

# LDI Specialty Drug News

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## FDA Approves Ixempra for Treatment of Breast Cancer

**On October 16, 2007 the FDA 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.**

Ixempra what given priority review status which cut four months off of the standard 10-month drug review. Priority review status is given to those products that are considered to be an advance over existing therapies on the market.

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

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 and has the potential to spread to almost any region of the body.

Ixempra, which belongs to a new class of drugs called epothilones, is designed to stop the growth of cancer cells. It does this by targeting

a protein called tubulin that helps cells proliferate.

*About 180,000 new cases of breast cancer are diagnosed each year in the United States.*

Ixempra is administered by intravenous infusion. Distributed by Bristol-Meyers

Squibb Company it is also being studied for use in the treatment of earlier-stage breast cancer, as well as ovarian, prostate, renal, pancreatic and non small lung cell cancers. \*Source: FDA News



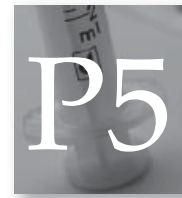
**FDA Approves Tasigna for Leukemia Treatment**



**New Chemo-Therapy Test: MiCK**



**2007 Third Quarter-Specialty Drug Pipeline**



**Specialty Drug Listing**

## FDA Approves Tasigna for Leukemia Treatment

*The Food and Drug Administration gave its approval on October 29, 2007 for Tasigna, a treatment for refractory chronic myeloid leukemia (CML).*

CML is one of the four most common types of leukemia, affecting about 4,500 people annually in the United States. Tasigna is a kinase inhibitor and joins others on the market such as Gleevec and Sprycel.

Tasigna is approved for the treatment of chronic phase and accelerated phase Philadelphia chromosome positive CML in adults that are resistant or intolerant to prior Gleevec therapy.

Tasigna is an oral medication that is given twice daily in 400mg doses. The drug is expected to be available within days of the FDA approval. The cost of the drug will range approximately \$5,700 per month.

## NOVEMBER AWARENESS

**-Diabetes Awareness Month**

**-Lung Cancer Awareness Month**

**-National Alzheimer's Awareness**

## New Chemotherapy Test Will Determine the Most Effective Drug to Improve Cancer Treatment

*Nine hospitals nationwide are participating in a new study that could change current cancer treatment.*

The research involved studying a new test that determines which chemotherapy drugs will be the most effective in destroying each individual patient's cancer cells.

The test was developed and patented by Vladimir Kravtsov II, M.D., Ph.D. when he was at Vanderbilt University. Dr. Kravtsov is the Medical Director at DiaTech Oncology in Nashville, TN.

Garry Latimer, CEO, of DiaTech Oncology says, "The process lowers the cost and time of finding the optimal drug regimen for a cancer patient. The patient's comfort is improved because candidate medications are applied and tested in lab tests rather than in the patient's body. It's a huge step forward increasing effectiveness, lowering costs, and improving patient outcomes."

Typically there are several chemotherapy agents that can be used during the course of treatment. Not all agents are equally effective in eliminating tumor cells. However, patients who undergo and receive test results have information about which drugs will most likely be effective in destroying their cancer cells. The test results are available in approximately two days. The new technology, called Microculture Kinetic (MiCK) assay, is the only test available that directly measures sensitivity for chemotherapy agents with each patient's specific cancer cells.

The test requires live cells from the patient's tumor. The tumor cells are sent to DiaTech Oncology, where the test is completed. Using an automated process the MiCK assay "counts" tumor cells destroyed by each drug at five-minute intervals zeroing in on which one would be expected to work best for that individual patient.

Case Managers, TPA's, cancer patients and physicians interested in knowing more about the study may call DiaTech Oncology toll-free at (877) 434-2832 or visit [www.diatech-oncology.com](http://www.diatech-oncology.com). \*Source: My Health Guide

***MiCK is the only test available that directly measures sensitivity for chemotherapy agents with each patient's specific cancer cells.***

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# 2007 THIRD QUARTER SPECIALTY DRUG PIPELINE

