

Specialty Pharmacy Pipeline Report

Fourth Quarter 2006

To help keep you informed about medications in development, the *Walgreens Specialty Pharmacy Pipeline Report* provides a summary of specialty medications that may be approved by the Food and Drug Administration (FDA) within the next few years. While not all-inclusive, this report focuses on medications (in the later stages of clinical trials) that may impact treatment for certain specialty disease states. It also highlights selected, newly approved or soon-to-be approved specialty medications of interest to the marketplace.

Medications to Watch

Here is a closer look at a few recently approved or soon-to-be approved medications that may have a significant impact on therapeutic classes and treatment for specific disease states.

Elaprase™ (idursulfase)

On July 24, 2006, the FDA announced the approval of Shire's Elaprase—the first treatment approved by the FDA for Hunter syndrome. Hunter syndrome is a rare disease that is inherited through the X chromosome. It is estimated that 2,000 patients worldwide are affected by the syndrome. The pathology of the disease is directly linked to the enzyme iduronate-2-sulfatase, which is not produced at all or is produced in a defective form. The enzyme is needed in humans to facilitate the breakdown of cellular waste products which, in Hunter syndrome patients, accumulate in tissues and organs and may lead to organ dysfunction, growth delay, and in severe cases, respiratory and cardiac symptoms, neurological deficits, and death.

To encourage manufacturers to bear the high cost of development of cures for rare disease states, the FDA

has granted Elaprase an orphan drug status. The approval of the drug came after the submission of a randomized, double-blind, placebo controlled trial in which patients receiving the drug demonstrated improved walking capacity compared to patients receiving placebo. Elaprase's recommended dose is 0.5 mg/kg of body weight given as an intravenous infusion once weekly. The annual cost for treatment is estimated to be \$300,000 per year, although the exact price depends on the patient's body weight.

Tykerb® (lapatinib)

A recent interim analysis of a phase III trial presented at the latest annual meeting of the American Society of Clinical Oncology in Atlanta, has prompted GlaxoSmithKline to submit a New Drug Application to the FDA for the approval of Tykerb® (lapatinib) in combination with Xeloda® (capecitabine) for the treatment of advanced or metastatic human epidermal growth factor receptor 2 (HER2, ErbB2) positive breast cancer.

This international, multicenter, open-label trial included 324 women with advanced or metastatic breast cancer and documented disease progression following treatment with other oncologic agents, including Herceptin® (trastuzumab). Patients in the study were randomized to receive Tykerb and Xeloda or Xeloda alone. A preplanned interim analysis revealed a statistically significant difference between patients who were treated with the combination of Tykerb and Xeloda and those who were treated with Xeloda alone.

GlaxoSmithKline reports that in patients who were treated with combination therapy, the median time for

disease progression was 36.7 weeks compared with patients who were treated with Xeloda alone, which was 19.1 weeks. According to GlaxoSmithKline, the most common adverse drug reactions observed during the trial were diarrhea, nausea, vomiting, and dermatologic reactions.

Tykerb is an oral agent that is reported to target and inhibit the tyrosine kinase components of epidermal growth factor receptor (EGFR, ErbB1) and HER2 receptors, which are associated with cell growth and tumor progression. It has been previously reported that these receptors are over-expressed in several human tumors, and therefore inhibiting these receptors is postulated to slow disease progression.

Fingolimod

A recent phase II study published in the *New England Journal of Medicine*, examined the effectiveness of fingolimod—an oral drug for the treatment of multiple sclerosis (MS).

Fingolimod, developed by Novartis, acts as an agonist of the sphingosine-1-phosphate-1-receptor, which leads to the internalization of this receptor in lymphocytes, thereby preventing these cells of a signal necessary for their development. In the study, 281 patients were randomized to receive either fingolimod 1.25 mg or 5.0 mg, or placebo once daily for six months. Study researchers assessed brain MRI images of fingolimod treated patients throughout the study and evaluated the number of newly formed brain lesions. At the end of the study, patients were offered the option to enter another phase of the study and those patients who formerly received a placebo, then received the active drug.

