be more potent than Synagis.

In one phase III trial, the efficacy of Numax versus Synagis was compared based on the incidence of RSV hospitalizations in each group. Although the incidence rate was low in both groups (Numax 1.4 percent, Synagis 1.9 percent), this difference was considered statistically significant.

*Respiratory syncytial virus (RSV) infection causes respiratory tract illness in people of all ages, and is a serious public health problem around the world.*

As a result, a BLA for Numax was filed in January 2008. The company expects a response to their BLA by November 2008.

The cost of treatment which is usually up to six months cost about \$18,000. *-continued top of page 2.*



2008 Medications to Watch



Update on Investigational Use Drugs for Multiple Myeloma



Specialty Medication Pipeline Report



Specialty Medication Listing

# 2008 Medications to Watch -continued

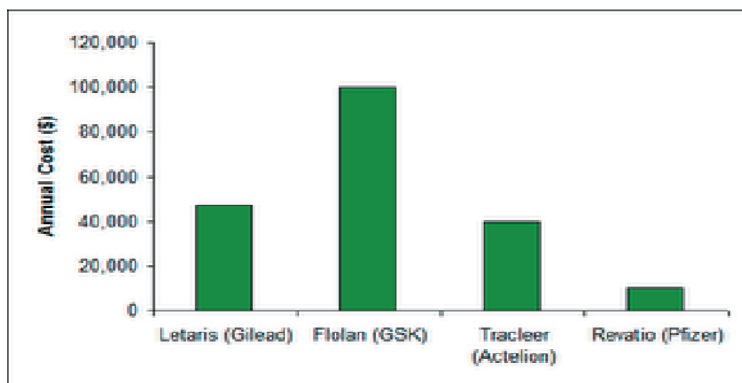
## 2. Pulmonary Hypertension Treatment

**Remodulin/Viveta (treprostinil)** For the treatment of Pulmonary Arterial Hypertension (PAH) Manufactured by UnitedTherapeutics and Lung Rx/

SC or IV infusion Inhalation Studied in combination with Tracleer® (bosentan) or Revatio® (sildenafil).

Pulmonary Hypertension (also called PH, PPH, primary or secondary pulmonary hypertension or PAH for Pulmonary Arterial Hypertension) is a disease that causes the arteries of the lungs to constrict leading to right heart failure.

In the past few years there has been an increasing awareness of pulmonary hypertension. Both the medical profession and several drug makers have focused attention on the disease. This has resulted in the development of promising new therapies including Tracleer, Ventavis and Remodulin, which promise to re-define future treatment. Pulmo-



nary Hypertension is a rare disease with less than 100,000 patients in the United States. However, the incidence of the disease appears to be on the rise and if left untreated it can be quickly fatal.

The annually therapy cost for Remodulin/Viveta is about \$85,000. Some studies have shown life expectancy and QLI estimated at 10 to 15 years.

## 3. Oncology (two medications to watch)

**A) Ixempra (ixabepilone)** a new anti-cancer treatment, for use in patients with metastatic or locally advanced breast cancer

The U.S. Food and Drug Administration has approved Ixempra (ixabepilone), a new anti-cancer treatment, for use in patients with metastatic or locally advanced breast cancer who have not responded to certain other cancer drugs. The FDA evaluated Ixempra under priority review, completing its assessment of the drug's safety and effectiveness in six months.

This approval is important because it provides certain patients with a new chemotherapy option in instances where other drugs have failed.

Ixempra was approved for use in combination with another cancer drug, capecitabine, in patients who no longer benefit from two other chemotherapy treatments. These prior treatments included an anthracycline (such as doxorubicin or epirubicin) and a taxane (such as paclitaxel or docetaxel).

Ixempra was also approved for use alone in patients who no longer benefit from an anthracycline, a taxane and capecitabine.

According to the American Cancer Society, about 180,000 new cases of breast cancer are diagnosed each year in the United States. Metastatic breast cancer is the most advanced stage of breast cancer and has the potential to spread to almost any region of the body.

Ixempra has been shown to bind to cancer cell microtubules, which are structures within cells that help to support and shape them. Microtubules also play a role in cell division.

The total cost of a full course of Ixempra is expected to run from \$18,440 to \$23,050.