## Drugs in Trials and Recent Approvals

Drug Name	Indication for Use	Route of Administration	Trial Phase/Approval Date
Maraviroc	HIV infection	Oral	Approved 8/6/07
Privigen	Treatment of primary immunodeficiency and chronic immune thrombocytopenic purpura	IV infusion	Approved 7/27/07
Torisel	Treatment of advanced renal cell carcinoma	IV infusion	Approved 5/30/07
Somatuline Depot	Treatment of Acromegaly	SC injection	Approved 8/30/07
Ixempra	Breast Cancer	IV infusion	Approved 10/30/07
eprodisate	Treatment of Amyloid A amyloidosis	Oral	Orphan Drug Phase III trial
Mircera	Treatment of anemia associated with chronic renal disease	SC or IV injection	Awaiting FDA recommendations on entire class of erythropoiesis-stimulating agents
Denufosal	Cystic fibrosis treatment	Inhalation	Orphan drug with fast track status.
Refacto AF	Treatment of hemophilia	Infusion	Phase II
Viramidine	Treatment of hepatitis C in combination with pegylated interferon alfa-2b	Oral	Phase II
raltegravir	HIV infection	Oral	Priority review status June 2007
Etravirine	HIV infection	Oral	FDA granted fast track status
Cimzia	Moderate to severe Crohn's disease, rheumatoid arthritis and severe psoriasis	SC injection	On-going trials for each disease state. Results for Crohn's study expected mid-2008
Rilonacept	Treatment of CAPS (rare genetic syndromes)	SC injection	Granted orphan drugs status
Fingolimod	Treatment of MS	Oral	Also in Phase III trials for kidney transplant rejection
Teriflunomide	Treatment of MS	Oral	Also being studied in combination with Copaxone
CoFactor	Treatment of metastatic colorectal cancer	IV injection	Phase III
Xyotax	Treatment of advanced non-small cell lung cancer in women	IV infusion	FDA granted fast track status
Xerecept	Treatment of peritumoral cerebral edema	SC injection	Orphan drug
Treanda	Treatment of chronic lymphocytic leukemia and non-Hodgkin's lymphoma in patients who failed Rituxan	IV infusion	Phase III completed
Atamestane	Treatment of breast cancer	Oral	Phase III
Virulizin	First line treatment of advanced pancreatic cancer in combination with Gemzar	IM injection	Orphan drug with fast track status

## Drugs in Trials and Recent Approvals, continued

Drug Name	Indication for Use	Route of Administration	Trial Phase/Approval Date
Tasigna	Treatment of chronic myeloid leukemia which is unresponsive or resistant to Gleevec	Oral	Orphan drug with fast track status
Denosumab	Treatment of postmenopausal osteoporosis	SC injection	All Phase III endpoints met
Numax	Prevention of RSV	IM injection	Pending approval/anticipated launch 2008-2009 RSV season
Certican	Prevention of solid organ transplant rejection in combination with Neoral	Oral	Clinical trial ongoing

## New Indications in the Pipeline

Drug Name	Current Indication for Use	Investigational Indication for Use	Route of Administration	Trial Phase
Tysabri	Relapsing forms of MS	Treatment of moderate to severe Crohn's disease	IV infusion	FDA recommended approval July 2007
Leukine	Improve immune cell function in myelogenous leukemia or following bone marrow transplant	Treatment of moderate to severe Crohn's disease	SC injection	
Vilread	HIV treatment	Treatment of chronic hepatitis C	Oral	Primary endpoints met in Phase III
Infergen	Treatment of hepatitis C	Treatment of chronic hepatitis C in combination with ribavirin after failure to respond to pegylated interferon plus ribavirin	SC injection	
Humira	Treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and Crohn's disease	Treatment of juvenile arthritis and chronic plaque psoriasis	SC injection	
Kineret	Treatment of rheumatoid arthritis	Treatment of polyarticular-course chronic juvenile rheumatoid arthritis	SC injection	
Orencia	Moderate to severe rheumatoid arthritis	Treatment of juvenile idiopathic arthritis	IV infusion	
Nexavar	Treatment of advanced renal cell cancer	Treatment of advanced liver cancer	Oral	Granted fast track status
Sutent	Treatment of gastrointestinal stromal tumor and advanced renal cell carcinoma	Treatment of metastatic colorectal cancer	Oral	
Reclast	Treatment of Paget's disease	Treatment of postmenopausal osteoporosis	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