The researchers found that MS disease relapse rates and the number of newly formed lesions were significantly lower among the fingolimod treatment groups. Although these results are encouraging, it is important to remember that longer trials are needed to assure the safety and efficacy of the drug. Since the drug clearly affects the function of the immune system, it may induce some adverse effects that were not seen during the published trial.

Due to the mechanism of action of the drug, there may be other therapeutic uses for fingolimod but no further information is available at this time. The results of this trial provide hope to thousands of patients suffering from MS.

According to the National Institute of Neurological Disorders, the exact number of patients diagnosed with MS is unknown. However, it is estimated that between 250,000 and 350,000 patients in the United States are diagnosed with MS, with 200 new patients diagnosed each week. At the same time that fingolimod is being investigated by Novartis, Serono and Ivax are continuing with phase III trials to investigate treatment of MS with oral cladribine.

Alfimeprase

Alfimeprase is a novel compound that was developed based on the structure of fibrolase—a known molecule isolated from the venom of the southern copperhead snake *Agkistrodon contortrix*.

The importance of drugs that treat or prevent thrombolytic events is evident as thrombolytic events triggered by the formation of blood clots may result in a stroke, deep vein thrombosis (DVT), pulmonary embolism (PE), or myocardial infarction (MI), all of which are documented to reduce quality of life and increase mortality rates.

Thrombolytic events are commonly treated with agents that induce the conversion of plasminogen to plasmin, an enzyme responsible for clot dissolution. The mechanism of action of alfimeprase differs from currently used agents as it dissolves fibrin (a protein involved in clot formation) with no relation to the cascade of events that current agents depend upon for activation. The suggested mechanism of action may result in faster activity, although studies demonstrating faster effects in humans are not yet available. Alfimeprase is therefore considered a direct fibrinolytic (clot dissolving agent).

Alfimeprase is being developed by Nuvelo and is currently in phase III trials for the treatment of peripheral arterial occlusion (PAO) and catheter occlusion. Currently, there are no other FDA-approved treatments for PAO, and off-label plasminogen is used to treat patients who present with acute PAO. The company expects to complete all phase III trials in the second half of 2006, and has indicated that it will launch phase II trials to pursue DVT and stroke indications during the second half of 2006 and 2007. The FDA has granted alfimeprase an orphan drug status for PAO, as well as a fast track designation due to the unmet medical needs of patients diagnosed with PAO.

Drugs/Devices Recently Approved

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Approval Date	Comments
Ankylosing Spondylitis					
*Abbott/ Humira® (adalimumab)	For reducing signs and symptoms in patients with active ankylosing spondylitis	Targets tumor necrosis factor alpha/Monoclonal antibody	SC injection	07/31/06	Previously approved for rheumatoid arthritis and psoriatic arthritis.
Enzyme Replacement Therapy					
Shire/ Elaprase™ (idursulfase)	For the treatment of Hunter syndrome (mucopolysacchraidosis type II, MPS II)	Replaces deficient lysosomal enzyme iduronate-2-sulfatase/Enzyme replacement therapy (ERT)	IV infusion	07/24/06	First treatment approved for Hunter syndrome. Designated as an orphan drug.

*New indication or device for an already approved medication.

Launch Expected in 2006

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Anemia					
Roche/ Mircera® (erythropoietin) Formerly CERA, R744	For the treatment of anemia associated with chronic kidney disease, including patients on dialysis	Stimulates red blood cell production/CERA (continuous erythropoietin receptor activator)	SC injection	III	BLA filed April 2006. †Also in phase II trials for the treatment of chemotherapy-associated anemia.
Hepatitis					
Idenix and Novartis/ Sebivo™ (telbivudine)	For the treatment of chronic hepatitis B virus (HBV) infection	Inhibits viral DNA replication/Nucleoside analogue	Oral	III	NDA filed December 2005.
Osteoporosis					
NPS Pharmaceuticals/ Preos® (parathyroid hormone)	For the treatment of osteoporosis in postmenopausal women	Stimulates new bone growth/Recombinant human parathyroid hormone	SC injection	III	NDA filed May 2005. Approvable letter March 2006.
Parkinson's Disease					
Schwarz Pharma/ Neupro® (rotigotine)	For the treatment of early stage Parkinson's disease	Increases level of dopamine/Dopamine receptor agonist	Transdermal	III	NDA accepted March 2005. Approvable letter March 2006. Also in phase III trials for the treatment of advanced-stage Parkinson's disease.
Pulmonary Arterial Hypertension					
Encysive Pharmaceuticals/ Thelin™ (sitaxentan)	For the treatment of pulmonary arterial hypertension	Reduces vascular smooth muscle constriction/Endothelin receptor antagonist	Oral	III	NDA filed May 2005. First approvable letter March 2006. Second approvable letter July 2006.

