資料 6−5

京都大学　福島　雅典

2002 January

New Drug Approvals In 2001

PRESENTED BY AMERICA'S PHARMACEUTICAL COMPANIES

Pharmaceutical Companies Added 32 New Treatments to the Nation's Medicine Chest in 2001

In 2001, pharmaceutical and biotechnology companies won approval for 24 new drugs and eight new biologics.

The new medicines approved by the Food and Drug Administration in 2001 include:

- 1 for HIV/AIDS, which affects 800,000 to 900,000 Americans
- 2 for arthritis, which afflicts more than 20 million Americans
- 3 for cancer, the second leading cause of death in the United States
- 2 for glaucoma, a leading cause of blindness
- 5 for heart disease, the leading killer of Americans
- 5 for infectious diseases, including bacterial, viral and fungal infections
- 1 for schizophrenia, which affects more than 2 million Americans
- 1 for Alzheimer's disease, which afflicts nearly half of all Americans 85 and older;
- 2 for migraine headaches, which affects about 10 percent of Americans and cost employers $13 billion a year in lost work costs
- 2 vaccines to prevent hepatitis

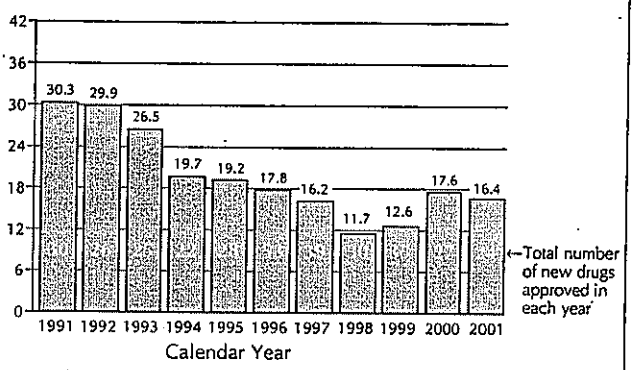
Detailed descriptions of the medicines approved in 2001 are on page 9.

All together, the new medicines made available this year treat or prevent 32 diseases with an annual cost to society of more than $250 billion and a terrible human cost to patients and their families.

Each approved medicine represents an average research and development cost of $802 million, according to data from the Tufts Center for the Study of Drug Development. This represents a 250 percent increase in the cost of drug development in just over a decade. This new figure reflects the fact that each new drug requires more study and larger, more complex clinical trials. It also reflects the fact that companies are tackling many difficult diseases, such as sepsis, AIDS, and Alzheimer's. In 2001, companies that are members of the Pharmaceutical Research and Manufacturers of America (PhRMA) spent an estimated $30.3 billion on R&D. This represents a 16.6 percent increase in research spending over the year 2000.

Drug development is not only expensive—it is a very lengthy process. According to Tufts, it takes an average of 10 to 15 years to bring a new medicine from the laboratory to the pharmacy. The tail end of this time is the time required for the review of the company's application by the Food and Drug Administration. This year, the 24 drugs approved were reviewed in an average of 16.4 months. This represents a slight improvement over last year's times, but approval times for drugs in 1998 and 1999 were somewhat shorter. Additionally, eight new biologics were approved in 2001, and were reviewed in an average of 19.6 months.

MEAN APPROVAL TIMES FOR NEW DRUGS, 1991–2001



Source: U.S. Food and Drug Administration

Pharmaceutical companies have more than a thousand promising new treatments in the pipeline and, with the mapping of the human genome, this number is expected to increase substantially. Expeditious and efficient reviews are essential so that patients may have timely access to safe and effective new medicines. For this reason, PhRMA will work with the FDA and with Congress this year to reauthorize the Prescription Drug User Fee Act, which sunsets on October 1, 2002. User fees now pay the salaries of 900 highly qualified drug reviewers and, if the law is not renewed promptly, FDA will have to dismiss a large number of reviewers.

The 32 medicines approved this year will add to the arsenal of formidable weapons America's pharmaceutical companies have developed against disease. The medicines in the pipeline promise an even healthier tomorrow.

