regiment prior to allogeneic hematopoietic progenitor cell transplantation for chronic myelogenous leukemia.

Panretin (Alitretinoin) gel 0.1%, by Ligand Pharmaceuticals received approval on February 2, 1999 for the topical treatment of cutaneous lesions in patients with AIDS-related Kaposi's sarcoma. Approval Letter Approved Labeling

(✓) Zofran ODT (odansetron) orally disintegrating tablets, by Glaxo Wellcome, Inc., received additional approval on January 27, 1999 for prevention of chemotherapy and radiation-induced nausea and vomiting, and prevention of postoperative nausea and vomiting (new dosage form).

1998

12・21/21 ✓ Photofrin (porfimer sodium), by QLT Phototherapeutics, Inc., received additional approval on December 22, 1998 for use in photodynamic therapy (PDT) for reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobroncial nonsmall cell lung cancer (NSCLC).

(9)

Hycamtin (topotecan hydrochloride) for injection, by SmithKline Beecham Pharmaceuticals received additional approval on November 30, 1998 for the use of Hycamtin in the treatment of small cell lung cancer sensitive disease after failure of first-line chemotherapy. In clinical studies submitted to support approval, sensitive disease was defined as disease responding to chemotherapy but subsequently progressing at least 60 days (in the phase 3 study) or at least 90 days (in the phase 2 studies) after chemotherapy. (Labeling)

✓ Sandostatin LAR∃ Depot (octreotide acetate for injectable suspension), by Novartis Pharmaceuticals, was approved on November 25, 1998 for the reduction of growth hormone and IGF-1 in acromegaly, the suppression of severe diarrhea and flushing associated with malignant carcinoid syndrome and for the treatment of the profuse watery diarrhea associated with VIPoma (vasoactive intestinal peptide tumor). (Labeling)

(✓) Actiq (fentanyl citrate), flavored sugar lozenge on a stick, by Anesta Corporation received approval on November 4, 1998 for management of chronic pain in cancer patients that are experiencing breakthrough pain on their regular narcotic (opioid) therapy. (Patient Package Insert)

(✓) Nolvadex (tamoxifen citrate) by Zeneca Pharmaceuticals received additional approval on October 29, 1998 to reduce the incidence of breast cancer in women at high risk for breast cancer.

✓ Camptosar (irinotecan hydrochlorise) by Pharmacia & Upjohn received additional approval on October 22, 1998 for the treatment of patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed following 5-FU-based therapy.

✓ Herceptin (trastuzumab) intravenous injection by Genentech, Inc., received approval on September 25, 1998 for use alone for certain

patients who have tried chemotherapy with little success or as a first-line treatment for metastatic disease when used in combination with paclitaxel (trade name Taxol)(additional information)

Valstar (valrubicin) Sterile Solution for Intravesical Instillation, 5 mL, Single-Use Vials (40 mg/mL) by Anthra Pharmaceuticals received approval on September 25, 1998 for intravesical therapy of BCG-refractory carcinoma in situ (CIS) of the urinary bladder in patients for whom immediate cystectomy would be associated with unacceptable morbidity or mortality.

√ Gemzar (gemcitabine HCL) for injection by Eli Lilly & Co. received additional approval on August 26, 1998 for use in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.

√ Zoladex, (goserelin acetate implant) by Zeneca Pharmaceuticals received additional approval on July 27, 1998 for use of 3.6 mg and 10.8 mg depots in combination with flutamide for the management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate. [New dosage and Administration]

Ceprate SC Stem Cell Concentration System, from CellPro Incorporated received additional approval for processing peripheral blood progenitor cells to obtain a CD34 positive cell enriched population which is intended for hematopoietic support after myeloablative chemotherapy in patients with CD34 negative tumors.

Urowave Microwave Thermotherapy System by Dornier Medical Systems, Inc., received approval on May 29, 1998 as a non-surgical treatment alternative to transurethral resection of the prostate (TURP). To treat symptomatic benign prostatic hyperplasia (BPH) in men withprostatic lengths between 30 mm and 55 mm.

√ Taxol (paclitaxel) injection by Bristol-Myers Squibb Pharmaceutical Research Institute received additional approval on June 30, 1998 for use in combination with cisplatin, for the first-line treatment of non-small cell lung cancer in patients who are not candidates for potentially curative surgery and/or radiation therapy.

Taxotere (docetaxel) injection concentrate (20 mg and 80 mg) by Rhone-Poulenc Rorer received additional approval on June 22, 1998 for the treatment of patients with locally advanced or metastatic breast cancer after failure of prior chemotherapy.