†This study is in phase II trials for the treatment of chemotherapy-associated anemia—not phase III—as previously reported in the third quarter 2006 issue of the *Walgreens Specialty Pharmacy Pipeline Report*.

Launch Expected in 2007

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Hepatitis					
Valeant Pharmaceuticals/ Viramidine® (taribavirin)	For the treatment of chronic hepatitis C virus (HCV) infection, in combination with pegylated interferon	Reduces virus synthesis/Antiviral (synthetic nucleoside analog)	Oral	III	Prodrug of ribavirin.
Hemophilia					
Wyeth/ ReFacto® AF (antihemophilic factor)	For the treatment of hemophilia A	Blood clotting factor/ Recombinant factor VIII	Infusion	III	Pending approval. Phase III completed.
Inflammatory Disease					
UCB/ Cimzia™ (certolizumab pegol)	For the treatment of moderate to severe or active Crohn's disease, moderate to severe or active rheumatoid arthritis, and moderate to severe psoriasis	Targets tumor necrosis factor alpha, which is involved in the inflammatory process/Monoclonal antibody	SC injection	III	BLA for the treatment of moderate to severe Crohn's disease filed March 2006.
Oncology					
Wyeth Pharmaceuticals/ Torisel™ (temsirolimus)	For the treatment of advanced renal cell carcinoma and mantle cell lymphoma	Controls tumor cell growth/Cell cycle inhibitor	Oral	III	Designated as an orphan drug.
GlaxoSmithKline/ Tykerb® (lapatinib)	For the treatment of advanced or metastatic HER2 positive breast cancer, in combination with capecitabine (Xeloda®), in women who have received prior therapy, including trastuzumab (Herceptin®)	Inhibits the tyrosine kinase components of EGFR and HER2 receptors/Dual kinase inhibitor	Oral	III	NDA filed September 2006. FDA granted fast track status. Also being investigated for solid tumors and lung cancer.
Protherics/ Voraxaze™ (glucarpidase) Formerly Carbo- xypeptidase G2	Adjunctive therapy for cancer patients undergoing chemotherapy who are at risk of methotrexate toxicity	Rapidly reduces serum methotrexate levels/Recombinant enzyme	IV injection	III	BLA filed September 2006. Designated as an orphan drug. Available on a compassionate use basis from the distributor.
MGI PHARMA/ Saforis™ (glutamine in UpTec)	For the prevention and treatment of chemotherapy- induced oral mucositis	Promotes healing and prevents damage to mucosa/Amino acid	Oral	III	FDA granted priority review. NDA filed April 2006.

Launch Expected in 2007 continued

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Pulmonary Arterial Hypertension					
Myogen/ (ambrisentan)	For the treatment of pulmonary arterial hypertension	Reduces vascular smooth muscle constriction/Endothelin receptor antagonist	Oral	III	Designated as an orphan drug. NDA filing planned for the end of 2006.

