

## PRODUCT UPDATE

Company	Product	Development
Affinity Biotech	Micro Emulsion	In a proof-of-concept trial, Affinity administered to six patients suppositories containing calcitonin formulated in its microemulsion delivery system. The formulation resulted in relative bioavailability of 5 percent, compared to an injected dose.
Amylin Pharmaceutical	AC137	In a phase II trial of 24 Type I diabetics, AC137—a modified form of the hormone amylin, which, along with insulin, is deficient in Type I diabetics—showed a statistically significant reduction in post-meal glucose rise.
Ares-Serono	Rebif	Ares-Serono has begun phase II/III trials in Europe for Rebif, recombinant beta interferon, to treat relapsing-remitting multiple sclerosis, with trials planned for North America and Australia. Rebif is already registered in Italy for several diseases, including viral hepatitis B and C.
AutoImmune	AI-200	Results from a 60-patient phase II study show that oral administration of AI-200, chicken Type II collagen, can be effective in patients with severe rheumatoid arthritis. The product creates regulatory T cells that bind to antigen fragments in joints then release suppressor cytokines that inhibit the disease.
Biomira	Theratope STn-KLH	Fully 84 patients are enrolled in phase II trials of the drug, a cancer therapeutic vaccine, with enrollment expected to reach 269 patients.
Cygnus Therapeutic Systems	Nicotrol	A one-year study showed that patients wearing Cygnus' nicotine patch, in conjunction with typical physician counseling, had a non-smoking rate of 25 percent, compared to a 9 percent rate for placebo patients. The "waking hours" patch is marketed by Parke-Davis as Nicotrol.
Genentech	Activase	In a study of 6,000 patients, Activase tissue plasminogen activator given from 6 to 12 hours after heart-attack onset showed a decrease in 35-day mortality of 25.6 percent, compared to placebo.
Genetics Institute	Neumega rhIL-11	A phase I trial of interleukin-11 (IL-11) involving breast-cancer patients undergoing chemotherapy showed that IL-11 increases platelet production at all doses studied.
Immunex	TNF receptor	In a 141-patient phase II trial, soluble tumor necrosis factor receptor (TNF receptor) showed no clinical benefit in sepsis patients. In fact, patients treated with higher doses of TNF receptor had higher mortality rates than placebo patients.
Medarex	MDX-11	In a phase I/II trial, MDX-11, a monoclonal-antibody-based therapeutic for acute myeloid leukemia, was well tolerated by 16 patients suffering from advanced or secondary disease. MDX-11 transiently destroyed an average of 90 percent of circulating leukemia cells in half of the patients.
NeoRx	OncoTrac	NeoRx has filed with the Food and Drug Administration (FDA) data demonstrating that the OncoTrac product produced by Dr. Karl Thomae, a wholly owned subsidiary of Boehringer Ingelheim, is the same as the product described in NeoRx's previously filed product license application for its OncoTrac small-cell-lung-cancer imaging kit.
Neoprobe	ACT	Neoprobe expanded its adoptive cellular therapy (ACT) pilot study for colorectal cancer. Neoprobe removes lymph nodes containing helper immune cells from patients, grows the cells in quantities <i>ex vivo</i> , and then reinjects them into patients.
SciClone	Zadaxin	Zadaxin thymosin alpha 1—a natural immune modulator—has received marketing approval to treat chronic hepatitis B from the Ministry of Health in the Republic of Singapore. The product license is being issued under comparable circumstances to the Food and Drug Administration's (FDA) accelerated marketing approval, with provisions for continued study.
Shaman Pharmaceutical	Provir	Results of a 32-patient challenge study of respiratory syncytial virus infection reinforced the safety of Provir, an antiviral respiratory product, as demonstrated by an earlier 90-patient phase I trial.
Syntex/Synergen	CNTF	The drug-treatment portion of the phase II/III trial of ciliary neurotrophic factor (CNTF)—a natural nerve-repair factor—for amyotrophic lateral sclerosis (ALS) has begun in about 30 U.S. centers. The trial's goal is to study the effect of CNTF on the rate of loss of muscle strength in ALS patients.
Telios Pharmaceutical	OcuNex	Telios has begun a phase II study of OcuNex ophthalmic solution to treat severe dry eye associated with ocular-surface disease. Comprised of a cell-adhesion molecule attached to the polymer chondroitin sulfate, the product is designed to promote cell-matrix interactions that restore normal corneal structure.
Telor Ophthalmic Pharmaceutical	Tekron	In a phase IIa trial of Tekron, a topical formulation of ethacrynic acid, to control elevated intraocular pressure associated with glaucoma and ocular hypertension, patients suffered unacceptable eye irritation. Telor will reconsider development of Tekron.
The Liposome Company	ABLC	The firm has initiated named-patient distribution of ABLC, its amphotericin B in a lipid complex, in the Republic of South Africa for patients with life-threatening systemic fungal infections for whom currently marketed drugs are ineffective. For such patients, ABLC is already available on a compassionate-use basis in the U.S. and Europe.

—Mike Ginsberg