Alan F. Holmer
President and CEO
PhRMA

New Drug Approvals in 2001

Product	Company	Indication/Use	NDA Received	FDA Approved	Review Time	Foreign Availability*
Arixtra® fondaparinux sodium (P)	Organon Inc. *West Orange, NJ* Sanofi-Synthelabo *New York, NY*	prevention of deep vein thrombosis, which may lead to pulmonary embolism after orthopedic surgery for hip fracture, hip replacement, and knee replacement	2/15/01	12/7/01	9.7 months	USA first marketing
For more information contact: Patrick J. Osinski (Organon), (973) 325-4805; Leslie Hare (Sanofi-Synthelabo), (212) 551-4314						
Axert™ almotriptan malate tablets (S)	Pharmacia *Peapack, NJ*	acute treatment of migraine with or without aura in adults	12/20/99	5/7/01	16.6 months	2000 Spain
For more information contact: Rose Talarico, (908) 901-8516						
Bextra® valdecoxib tablets (S)	Pharmacia *Peapack, NJ*	treatment of signs and symptoms of osteoarthritis and adult rheumatoid arthritis and the treatment of pain associated with menstrual cramping	1/16/01	11/16/01	10.0 months	none
For more information contact: Craig Buchholz, (908) 901-8896						
Cancidas® caspofungin acetate (P)	Merck *Whitehouse Station, NJ*	treatment of invasive aspergillosis	7/28/00	1/26/01	6.0 months	USA first marketing
For more information contact: Mary Daigler, (908) 423-4003						
Clarinex® desloratadine (S)	Schering-Plough *Kenilworth, NJ*	treatment of nasal and non-nasal symptoms of seasonal allergic rhinitis in adults and children 12 years of age and older	10/21/99	12/21/01	26.0 months	23 countries including: 2001 Germany 2001 Denmark 2001 Sweden 2001 Ireland 2001 UK 2001 EMEA**
For more information contact: William O'Donnell, (908) 298-7476						
Definity™ vial for perflutren lipid microsphere injectable suspension (S)	Bristol-Myers Squibb Medical Imaging, Inc. *N. Billenica, MA*	ultrasound contrast agent for use with suboptimal echocardiograms	12/9/98	7/31/01	31.7 months	Canada
For more information contact: Lili Gordon, (978) 671-8924						

(S)–Standard Approval
(P)–Priority Approval
* Foreign markets where the product was available *prior* to FDA approval.
** European Medicines Evaluation Agency

Product	Company	Indication/Use	NDA Received	FDA Approved	Review Time	Foreign Availability*
Dutasteride dutasteride (S)	GlaxoSmithKline *Philadelphia, PA* *Rsch. Triangle Park, NC*	benign prostatic hyperplasia	12/21/00	11/20/01	11.0 months	none
For more information contact: Mary Faye Dark, (919) 483-2839						
Elidel® pimecrolimus cream 1% (S)	Novartis Pharmaceuticals *East Hanover, NJ*	first non-steroid cream for mild to moderate atopic dermatitis in patients age 2 years and older	12/15/00	12/13/01	11.9 months	none
For more information contact: Megan Humphrey, (973) 781-6724						
Foradil® formoterol fumarate inhalation powder (S)	Novartis Pharmaceuticals *East Hanover, NJ*	maintenance treatment of asthma and the prevention of bronchospasm in reversible obstructive airways disease (ROAD)	6/26/97	2/16/01	24.0 months†	85 countries
For more information contact: Megan Humphrey, (973) 781-6724						
Frova™ frovatriptan succinate (S)	Elan Pharmaceuticals *South San Francisco, CA*	acute treatment of migraine attacks with or without aura in adults	1/29/99	11/8/01	21.0 months††	unavailable
For more information contact: Elan Pharmaceuticals, (650) 877-0900						
Geodon™ ziprasidone HCl capsules (S)	Pfizer *New York, NY*	treatment of schizophrenia	3/17/97	2/5/01	46.7 months	2000 Sweden
For more information contact: Mariann Caprino, (212) 733-4554						
Gleevec® imatinib mesylate (P) **(Orphan Drug)**	Novartis Pharmaceuticals *East Hanover, NJ*	treatment of patients with chronic myeloid leukemia in the blast crisis, accelerated phase or in chronic phase after failure of interferon-alpha therapy	2/27/01	5/10/01	2.4 months	2001 Palestine
For more information contact: Gloria Stone, (973) 781-5587						
Invanz™ ertapenem sodium (S)	Merck *Whitehouse Station, NJ*	treatment of adults with moderate to severe bacterial infections, including complicated intra-abdominal infections, complicated skin and skin structure infections, community-acquired pneumonia, complicated urinary tract infections, and acute pelvic infections	11/30/00	11/21/01	11.7 months	2001 Mexico 2001 Brazil 2001 New Zealand
For more information contact: Nancy Daigler, (908) 423-4003						

† Due to additional activities on this submission at the company, FDA calculated review time excluding the time periods 6/26/98 to 11/24/99 and 5/24/00 to 8/18/00.