Launch Expected in 2008

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Anemia					
Advanced Magnetics/ (ferumoxytol)	For the treatment of anemia due to chronic kidney disease	Iron replacement	IV injection	III	NDA filing planned for mid-2007.
Crohn's Disease					
NPS Pharmaceuticals/ (teduglutide)	For the treatment of Crohn's disease	Regulates cells that line GI tract/Analog of glucagon-like peptide-2	SC injection	II	Also in phase III for short-bowel syndrome. NDA filing for short-bowel syndrome is anticipated for 2008.
HIV					
Pfizer/ (maraviroc)	For the treatment of HIV	Inhibits entry of virus into human CD4 T-cells/Cellular chemokine receptor antagonist (CCR-5)	Oral	III	FDA granted fast track status.
Tibotec Therapeutics and J&J/ (TMC125)	For the treatment of non-nucleoside reverse transcriptase inhibitor (NNRTI)-resistant HIV infection	Inhibits viral DNA replication/NNRTI	Oral	III	NDA filing planned for 2007. FDA granted fast track status.
Oncology					
Novartis and Schering AG/ (vatalanib)	For the treatment of solid tumors	Inhibits formation of blood vessels that supply nutrients to tumors/VEGFR tyrosine kinase inhibitor	Oral	III	NDA filing expected in early 2007.
Adventrx/ CoFactor® (ANX-510)	For the treatment of metastatic colorectal cancer in combination with 5-fluorouracil (5-FU)	Binds 5-FU to the enzyme thymidylate synthase/Folate biomodulator	IV injection	III	Phase III trials initiated June 2006.

Launch Expected in 2008 continued

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Respiratory Syncytial Virus (RSV)					
MedImmune/ Numax [®] (motavizumab)	For the prevention of respiratory syncytial virus (RSV) infection in high-risk pediatric populations	Inhibits RSV replication/Monoclonal antibody	IM injection	III	Expected to be more potent than palivizumab (Synagis [®]), which is the current standard of treatment for the prevention of RSV.
Transplant					
Bristol-Myers Squibb/ (belatacept)	For the treatment of solid organ transplant rejection	Inhibits T-cells, which are involved in the rejection process/ Costimulation blocker	IV injection	III	

Drugs on the Horizon

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Anemia					
Icagen and McNeil/ (ICA-17043)	For chronic preventive treatment of sickle cell disease	Prevents red blood cell dehydration and formation of sickle cells/Gardos ion channel blocker	Oral	III	NDA filing planned for mid-2007. Designated as an orphan drug with fast track status.
Blood Modifiers					
Nuvelo/ (alfimeprase)	For the treatment of acute peripheral arterial occlusion (PAO) and central venous catheter occlusion	Degrades fibrin/Fibrinolytic agent	IV injection	III	Designated as an orphan drug with fast track status.
Cystic Fibrosis					
Inspire Pharmaceutical/ (denufosal)	For the treatment of cystic fibrosis	Designed to enhance mucosal hydration and mucociliary clearance/Second generation P2Y ₂ agonist	Inhalation	III	Designated as an orphan drug with fast track status. Phase III trials initiated July 2006.
Multiple Sclerosis					
Novartis/ (fingolimod)	For the treatment of relapsing-remitting multiple sclerosis (MS)	Reduces inflammation and myelin damage in the brain and spinal cord/ Immunomodulatory agent	Oral	III	If approved, would be first oral agent available to treat MS. Also in phase III trials for prevention of kidney transplant rejection.

