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FDA Creates Web Page With Drug Safety Information for Patients and Health Care Professionals

Patients and health care professionals can now access a single page on the FDA web site to find a variety of safety information about prescription medications.

Web page www.fda.gov/cder/drugSafety.htm, provides links in these categories:

- Drug labeling, including patient labeling, professional labeling, and patient package inserts;
- Drugs that have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that their benefits outweigh their risks;
- A searchable database of postmarket studies that are required from, or agreed to by, drug companies to provide the FDA with additional information about a drug's safety, efficacy, or optimal use;
- Clinicaltrials.gov, a searchable database of clinical trials, including information about each trial's purpose, who may participate, locations, and useful phone numbers;
- Drugs-specific safety information, including safety sheets with the latest information about the drug as well as related FDA press announcements, fact sheets,

Establishing this web page is one of the requirements of the Food and Drug Administration Amendments Act of 2007.

and drug safety podcasts;

- Quarterly reports that list certain drugs that are being evaluated for potential safety issues, based on a review of information in the FDA's Adverse Event Reporting System (AERS);
- Warning Letters, Import Alerts, Recalls, Market Withdrawals, and Safety Alerts;
- Regulations and guidance documents;
 - Consumer information about using medications safely and disposing of unused medicines;
 - Instructions how to report problems to the FDA through its MedWatch program;
 - Consumer articles on drug safety; and
- The FDA's response to the Institute of Medicine's 2006 report on the future of drug safety.

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Experimental Hepatitis C Drug Data

Vertex Pharmaceuticals, Inc. is currently developing a hepatitis C drug which is showing impressive results in clinical trials. The experimental drug, telaprevir, showed the ability to knock out the virus in patients who failed on other treatments and those not previously treated for the serious liver disease.

Telaprevir, when combined with standard treatments, showed the potential to cut in half the 48 weeks of treatment needed with the current standard of care and with greater efficacy. Of the 453 patients in the study, who had previously failed with pegylated-interferon and ribavirin, 52 percent of those received telaprevir saw the virus fall to undetectable levels and remain there 12 weeks after stopping treatment. The percentage of undetectable virus 24 weeks after stopping treatment will yield the critical measure known as sustained viral response (SVR).

The study results are noteworthy as patients who have failed therapy are difficult to manage as there are limited therapies and they are at greater risk of their liver disease progressing.

Hepatitis C is a blood-borne liver disease that can lead to chronic liver disease, liver cancer, cirrhosis and death. The virus affects an estimated 3.2 million people in the United States.

FDA Approves Chemotherapy Drug, Treanda, for Lymphoma

On November 3, 2008 the FDA approved bendamustine hydrochloride (Treanda) for use against indolent B-cell non-Hodgkin's lymphoma that has progressed within six months of treatment with a regimen including rituximab. The drug was approved after a clinical trial of 100 patients showed a high response (74%) to the treatment.

The recommended infusion dosage is 120mg administered on days one and two of a 21-day cycle, for up to eight cycles.

Treanda, with a list price of \$1,800 per 100 milligram vial, had \$26 million in sales from April to August. The average monthly cost for treatment is upwards of \$4,500. The drug was previously approved last March for treating patients with chronic lymphocytic leukemia.

What is an Orphan Drug?

The Food and Drug Administration's Orphan Drug Act was designed to encourage the development of products that demonstrate promise for the diagnosis, prevention and/or treatment of life-threatening or very serious conditions affecting 200,000 persons or less in the United States. Orphan drug designation provides an important economic incentive for the development of new products in the cancer field. U.S. orphan drug designation provides for seven years of market exclusivity, reduction in regulatory fees, and additional regulatory support for Research and Development initiatives.

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Specialty Pharmacy Pipeline Drugs to Watch

As we quickly come to a close of 2008 there are a number of anticipated drug launches on target through the end of the year. Each of these drugs is still pending FDA approval.

Drug Name	Indication	Route of Admin	Disease Prevalence
Actemra	Rheumatoid Arthritis	Injection-IV Infusion	RA affects 1.3 million people, 75% are women.
Aztreonam lysine for inhalation	Control of gram-negative respiratory tract infections in cystic fibrosis	Inhalation	Approximately 30,000 children and adults in the U.S. suffer from CF. About 1,000 new cases are diagnosed each year.
Cinryze	Treatment and prevention of acute hereditary angioedema (HAE) attacks	Injection-IV	HAE is a rare genetic disorder. Patients with HAE experience recurrent, unpredictable, and potentially life threatening attacks of inflammation affecting the larynx, abdomen, face extremities and urogenital tract. Approximately 10,000 people in the U.S. have HAE.
Ferumoxytol	Treatment of iron deficiency anemia in patients with chronic kidney disease	Injection-IV	More than 50% of patients with end-stage renal disease are iron deficient.
Fludara	Treatment of relapsed B-cell chronic lymphocytic leukemia	Oral	CLL is a bone marrow cancer of the white blood cells. It is estimated that 15,000 new cases will be diagnosed in 2008.
Motavizumab	Prevention of RSV disease in high-risk infants	Injection-IM	125,000 children are hospitalized annually in the U.S. due to RSV.
Nplate	Treatment of chronic idiopathic thrombocytopenic purpura (ITP)	Injection-SC	ITP is rare bleeding disorder in which the blood does not clot normally. It is estimated that 200,000 people in the U.S. have ITP.
Prograf MR	Organ rejection prevention in patients receiving allogenic kidney or liver transplants	Oral	In 2007, approximately 6,500 liver transplants and 16,600 kidney transplants were performed in the U.S.
Promacta	Treatment of adults with previously treated chronic idiopathic thrombocytopenic purpura (ITP)	Oral	ITP is rare bleeding disorder in which the blood does not clot normally. It is estimated that 200,000 people in the U.S. have ITP.
Rebif	Treatment of relapsing forms of MS	Injection-SC	Approximately 350,000 Americans have MS, with women being affected twice as frequently as men.
Sabril	Treatment of infantile spasm (IS) and refractory complex partial seizures (CPS)	Oral	IS are seizures that begin during early infancy.
Synvisc One	Treatment of pain associated with osteoarthritis (OA)	Injection	In 2001, 13.5 million people in the U.S. reported having symptoms of knee osteoarthritis.
Ustekinumab	Treatment of moderate to severe plaque psoriasis	Injection-SC	Approximately 2.2% of Americans are affected by psoriasis. Nearly one-fourth of these have moderate to severe cases.

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
Monoclote P
Recombinate
ReFacto

Anti-nausea

Aloxi
Anzemet
Emend
Kytril
Zofran

Asthma

Xolair

Cancer/Related

Adriamycin
Aducil
Alkeran
Aredia
Avastin
BiCNU
Blenoxane
Busulfex
Campath
Camptosar
Cerubidine
Cosmegen
Cytarabine
Cytosan
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
Zinecard

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