## 2008 Medications to Watch-continued

### B) Nexavar (sorafenib)

Nexavar (sorafenib) is for use in patients with a form of liver cancer known as hepatocellular carcinoma, when the cancer is inoperable.

Nexavar was originally approved in 2005 for the treatment of patients with advanced renal cell carcinoma, a form of kidney cancer.

In a randomized clinical trial, the group of patients with inoperable hepatocellular carcinoma who received Nexavar survived 2.8 months longer than the group of patients who didn't receive the drug.

This is an important new treatment option for patients who are fighting this very difficult form of cancer."

According to the National Library of Medicine, hepatocellular carcinoma accounts for 80 to 90 percent of all liver cancers. This type of cancer can be difficult to remove completely using sur-

gery. If all of the cancer cannot be removed, the disease is usually fatal within three to six months. The American Cancer Society estimates that there will be 19,160 new cases and 16,780 deaths from cancer of the liver and intrahepatic bile duct in the United States in 2007.

Nexavar is a type of anticancer drug called a kinase inhibitor. It interferes with molecules that are thought to be involved in chemical messages sent within cancer cells, in the formation of blood vessels that supply tumors, and in cell death.

Nexavar treatment cost about \$5,000 per month.

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## Update on Investigational Use Drugs for Multiple Myeloma

The pace of change in treating myeloma is unprecedented. Currently there are over 600 clinical trials involving treatments for multiple myeloma. Many of these trials include investigational agents that are not commercially available, but a large number include commercially available agents used in new combinations. Health care plans need to be aware of the Unapproved or Investigational Use of these new combinations so that a determination of benefits can be made.

Generic Name	Trade Name	Approved Use	Unapproved Investigational Use
Bortezomib	Velcade	Multiple myeloma patients who have received at least one prior therapy	Front-line therapy in combination with melphalan-prednisone, with cyclophosphamide, with thalidomide-dexamethasone, or with lenalidomide-dexamethasone
Lenalidomide	Revlimid	In combination with dexamethasone in MM patients who have received at least one prior therapy	Front-line therapy in combination with dexamethasone or with bortezomib-dexamethasone
Thalidomide	Thalomid	Front-line therapy in combination with dexamethasone	Front-line therapy in combination with bortezomib

\*Source: American Society of Hematology

# Specialty Medication Pipeline Update

## 1st Quarter 2008

Recent Approvals				
Drug Name	Indication for Use	Route of Administration	Approved	Notes
Tysabri	Adult patients with moderate to severe Crohn's Disease	IV infusion	1/14/2008	Previously approved for MS
Accretropin	Growth failure in children	SC injection	1/23/2008	
Intelence	HIV	Oral	1/18/2008	
Kuvan	PKU	Oral	12/31/2007	First medication approved specifically to treat PKU
Humira	Treatment of moderate to severe chronic plaque psoriasis	SC Injection	1/18/2008	Previously approved for RA, psoriatic arthritis, ankylosing spondylitis and Crohn's disease
Phase III Trials				
Kiacta	Treatment of Amyloid A amyloidosis	Oral	Pending	Orphan Drug
Denufosal	Cystic Fibrosis	Inhalation	Pending	Fast-track orphan drug status.
ReFacto AF	Hemophilia	Infusion	Pending	Launch in 2008
Albuphron	Treatment of chronic HCV infection	Injection	Pending	Phase III data expected by spring 2009
Viramidine	Treatment of chronic HCV infection	Oral	Pending	Phase II trial initiated March 2007
Viciviroc	HIV	Oral	Pending	Phase III trials initiated September 2007
Nplate	Thrombocytopenia in adults with chronic ITP	SC injection	Pending	Granted priority review status January 2008
Promacta	Short-term treatment for patients with chronic ITP	Oral	Pending	
Golimumab	RA, psoriatic arthritis, ankylosing spondylitis	SC injection	Pending	
Riloncept	Treatment of crypyrin-associated periodic syndrome	SC injection	Pending	Orphan drug with fast track status
Cimzia	Crohn's disease, RA, severe psoriasis	SC injection	Pending	
Fingolimod	MS	Oral	Pending	
Teriflunomide	MS	Oral	Pending	Also being studied in combination with Copaxone
Xyotax	Advanced non-small cell lung cancer in women	IV infusion	Pending	Granted fast track status
Xerecept	Treatment of peritumoral brain edema	SC Injection	Pending	