Xeloda (capecitabine) tablets by Hoffman-La Roche received accelerated approval on April 30, 1998 for treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy may be contraindicated, e.g., patients who have received cumulative doses of 400 mg/m^2 of doxorubicin or doxorubicin equivalents.

√ **Taxol** (paclitaxel) injection by Bristol-Myers Squibb Pharmaceutical Research Institute received additional approval on April 9, 1998 **for first-line therapy for the treatment of advanced carcinoma of the ovary in combination with cisplatin.**

√ **Zoladex** (goserelin acetate implant) by Zeneca Pharmaceuticals, Inc., received additional approval on April 9, 1998 **for palliative treatment of advanced carcinoma of the prostate. [New Route of Administration]**

√ **Neupogen** (filgrastim) by Amgen, Inc. received additional approval on April 2, 1998 **for use in patients with acute myeloid leukemia.**

Daunorubicin HCL (daunorubicin hydrochloride) by Bedford Laboratories, Div. Ben Venue Laboratories, Inc., received approval on January 30, 1998, **to provide a new 5 mg/mL, 4 mL ready-to-use solution which can be immediately used in an IV infusion without the possibility of reconstitution error.** Daunorubicin HCL's indication is for use in combination with other approved anticancer drugs for remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) of adults and for remission induction in acute lymphocytic leukemia of children and adults.

Proleukin (aldesleukin) sponsored by Chiron Corporation received an additional indication on January 9, 1998, for **treatment of adults with metastatic melanoma and updated response data for metastatic renal cell carcinoma patients, as well as revised package insert information.**

√ **Photofrin** (porfimer sodium) sponsored by QLT Phototherapeutics, Inc., received an additional indication on January 9, 1998, **for treatment in photodynamic therapy for treatment of microinvasive endobronchial nonsmall cell lung cancer in patients for whom surgery and radiotherapy are not indicated.**

1997

√ **Rituxan** (rituximab) sponsored by Genentech, Inc., received approval on November 26, 1997, **for the treatment of patients with relapsed or refractory low-grade or follicular, B-cell non-Hodgkin's lymphoma.**

Neumega (oprelvekin) sponsored by Genetics Institute, Inc., received approval on November 25, 1997, **for the prevention of severe thrombocytopenia and the reduction of the need for platelet transfusion following myelosuppressive chemotherapy in patients with nonmyeloid malignancies who are at high risk of severe thrombocytopenia.**

(√) **Intron A** (interferon alfa-2a) sponsored by Schering Corp., received approval on November 6, 1997, **for use in conjunction with chemotherapy in patients with follicular lymphoma.**

(√) **Zofran** (ondanstron hydrochloride) sponsored by Glaxo Wellcome Inc., received approval on October 31, 1997, **for intramuscular administration as an alternative to intravenous administration in the prevention of postoperative nausea and vomiting (new route of administration.)**

Anzemet (dolasetron mesylate Tablet) sponsored by Hoechst Marion Roussel, Inc., received approval on September 11, 1997, **for the prevention of chemotherapy-induced nausea and vomiting, and prevention of postoperative nausea and vomiting.**

Anzemet (dolasetron mesylate Injectable) sponsored by Hoechst Marion Roussel, Inc., received approval on September 11, 1997, **for the prevention of chemotherapy-induced emesis, prevention of postoperative nausea and vomiting, and treatment of postoperative nausea and vomiting.**

(✓) **Taxol** (paclitaxel) **for Injection**, sponsored by Bristol Myers Squibb Co. Pharmaceutical Research Institute, received an additional indication on August 4, 1997, **for the second line treatment of AIDS-related Kaposi's sarcoma.** Taxol was previously indicated, after failure of first-line or subsequent chemotherapy for the treatment of metastatic carcinoma of the ovary, and for treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy.

Femara (letrozole) **Tablets**, sponsored by Novartis Pharmaceuticals Corporation, received approval on July 25, 1997, **for the treatment of advanced breast cancer in postmenopausal women.**

(✓) **Lupron Depot** (leuprolide acetate) **for Injection**, sponsored by TAP Holdings Incorporated, received an additional indication on May 30, 1997, **to help relieve the symptoms associated with advanced prostate cancer.** Lupron was previously indicated for management of endometriosis, preoperative hematologic improvement of anemia caused by uterine leiomyomata, palliative treatment of advanced prostate cancer and central precocious puberty.

✓ **Fareston** (toremifene citrate) **Tablets**, sponsored by Orion Corporation, received approval on May 29, 1997, **for the treatment of metastatic breast cancer in postmenopausal women with estrogen receptor positive or receptor unknown tumors.**

Quadramet (samarium sm 153 edtmp) **for Injection**, sponsored by Cytogen Corporation, received approval on March 28, 1997, **for the relief of pain in patients with confirmed osteoblastic metastatic bone lesions that enhance on radionuclide bone scan.**

(✓) **Zofran** (ondansetron hydrochloride) **Oral Solution**, sponsored by Glaxo Wellcome Incorporated, received approval on January 24, 1997, **for the prevention of chemotherapy, radiotherapy, and postoperative induced nausea and vomiting.** Zofran was previously available in oral tablet and injectable formulations.