Drugs on the Horizon *continued*

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Neuroendocrine Disorders					
Novartis/ (pasireotide)	For the treatment of acromegaly, neuroendocrine tumors, and Cushing's syndrome	Binds somatostatin receptors/ Somatostatin analogue	SC injection/IV	II	NDA filing planned for 2009.
Oncology					
Intarcia Therapeutics/ (atamestane)	For first-line treatment of hormone-dependent breast cancer in combination with estrogen receptor blocker toremifene (Fareston [®])	Interferes with estradiol production/Steroidal aromatase inhibitor	Oral	III	
Threshold Pharmaceuticals/ (glufosfamide)	For second-line treatment of metastatic pancreatic cancer	Decreases tumor size/Modified alkylating agent	IV infusion	III	FDA granted fast track status.
Lorus Therapeutics/ Virulizin [®]	For first-line treatment of advanced pancreatic cancer in combination with gemcitabine	Increases the cytogenic effects of macrophages/ Biologic response modifier	IM injection	III	Rolling NDA accepted July 2005. Designated as an orphan drug with fast track status. Also being investigated for malignant melanoma.
Marshall Edwards/ (phenoxodiol)	For the treatment of hormone-refractory prostate cancer in docetaxel non-responders	Causes cell death through inhibition of anti-apoptotic proteins/ Antineoplastic (multiple signal transduction regulator)	IV injection/ Oral	III	FDA granted fast track status.
Neurobiological Technologies/ Xerecept [®] (corticoirelin)	For the treatment of peritumoral cerebral edema	Reduces edema/ Synthetic human corticotropin releasing factor	SC injection	III	Designated as an orphan drug.
Sanofi-Aventis/ Tirazone [®] (tirapazamine)	For the treatment of head and neck squamous cell carcinoma and cervical cancer	Selective toxicity against cells with low oxygen/Antineoplastic	IV injection	III	
Osteoporosis					
Amgen/ (denosumab)	For the treatment of postmenopausal osteoporosis and treatment-induced bone loss	Inhibits bone destruction/Monoclonal antibody	SC injection	III	

Drugs on the Horizon continued

Manufacturer/ Drug Name	Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Transplant					
Novartis/ Certican™ (everolimus)	For the prevention of solid organ transplant rejection in combination with cyclosporine (Neoral®)	Inhibits T-cell proliferation, which are cells involved in the rejection process/ Immunosuppressant	Oral	III	NDA filed December 2002. First approvable letter October 2003. Second approvable letter August 2004.
Fresenius Medical Care AG and Nabi/ (ATG-Fresenius S)	For the prevention of graft-versus-host disease in lung transplantation	Targets a range of antigens on activated T-cells/Polyclonal antibody	Injection	III	BLA expected early 2009. FDA granted fast track status.
Vaccines					
Neurocrine Biosciences/ NBI-5788	For the treatment of relapsing-remitting and progressive multiple sclerosis (MS)	Targets disease causing MS cells/ Altered peptide ligand product	Injection	II	

New Dosage Forms and Chemical Entities in the Pipeline

Manufacturer(s)/ Drug Name	Indication	Mechanism of Action/Drug Class	Current Route of Administration	Investigational Route of Administration	Phase	Comments
Cystic Fibrosis						
Corus Pharma/ Cayston™ (aztreonam lysine)	For the treatment of cystic fibrosis lung infections	Inhibits bacterial cell wall synthesis/ Monobactam antibiotic	IV injection	Inhalation	III	NDA filing planned 2007. Designated as an orphan drug.
Multiple Sclerosis						
Serono and IVAX Corporation/Mylinax® (cladribine)	For the treatment of multiple sclerosis (MS)	Interferes with lymphocytes, which are involved in MS/ Antineoplastic (purine nucleoside analogue)	IV infusion	Oral	III	FDA granted fast track status.
Oncology						
Cell Therapeutics/ Xyotax™ (paclitaxel poliglumex)	For second-line treatment of non-small cell lung cancer (NSCLC)	Promotes assembly and stabilizes microtubules resulting in inhibition of cellular division/ Antimicrotubule chemotherapy agent	IV infusion	IV infusion	III	Links paclitaxel to a biodegradable polyglutamate polymer that delivers more chemotherapy to tumor cells.