Phase III Trials - continued				
Drug Name	Indication for Use	Route of Administration	Approved	Notes
Lestaurtinib	Acute myeloid leukemia	Oral	Pending	Designated as an orphan drug
Treanda	Treatment of chronic lymphocytic leukemia and non-Hodgkin's lymphoma in patients who failed Rituxan	IV infusion	Pending	
Provenge	Treatment of metastatic prostate cancer	IV infusion	Pending	
Atamestane	Breast cancer	Oral	Pending	Phase III studies ongoing
Virulizin	Pancreatic cancer in combination with Gemzar	IM injection	Pending	Orphan drug with fast track status
Phenoxodiol	Prostate cancer	IV injection/Oral	Pending	Fast track designation
Saforis	Prevention and treatment of chemotherapy induced oral mucositis	Oral	Pending	FDA has requested additional Phase III efficacy trial
Voraxaze	Adjunctive therapy in cancer patients who are at risk for methotrexate toxicity	IV injection	Pending	Orphan drug with fast track status
Denosumab	Postmenopausal osteoporosis and treatment-induced bone loss	SC injection	Pending	All endpoints met in Phase III trial.
Preos	Treatment of postmenopausal osteoporosis	SC injection	Pending	
Ustekinumab	Adult patients with moderate to severe plaque psoriasis	SC injection	Pending	
Thelin	Pulmonary arterial hypertension	Oral	Pending	Orphan drug
Numax	Prevention of RSV in high-risk infants	IM injection	Pending	Expected to be more potent than Synagis
Actemra	Treatment of RA	IV infusion	Pending	
Anti-T-lymphocyte immune globulin	Prevention of graft-versus-host disease in lung transplants	Injection	Pending	Granted fast track status
Certican	Prevention of solid organ rejection in combination with Neoral	Oral	Pending	Clinical trials ongoing

**New Dosage Forms of Approved Drugs Being Investigated**

<b>Drug Name</b>	<b>Indication for Use</b>	<b>Current Route of Administration</b>	<b>Investigational Route of Administration</b>
Cayston	Cystic fibrosis for patients who have pulmonary Pseudomonas aeruginosa	IV injection	Inhalation
Mylinax	Relapsing forms of MS	IV infusion	Oral
Fludarabine	Relapsing B-cell CLL	IV infusion	Oral
Viveta	Treatment of pulmonary arterial hypertension	SC or IV infusion	Inhalation

**New Dosage Forms of Approved Drugs Being Investigated**

<b>Drug Name</b>	<b>Current Indication</b>	<b>Investigational Indication</b>	<b>Route of Administration</b>
Leukine	Improvement of immune cell function for myelogenous leukemia or following bone marrow transplant	Treatment of moderate to severe Crohn's disease	SC injection
Viread	HIV	Chronic Hepatitis B	Oral
Infergen	HCV infection	Treatment of chronic HCV in combination with ribavirin after failure to respond to previous course of pegylated interferon plus ribavirin	SC injection
Humira	Treatment for RA, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and plaque psoriasis	Treatment for juvenile rheumatoid arthritis	SC injection
Kineret	Treatment of RA	Treatment of polyarticular-course chronic juvenile rheumatoid arthritis	SC injection
Orencia	Treatment of moderate to severe RA in patients who have had an inadequate response to one or more disease modifying anti-rheumatic drugs	Treatment of juvenile rheumatoid arthritis in patients who have had an inadequate response to one or more disease modifying anti-rheumatic drugs	IV infusion FDA approved for this application April 10, 2008
Velcade	Treatment of multiple myeloma and mantle cell lymphoma in patients who have received at least one prior therapy	Treatment of multiple myeloma in newly diagnosed patients	IV injection
Sutent	Treatment of gastrointestinal stromal tumor and advanced renal cell carcinoma	Treatment of metastatic colorectal cancer	Oral
PegIntron	Treatment of HCV injection	For the adjuvant treatment of stage III melanoma	SC injection
Forteo	Treatment of men and postmenopausal women with osteoporosis who are at high risk for fracture	Treatment of glucocorticoid-induced osteoporosis	SC injection
Rituxan	Treatment of non-Hodgkin's lymphoma and moderately to severely active RA in patient 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 a biologic medication for treatment of RA	IV infusion

# 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