†† Due to additional activities on this submission at the company, FDA calculated review time excluding the time period 4/28/00 to 5/8/01.

Product	Company	Indication/Use	NDA Received	FDA Approved	Review Time	Foreign Availability*
Lumigan™ bimatoprost ophthalmic solution, 0.03% (P)	Allergan *Irvine, CA*	reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	9/18/00	3/16/01	5.9 months	unavailable
For more information contact: Suki Shattuck, (714) 246-5621						
Natrecor® nesiritide (S)	Scios *Sunnyvale, CA*	treatment of acute decompensated congestive heart failure	4/27/98	8/10/01	19.0 months†	USA first marketing
For more information contact: Scios Medical Information, (877) 462-8732						
NuvaRing® etonogestrel/ ethinyl estradiol vaginal ring (S)	Organon Inc. *West Orange, NJ*	monthly vaginal ring for birth control	12/28/99	10/3/01	21.2 months	none
For more information contact: Patrick J. Osinski, (973) 325-4805						
Ortho Evra™ norelgestromin/ ethinyl estradiol transdermal system (S)	Ortho-McNeil Pharmaceutical *Raritan, NJ*	patch for the prevention of pregnancy	12/21/00	11/20/01	11.0 months	unavailable
For more information contact: Ortho-McNeil Medical Information, (800) 682-6532						
Reminyl® galantamine hydrobromide (S)	Janssen Pharmaceutica *Titusville, NJ* Ortho-McNeil Pharmaceutical *Raritan, NJ*	treatment of mild to moderate Alzheimer's disease	9/29/99	2/28/01	17.0 months	10 countries including: 2000 UK 2000 Austria 2000 Denmark 2000 Ireland 2000 Norway 2000 Sweden
For more information contact: Pam Rasmussen, (Janssen), (609) 730-2986						
Spectracef™ cefditoren pivoxil (S)	TAP Pharmaceutical Products *Lake Forest, IL*	treatment of acute exacerbations of chronic bronchitis, pharyngitis/ tonsillitis, and uncomplicated skin and skin structure infections in adults and children 12 years of age and older	12/29/99	8/29/01	20.0 months	1994 Japan 1997 Korea
For more information contact: TAP Pharmaceutical Products, (847) 582-2461						
Tracleer™ bosentan (S) **(Orphan Drug)**	Actelion Pharmaceuticals *South San Francisco, CA*	to improve exercise ability and decrease the rate of clinical worsening in patients with pulmonary arterial hypertension with significant limitation of physical activity	11/17/00	11/20/01	12.1 months	USA first marketing
For more information contact: Actelion Pharmaceuticals, (650) 624-6900						

† Due to additional activities on this submission at the company, FDA calculated review time excluding the time period 4/27/99 to 1/10/01.

Product	Company	Indication/Use	NDA Received	FDA Approved	Review Time	Foreign Availability*
Travatan™ travoprost ophthalmic solution (P)	Alcon Laboratories *Fort Worth, TX*	reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	7/7/00	3/16/01	8.3 months	USA first marketing
For more information contact: Mary Dulle, (817) 551-8058						
Viread™ tenofovir disoproxil fumarate (P)	Gilead Sciences *Foster City, CA*	treatment of HIV infection	5/1/01	10/26/01	5.9 months	USA first marketing
For more information contact: Amy Flood, (650) 522-5643						
Yasmin® drospirenone and ethinyl estradiol (S)	Berlex Laboratories *Montville, NJ*	low-dose monophasic oral contraceptive	5/17/99	5/11/01	23.8 months	9 countries including: 2000 Germany 2001 Denmark 2001 Norway 2001 Sweden 2001 Netherlands 2001 Ireland
For more information contact: Kim Schillace, (973) 487-2461						
Zometa™ zoledronic acid for injection (P)	Novartis Pharmaceuticals *East Hanover, NJ*	treatment of hypercalcemia of malignancy	12/21/99	8/20/01	20.0 months	more than 30 countries including: European Union Brazil Switzerland Canada Australia
For more information contact: Gloria Stone, (973) 781-5587						