New Indications in the Pipeline

Manufacturer(s)/ Drug Name	Current Indication	Investigational Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Crohn's Disease						
Abbott/ Humira® (adalimumab)	For the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	Moderate to severely active Crohn's disease	Targets tumor necrosis factor (TNF) alpha, which is involved in the inflammation process/ Monoclonal antibody	SC injection	III	sBLA filed September 2006.
Immunex Corporation and Schering AG/ Leukine® (sargramostim)	For the treatment of myelogenous leukemia and bone marrow transplant	Moderate to severely active Crohn's disease	Modulates immune system/Granulocyte macrophage colony stimulating factor	SC injection	III	BLA filing expected 2006. Launch in 2009.
Hepatitis						
Gilead/Viread® (tenofovir)	For the treatment of HIV	Treatment of chronic hepatitis B virus (HBV) infection	Inhibits the formation of viral DNA/ Nucleotide reverse transcriptase inhibitor	Oral	III	
Valeant/ Infergen® (interferon alfacon-1)	For the treatment of hepatitis C virus (HCV) infection	Treatment of chronic HCV in combination with ribavirin after failure to respond to previous course of pegylated interferon alfa-2 plus ribavirin	Inhibits viral replication/Interferon	SC injection	III	
Juvenile Rheumatoid Arthritis						
Amgen/Kineret® (anakinra)	For the treatment of rheumatoid arthritis	Treatment of polyarticular-course chronic juvenile rheumatoid arthritis	Blocks the biologic activity of IL-1/Interleukin-1 inhibitor	SC injection	III	
Psoriasis						
Abbott/ Humira® (adalimumab)	For the treatment of rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis	Treatment of chronic plaque psoriasis	Targets tumor necrosis factor (TNF) alpha/ Monoclonal antibody	SC injection	III	sBLA filing expected 2007.
GlaxoSmithKline/ Avandia® (rosiglitazone)	For the treatment of type 2 diabetes	Treatment of psoriasis	Mechanism of action in psoriasis is not clearly understood/ Thiazolidinedione	Oral	III	

New Indications in the Pipeline continued

Manufacturer(s)/ Drug Name	Current Indication	Investigational Indication	Mechanism of Action/Drug Class	Route of Administration	Phase	Comments
Psoriasis						
Centocor/ Remicade® (infiximab)	For the treatment of rheumatoid arthritis, adult and pediatric Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and ulcerative colitis	Treatment of moderate to severe plaque psoriasis	Mechanism of action in psoriasis is not clearly understood/ Monoclonal antibody	IV infusion	III	sBLA accepted November 2005.

Glossary of Terms

Approvable designation or letter – indicates that an FDA committee has reviewed the NDA and has suggested to the FDA that it approve the new medication. The FDA does not have to follow the advice of the committee.

BLA – stands for “biologic license application”; similar to an NDA, but used for investigational drugs that are considered to be biologic agents.

Double-blind – a type of study in which the participants and the investigators are blinded to treatment; this type of study has less bias than nonblinded studies.

Fast track status – designation granted by the FDA to an investigational agent, indicating an expedited review of the NDA; usually done for medications that treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

NDA – stands for “new drug application”; the process by which a drug company submits information to the FDA to get approval for the agent; done after phase III development is completed.

NDA rolling submission – usually done for fast track medications; indicates that the review process can be started even before the FDA receives all the information. However, the FDA requires all the information before a final decision about approval can be made.

Orphan drug – a medication that treats a rare disease that affects fewer than 200,000 Americans. A medication granted orphan drug status is entitled to seven years of marketing exclusivity.

Phase II – second phase of drug development; typically involves several hundred patients to determine safety and preliminary data on efficacy.

Phase III – last phase of drug development; involves safety and efficacy trials of the new drug. This phase of development can take years to complete.

Priority review – similar to fast track status in that the NDA will undergo an expedited review.

Randomized Controlled Trial (RCT) – a study in which people are allocated at random (by chance alone) to receive one of several clinical interventions; it is the most powerful study in clinical research.

sBLA – stands for “supplemental biologic license application”; similar to sNDA, but used for already-approved investigational drugs that are considered to be biologic agents.

sNDA – stands for “supplemental new drug application”; the process by which a drug company submits information to the FDA to get a new indication approved for an agent that has already been approved by the FDA.

References

Manufacturers' web sites
U.S. Food and Drug Administration
www.fda.gov
Inteleos™
www.inteleos.com/inteleos.html
ClinicalTrials.gov
www.clinicaltrials.gov
Christopher F. Toombs. *Haemostasis*. 2001; 31:141-147
Ludwig Kappos, M.D., Jack Antel, M.D., Giancarlo Comi, M.D., et al. *New England Journal of Medicine* 2006; 355:1124-40.

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