1996

(✓) **Dostinex** (cabergoline) **Tablets**, sponsored by Pharmacia & Upjohn Company, received approval on December 23, 1996, **for the treatment of hyperprolactinemic disorders, either idiopathic (i.e. of unknown cause) or**

due to pituitary adenomas.

Novantrone (mitoxantrone hydrochloride) **for Injection**, sponsored by Immunex Corporation, received an additional indication on November 13, 1996, **for use in combination with corticosteroids as initial chemotherapy for the treatment of patients with pain related to advanced hormone refractory prostate cancer**. Novantrone was previously indicated for use in combination with other approved drugs in the initial therapy of acute nonlymphocytic leukemia (ANLL) in adults. This category includes myelogenous, promyelocytic, monocytic, and erythroid acute leukemias.

Duraclon (clonidine hydrochloride) **for Injection**, sponsored by Fujisawa USA Incorporated, was approved on October 2, 1996, **for continuous epidural administration** (a type of injection) **as additional therapy with intraspinal opiates** (pain medication injected into the spinal column) **for the treatment of severe pain in cancer patients that is not adequately relieved by opioid pain relievers alone**.

Elliotts B Solution (calcium chloride, dextrose, magnesium sulfate, potassium chloride, sodium bicarbonate, sodium chloride, sodium phosphate, dibasic) **for Injection**, sponsored by Orphan Medical Incorporated, was approved on September 27, 1996, **for use in mixing methotrexate sodium and/or cytarabine for intrathecal administration (a type of injection) to prevent or treat meningeal leukemia or lymphocytic lymphoma**.

Gliadel (carmustine wafer) **for Implantation**, sponsored by Guilford Pharmaceuticals Incorporated, was approved on September 23, 1996, **for use in addition to surgery to prolong survival in patients with recurrent glioblastoma multiforme who qualify for surgery.**

Nilandron (nilutamide) **Tablets**, sponsored by GH Besselaar Associates Incorporated, was approved on September 19, 1996, **for use in combination with surgical castration for the treatment of stage D2 metastatic prostate cancer**.

Aredia (pamidronate disodium) **for Injection**, sponsored by Ciba Geigy Corporation Pharmaceuticals Division, received an additional indication on July 16, 1996, **for the treatment of osteolytic bone metastases of breast cancer**. Aredia was previously indicated for hypercalcemia associated with malignancy, osteolytic bone lesions of multiple myeloma, and Paget's disease of bone.

Camptosar (irinotecan HCL) sponsored by Pharmacia and Upjohn, received accelerated approval on June 14, 1996, for **treatment of metastatic carcinoma of the colon or rectum which has progressed or recurred after treatment with 5-fluorouracil (5FU).**

Hycamtin (topotecan HCL), from SmithKline Beecham, received approval on May 28, 1996 **for the treatment of metastatic ovarian cancer after failure of first line chemotherapy.**

Zyloprim (allopurinol sodium) from Glaxo Wellcome, received approval on

May 17, 1996 **for the management of patients with leukemia, lymphoma, and solid tumor malignancies who are receiving cancer therapy which causes elevation of uric acid levels and who cannot tolerate oral therapy.**

✓ **Etopophos** (etoposide phosphate) from Bristol-Myers Squibb, received approval on May 17, 1996 **for the management of small cell lung cancer, firstline and refractory testicular tumors, in combination with other approved chemotherapeutic agents.**

✓ **Gemzar** (gemcitabine HCL), from Lilly, received approval on May 16, 1996 **for first line treatment for locally advanced (nonresectable stage II or III) or metastatic (stage IV) pancreatic cancer; second-line treatment for pancreatic cancer previously treated with 5-fluorouracil.**

✓ **Taxotere** (docetaxel) from Rhone-Poulenc Rorer, received approval on May 14, 1996 **for the treatment of locally advanced or metastatic breast cancer which has progressed during anthracycline-based treatment or relapsed during anthracycline-based adjuvant therapy.**

DaunoXome (daunorubicin citrate liposome) from NeXstar, received approval on April 8, 1996 **for the first line cytotoxic treatment of advanced HIV-associated Kaposi's sarcoma.**

Ethyol (amifostine), from Alza, received approval on March 15, 1996, **for chemoprotectant/ cisplatin non-small cell lung cancer (NSCLC).**