New Biologic Approvals in 2001

Product	Company	Indication/Use	BLA Received	FDA Approved	Review Time	Foreign Availability*
Aranesp™ darbepoetin alfa (S)	Amgen *Thousand Oaks, CA*	treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis	12/28/99	9/17/01	20.7 months	unavailable
For more information contact: Amgen, (805) 447-1000						
Campath® alemtuzumab (P)	Berlex Laboratories *Montville, NJ* ILEX Oncology *San Antonio, TX* Millennium Pharmaceuticals *Cambridge, MA*	treatment of B-cell chronic lymphocytic leukemia	12/23/99	5/7/01	16.5 months	USA first marketing
For more information contact: Kimberley Jordan, (Berlex), (973) 487-2592						

Product	Company	Indication/Use	BLA Received	FDA Approved	Review Time	Foreign Availability*
DigiFab™ digoxin immune Fab (ovine) (S)	Protherics *Brentwood, TN*	treatment for digoxin toxicity	8/3/99	8/31/01	24.9 months	2000 Sri Lanka
For more information contact: Suzanne Ward, (615) 963-4528						
Kineret™ anakinra (S)	Amgen *Thousand Oaks, CA*	reduction of signs and symptoms of moderate to severe active rheumatoid arthritis	12/28/99	11/14/01	22.6 months	unavailable
For more information contact: Amgen, (805) 447-1000						
Nabi-HB™ Hepatitis B immune globulin (human) (S)	Nabi *Boca Raton, FL*	hepatitis B	12/16/99	10/23/01	22.2 months	unavailable
For more information contact: Nabi, (561) 989-5800						
PEG-Intron™ peginterferon alfa-2b (S)	Schering-Plough *Kenilworth, NJ*	treatment of chronic hepatitis C	12/23/99	1/19/01	12.9 months	2001 European Union
For more information contact: Robert J. Consalvo, (908) 298-7409						
Twinrix® Hepatitis A inactivated and Hepatitis B (recombinant) vaccine (S)	GlaxoSmithKline *Philadelphia, PA* *Rsch. Triangle Park, NC*	prevention of hepatitis A & B in adults	2/1/99	5/11/01	27.3 months	unavailable
For more information contact: Ramona DuBose, (919) 483-2839						
Xigris™ drotrecogin alfa (activated) (P)	Eli Lilly *Indianapolis, IN*	reduction of mortality in adults with severe sepsis at high risk of death	1/26/01	11/21/01	9.9 months	USA first marketing
For more information contact: Dan Collins, (media only), (317) 277-2688 and Holger Schilske, M.D., (317) 277-5505						

The content of this survey has been obtained through government and industry sources. The information may not be comprehensive. For more specific information about a particular product, contact the individual company directly.

PhRMA Internet address: http://www.phrma.org

Provided as a Public Service by PhRMA. Founded in 1958 as the Pharmaceutical Manufacturers Association.

U.S. Food and Drug Administration

Product Approvals for Cancer Indications September 2001 through June 1996 Listed by Approval Date

Last Updated September 15, 2001

2001

- **Xeloda** (capecitabine, product insert) from Roche and **Taxotere** (docetaxel) from Aventis, Inc. received approval on September 10, 2001 for treating patients with metastatic breast cancer whose cancer has progressed after treatment with an anthracycline-containing cancer therapy (such as Adriamycin and doxorubicin). (Talk Paper)

- **Zometa** (zoledronic acid for injection) from Novartis Pharmaceuticals Corporation, received approval on August 20, 2001, **for the treatment of hypercalcemia of malignancy.**

- Gleevec (imatinib mesylate) from Novartis Pharmaceuticals Corporation, received accelerated approval on May 10, 2001 **for the treatment of patients with chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy.**
(Approval Letter, Package Insert, Gleevec Information Page)

