

Coming Attractions

Drug	Category	Sponsor	Cancer Indication	Phase of Development	Comments
Picoplatin	Chemotherapy	Poniard Pharmaceuticals	Small Cell Lung Cancer	Phase III for more info call 888-879-7007	May be helpful for those who fail platinum-based therapy. Phase II studies for colorectal and prostate cancer.
PDX (pralatrexate)	Chemotherapy	Allos Therapeutics, Inc.	Peripheral T-Cell Lymphoma	Phase II for more info call 303-426-6262	Patients on this trial receive study drug and vitamins B12 and folic acid to help lessen stomatitis.
Promacta™ Revolade™ (eltrombopag)	Platelet Growth Factor	GlaxoSmithKline	Chronic ITP	Phase III for more info visit www.gsk.com	This treatment is convenient for patients because it is in an oral formulation.
CDX-110	Immunotherapy Vaccine	Celldex Therapeutics	Glioblastoma multiforme	Phase II/III for more info call 908-454-7120 ext. 305	Fast track designated by the FDA and granted orphan drug status, this drug targets EGFRvIII, a variant of EGFR.
XL184	Small Molecule Inhibitor	Exelixis, Inc.	NSCLC	Phase I/II for more info visit www.exelixis.com	Another option for those who have progressed when taking erlotinib (Tarceva).
Elesclomol	Small Molecule ROS Inducer	Synta Pharmaceuticals Corporation	Metastatic Melanoma	Phase III for more info visit www.syntapharma.com	A new category of anti-cancer therapy that increases ROS (reactive oxygen species) to induce apoptosis.
Pazopanib (GW786034)	VEGF tyrosine kinase inhibitor	GlaxoSmithKline	Gynecologic Cancers/ Soft Tissue Sarcoma/ Renal Cell Carcinoma	Phase II for more info visit www.gsk.com	This second generation tyrosine kinase inhibitor may offer less toxicity and may be effective in treating many tumor types.

*We realize that there are many drugs in research and development. The ones listed above are a select few that have been chosen as potential coming attractions.

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ZD4054	Endothelin A receptor antagonist	AstraZeneca	Hormone Refractory Prostate Cancer (HRPC)	Phase III for more info e-mail zd4054@icon.irl.com	This oral drug would provide another treatment option for HRPC whose only approved treatment now is docetaxel.
Ofatumumab (HuMax-CD20)	Monoclonal Antibody	Genmab	B- Cell Chronic Lymphocytic Leukemia	Phase III for more info visit www.genmab.com	Fast track designated by the FDA, this study has been amended to add more patients to the trial.
Actimid (CC-4047)	Immuno-modulator	Celgene	Multiple Myeloma	Phase II for more info call 507-538-7623	Another potent IMiD (immunomodulator), this study was initiated in Fall 2007.

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The Provenge Debate

There has been a heated debate this past year between the FDA and Provenge (Sipuleucel-T) a dendritic cell vaccine used for the treatment of metastatic prostate cancer. For those who may have or have not followed it, here is a play by play of the debate.

- ▶ March 30, 2007- FDA advisors vote 13-4 endorsing the vaccine
- ▶ May 15, 2007- FDA voted against the vaccine's approval
- ▶ July 30, 2007- Patient advocacy group sues FDA for withholding approval
- ▶ December 14, 2007- Congressional hearings called for lawmakers over the Provenge debate
- ▶ January 11, 2008- Editorial written, "The Regulator Disapproves" in Nature Biotechnology weighing the pros vs. cons of approval
- ▶ January 15, 2008- Dendreon Corporation receives European patent for the vaccine
- ▶ February 13, 2008- Congress decides not to hold hearings on this debate
- ▶ February 14, 2008- Data from a Phase III study on the vaccine shows prolonged patient survival with higher cumulative doses

No matter which side you fall on, this debate is far from over. For more information go to www.dendreon.com.

The Food and Drug administration (FDA) has how many drug categories?