(✓) **Blenoxane** (bleomycin sulfate), from Bristol-Myers Squibb, received approval on February 20, 1996 **as a sclerosing agent for the treatment of malignant pleural effusion and prevention of recurrent pleural effusions.**

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Privacy Statement

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Therapeutic Antibodies

General Name	Product Name	Product Type	Indication	Approval Date	Company
Muromonab/OKT3	Orthoclone®	Murine anti-CD3	Acute allograft rejection in renal, cardiac and hepatic transplant patients	1986 in US	Ortho/J&J
Abciximab/C7E3	ReoPro®	Chimeric Fab fragment of anti-gpIIb/IIIa monoclonal antibody 7E3.	• Adjunct to percutaneous coronary intervention (PCI) for the prevention of cardiac ischemic complications • The drug is also now indicated for unstable angina patients not responding to conventional medical therapy when PCI is planned within 24 hours	• 12/94 in US • Expanded in 1997	Centocor/Lilly/ Fujisawa
Edrecolomab/Anti-17-1A	Panorex®	Murine anti-17-1A	Duke's C stage colon cancer with lymph node	1994 in Germany only	Centocor/GSK

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			metastases (in Germany only)		
Rituximab/C2B8	Rituxan®/ MabThera®	Chimeric anti-CD20	Refractory Low grade non-Hodgkin's lymphoma	• 11/97 in US • 4/01 expanded dosing schedule	IDEC/Genentech/ Zenyaku/ Roche
Daclizumab	Zenapax®	Humanized murine anti-IL2 receptor α chain or Tac	Acute organ rejection in patients receiving renal transplants	10/97 in US	Protein Design Labs/Roche
Basiliximab	Simulect®	Chimeric anti-IL2 receptor	Acute rejection in renal transplants.	5/98 in US	Novartis
Palivizumab/ MEDI-493	Synagis®	Humanized murine anti-RSV F-protein	Prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in pediatric patients at high-risk of RSV disease	6/98 in US	MedImmune/Abbott
Infliximab	Remicade®	Chimeric anti-TNF-α	• Moderate to severe Crohn's disease and patients with	• 8/24/98 monotherapy in US	Centocor/J&J

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			fistular disease • Combination with methotrexate for RA patients who fail to respond to methotrexate alone • Combination with methotrexate to inhibit progression of structural damage in RA patients	• 11/10/99 combination with MTX inUS • 12/00 inhibit progression of structural damage in RA	
Trastuzumab	Herceptin®	Humanized murine antibody 4D5 against Her-2 (EGFR2)	Patients with metastatic breast cancer whose tumors overexpress the HER2 protein and who have received one or more chemotherapy regimens for their metastatic disease	9/98 in US	Genentech/Roche
Gemtuzumab zogamicin/ CMA-676	Mylotarg®	Anti-CD33/ calicheamicin conjugate	relapsed adult acute myelocytic leukemia	5/00 in US	Celltech/Wyeth-Ayerst

Ibritumomab tiuxetan/ Y2B8	Zevalin®	^{90}Y labeled murine anti-CD20	Treatment of relapsed or refractory low grade, follicular, or transformed B-cell non-Hodgkin's lymphoma (NHL) including patients with Rituxan® (rituximab) refractory follicular NHL	2/02 in US	IDEC/Schering AG
Alemtuzumab/ Campath-1H	Campath®	Humanized murine anti-CD52	Refractory B-cell chronic lymphocytic leukemia	5/01 in US	Berlex/Millenium/ ILEX

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Imaging Antibodies

General Name	Product Name	Product Type	Indication	Approval Date	Company
Satumomab Pendetide/ B72.3/ 111-In-CYT-103	OncoScint®	^{111}In labeled murine antibody B72.3 binds TAG72	Colorectal and ovarian	12/92 in US	Cytogen
Arcitumomab	CEA-Scan®	Tc99m-labeled murine antibody fragment against CEA for nuclear imaging of CEA-expressing cancers.	Colorectal cancer To determine presence, location, extent of metastatic disease in primary/recurrent colorectal cancer	Marketed in US & EU Approved in Canada	Immunomedics
Sulesomab	LeukoScan®	Tc99m-labeled murine Fab fragment against antigen NCA90 for nuclear imaging of activated granulocytes	Use in the diagnosis of osteomyelitis in long bones and in patients with diabetic foot ulcers	Marketed in EU for diagnosing osteomyelitis BLA under review by US FDA, Switzerland and Canada	ImmunoMedics/ Mallinckrodt
Capromab Pendetide	ProstaScint®	^{111}In labeled murine antibody 7E11-C5.3 against PSMA	Newly-diagnosed patients with biopsy-proven prostate cancer	10/96 in US	Cytogen