- Campath (alemtuzumab) from Millennium and ILEX Partners, LP, received accelerated approval on May 7, 2001 **for the treatment of patients with B-cell chronic lymphocytic leukemia who have been treated with alkylating agents and who have failed fludarabine therapy**
(Approval Letter *(Text)*, *(PDF)* Label *(PDF)*)

- Femara (letrozole) from Novartis Pharmaceuticals Company received additional approval on January 11, 2001 **for first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.** (Approval Letter, Package Insert)

2000

- Trisenox (arsenic trioxide) from Cell Therapeutics, Inc, received approval on september 25, 2000 **for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.**(Approval Letter, Package Insert)

- **Arimidex** (anastrozole) from AstraZeneca Pharmaceuticals, received additional approval on September 1, 2000, **for first-line treatment of postmenopausal women with hormone receptor positive or hormone receptor unknown locally advanced or metastatic breast cancer.**(Approval Letter)

- **Nolvadex** (tamoxifen citrate) from AstraZeneca Pharmaceuticals, received additional approval on June 29,2000 **for use in women with DCIS, following breast surgery and radiation, Nolvadex is indicated to reduce the risk of invasive breast cancer.**(Approval Letter, Package Insert)

- **Taxol** (paclitaxel) from Bristol-Myers Squibb Company, received additional approval for **the first-line and subsequent therapy for the treatment of advanced carcinoma of the ovary. As first-line therapy, Taxol, is indicated in combination with cisplatin.** (Approval Letter, Package Insert)

- **Trelstar Depot** (triptorelin pamoate) for injectable suspension, from Debio Recherche Pharmaceutique S.A., received approval on June 15, 2000 **for the palliative treatment of advanced prostate cancer.** (Approval Letter, Package Insert)

- **Fludeoxyglucose** (F-18) injection from Downstate Clinical PET Center, received approval on June 2, 2000 as an **(a) Assessment of abnormal glucose metabolism to assist in the evaluation of malignancy in patients with known or suspected abnormalities found byother testing modalities, or in patients with an existing diagnosis of cancer. (b) Assessment of patients with coronary artery disease and left ventricular dysfunction, when used together with myocardial perfusion imaging, for the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function.** (Approval Letter, Package Insert)

- **FocalSeal-L Surgical Sealant** from Focal Inc., received approval on May 30, 2000 **as a surgical sealant for use in lungs to seal air leaks following removal of cancerous lung tumors.** (More Information)

- **Mylotarg** (gemtuzumab ozogamicin) for injection, from Wyeth-Ayerst Research, recevied approval on May 17, 2000, **for the treatment of patients with CD33 positive acute myeloid leukemia in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy.** (More Information)

- **Camptosar** (irinotecan hydrochloride) injection, from Pharmacia & Upjohn, received additional approval on April 20, 2000, as a **component of first-line therapy in combination with 5-fluorouracil and leucovorin for patients with metastatic carcinoma of the colon or rectum.**

- **Pacis** (BCG,live), from BioChem Pharma Inc. received approval on March 9, 2000, **for the treatment of carcinoma-in-situ (CIS) in the absence of associated invasive cancer of the bladder.**

- **Viadur** (leuprolide acetate implant), from Alza Corporation, received additional approval on March 3, 2000 **for palliative treatment of advanced prostate cancer.** The drug product is delivered through a titanium device that is implanted in the upper arm, this is a new rout of administration for leuprolide acetate.

1999

Targretin (bexarotene) capsules, from Ligand Pharmaceuticals Inc.,

received approval on December 29, 1999 for the **treatment of cutaneous manifestations of cutaneous T-cell lymphoma in patients who are refractory to at least one prior systemic therapy.**

Taxotere (docetaxel), from Aventis Pharmaceuticals, received approval on December 23, 1999 for the **treatment of non-small cell lung cancer that does not respond to cisplatin-based chemotherapy.**

Celebrex (celecoxib), from G.D. Searle & Co., received accelerated approval on December 23, 1999 to **reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP), as an adjunct to unual care** (e.g. endoscopic surveillance surgery). (Approval Letter, Approved Labeling)

Levulan Kerastick (aminolevulinic acid HCL) for Topical Solution, 20%, received approval on December 3, 1999 **to be used in conjunction with photodyamic therapy for treatment of actinic keratoses (AKs) (pre-cancerous skin lesiions) of the face or scalp. This is the first combined drug and device treatment designed for targeted treatment that can be limited just to the lesion site(s).** Aminolevulinic acid HCL is marketed by DUSA Pharmaceuticals, Inc. of Valhalla, NY and will be marketed under the trade number Levulan Kerastick for Topical solution, 20%. It is to be marketed in combination with the light source BLU-U Blue Light Photodynamic Therapy Illuminator. (Approval Letter, Labeling)

Taxol (paclitaxel) injection, from Bristol-Myers Squibb, received additional approval on October 25, 1999 for **adjuvant treatment of node-positive breast cancer administered sequentially to standard doxorubicin-containing combination chemotherapy. In the clinical trial, there was an overall favorable effect on disease-free and overall survival in the total population of patients with receptor-positive and receptor-negative tumors, but the benefit has been specifically demonstrated by available data (median follow up 30 months) only in the patients with estrogen and progesterone receptor negative tumors.**

Aromasin (exemestane) Tablets, from Pharmacia & Upjohn Company, received approval on October 21, 1999 for the **treatment of advance breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.**

Ellence (epirubicin hydrochloride), from Pharmacic & Upjohn received approval on September 15, 1999 for use as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.

Zofran (ondansetron), from Glaxo Wellcome received additional approval on August 27, 1999 **for the prevention of nausea and vomiting associated with highly emetogenic cancer chemotherapy, including cisplatin.**

Temodar (temozolomide), from Schering-Plough Corporation received accelerated approval on August 11, 1999 **for the treatment of adult patients with refractory anaplastic astrocytoma, (i.e. patients at first**

relapse who have experienced disease progression on a drug regimen containing a nitgrosourea and procarbazine).

Isolex 300 and 300i Magnetic Cell Selection System, Nexell Therapeutics, Inc., received approval on July 2, 1999, for processing autologous peripheral blood progenitor cell products to obtain a CD34+ cell enriched population intended for hematopoietic reconstitution after myeloablative therapy in patients with CD34 negative tumors.

√ Kytril (granisetron), from SmithKline Beecham, received additional approval on June 27, 1999 for the prevention of nausea and vomiting associated with radiation, including total body irradiation (TBI) and fractionated abdominal radiation.

Doxil (doxorubicin HCL liposome injection), from Alza Corporation, received accelerated approval on June 28, 1999 for a supplemental indication for the treatment of metastatic carcinoma of the ovary in patients with disease that is refractory to both paclitaxel- and platinum-based chemotherapy regimens. Refractory disease is defined as disease that has progressed while on treatment, or within 6 months of completing treatment.(Labeling)

Ethyol (amifostine) for Injection, by US Bioscience, received additional approval on June 24, 1999 to reduce the incidence of moderate to severe xerostomia in patients undergoing post-operative radiation treatment for head and neck cancer, where the radiation port includes a substantial portion of the parotid glands. Ethyol is also marketed by Alza Pharmaceuticals. (Labeling)

DepoCyt (cytarabine liposomal injection, 10 mg/mL), by DepoTech Corporation, received accelerated approval on April 1, 1999 for the intrathecal treatment of lymphomatous meningitis. This indication is based on demonstration of increased complete response rate compared to unencapsulated cytarabine. There are no controlled trials that demonstrate a clinical benefit resulting from this treatment, such as improvement in disease-related symptoms, or increased time to disease progression, or increased survival. (Labeling)

(√) UVADEX (methoxsalen sterile solution, 20 mcg/mL), by Therakos, Inc. received approval on February 25, 1999 for the use of UVADEX with the UVAR Photopheresis System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) that is unresponsive to other forms of treatment.(Labeling)

Ontak (denileukin diftitox), marketed by Ligand Pharmaceuticals and manufactured by Seragen, Inc., received accelerated approval (based on tumor reduction) on February 5, 1999 for the treatment of persistent or recurrent cutaneous t-cell lymphoma, (CTCL), a rare slow-growing form of non-Hodgkin's lymphoma, whose malignant cells express the CD25 component of the IL-2 receptor.

(√) Busulfex (busulfan), by Orphan Medical Inc received approval on February 4, 1999 for use in combination with cyclophosphamide as a conditioning