FDA APPROVED THERAPEUTIC DRUGS AND VACCINES

DEVELOPED WITH TECHNOLOGIES FROM THE INTRAMURAL RESEARCH PROGRAM AT

THE NATIONAL INSTITUTES OF HEALTH

AS OF JULY 1, 2004

Licensee	Therapeutic	FDA Approval Date/First Commercial US Sale

Berlex Laboratories **Fludara** **18 Apr 1991/1991**

- **A DNA polymerase inhibitor (fludarabine) that has been shown to have potent activity in the treatment of B-cell leukemia. This compound is a cancer chemotherapeutic drug, 2-F-araA.**

Bristol Myers Squibb **Videx** **09 Oct 1991/1991**

- **A treatment of HIV infection with ddI. Selectively inhibits the replication of HIV by interfering with a critical element known as reverse transcriptase. Because of being better tolerated or having a different pattern of toxicity than other treatments, patients may find it useful in either individual or combination treatment therapy.**

Hoffmann LaRoche **Hivid** **19 Jun 1992/1992**

- **A treatment of HIV infection with ddC. Inhibits the replication of HIV by interfering with the critical enzyme reverse transcriptase. Patients find it useful in either individual or combination treatment therapy.**

Bristol Myers Squibb **Taxol** **29 Dec 1992/1996**

- **An improved method for administering Taxol (paclitaxel) has significantly improved the treatment of cancerous tumors, particularly advanced stage epithelial ovarian and breast cancers. Paclitaxel is a compound derived from the bark of the Western Yew tree.**

MedImmune Inc. **NeuTrexin** **17 Dec 1993/1994**

- **A treatment using trimetrexate as an anti-parasitic agent for infection. Infections due to Toxoplasma gondii and Pneumocystis carinii, as seen in AIDS patients are extremely refractory to standard therapy can be effectively treated by administering this drug.**

GlaxoSmithKline **Havrix** **22 Feb 1995/1997**

- **A vaccine from the isolation of Hepatitis A virus strain HM-175. Hepatitis A is probably the most widespread of viral hepatitis diseases and is an endemic childhood disease in the underdeveloped countries of the world.**

Janssen Pharmaceuticals **Sporanox Oral** **21 Feb 1997/1997**

- **Oral formulation of the anti-fungal agent itraconazole that is used for the treatment of painful and debilitating fungal infections of the esophagus and mouth, commonly called thrush. Itraconazole is solubilized for this application through coupling with hydroxy-propyl-cyclodextrin, a molecular inclusion complex.**

Protein Design Laboratory / Hoffman LaRoche **Zenapax** **10 Dec 1997/1998**

- **A humanized monoclonal antibody used for the prevention of acute kidney transplant rejection. This recombinantly produced antibody achieves its immunosuppressive properties by binding to the alpha (or Tac) subunit of human interleukin-2 (IL-2) receptor that is expressed on the surface of activated lymphocytes.**

MedImmune Inc. **Synagis** **19 Jun 1998/1998**

- **A monoclonal antibody used for the prevention and treatment of serious lower respiratory tract disease by respiratory syncytial virus (RSV). RSV is the most common cause of pneumonia and bronchiolitis in infancy and early childhood. Synagis is the world's first monoclonal antibody licensed by the FDA for any infectious disease.**

Baxter Pharmaceuticals **Certiva** **29 Jul 1998/1998**

- **A combined diphtheria, tetanus and acellular pertussis vaccine for use in infants and children. A special process that reduces local and systemic adverse events commonly associated with traditional whole-cell DPT vaccine administration has detoxified the acellular pertussis component of this vaccine. Certiva is the first pediatric vaccine introduced into the U.S. market by a new independent vaccine producer in over ten years.**

Isis Pharmaceuticals, Inc. **Vitravene** **26 Aug 1998/1998**

- **A phosphorothioate oligonucleotide that inhibits cytomeglovirus (CMV) infections in the eye. Such infections commonly occur in immunocompromised patients with resultant damage to the retina. Vitravene is the first antisense therapeutic approved for use in humans.**

Wyeth Laboratories Inc. **RotaShield** **31 Aug 1998/1998**

- **A live oral vaccine for the prevention of rotavirus gastroenteritis in infants. Rotavirus is the single most common cause of epidemic severe acute gastroenteritis (diarrhea and vomiting) in infants and children from both developed and developing countries. RotoShield is the first rotavirus vaccine approved for use in humans. (Manufacturer has temporarily suspended sales)**

Genzyme Corp. **Thyrogen** **30 Nov 1998/1998**

- **A recombinant form of human thyroid stimulating hormone (TSH) for use in follow-up screening of patients who have been treated for thyroid cancer. Thyrogen permits these patients to avoid the debilitating effects of thyroid hormone withdrawal while undergoing standard diagnostic procedures such as serum thyroglobulin testing and radioiodine imaging.**

GlaxoSmithKline **Lymerix** **21 Dec 1998/1999**

- **The world's first vaccine for the prevention of Lyme disease. Lyme disease is one of the fastest vector-borne diseases in the US. It can lead to severe and debilitating problems such as arthritis, heart abnormalities and Bell's palsy. (Manufacturer has withdrawn the product from the market)**

GlaxoSmithKline **Twinrix** **11 May 2001/2001**

- **A vaccine formulation that combines both Hepatitis A and Hepatitis B. Combining the two vaccines, for two of the most common infectious diseases that represent serious public health problems, Twinrix offers significant advantages such as increased convenience for patient and physician, fewer injections and greater compliance compared with two separate vaccines.**

IDEC Pharmaceuticals **Zevalin** **19 Feb 2002/2002**

- **A treatment for non-Hodgkin's lymphoma, which affects 50,000 Americans annually. A majority of these cases are low-grade lymphomas that do not respond to other treatments. Treatment with Zevalin, which is simple and fast, and has less severe side effects, is especially suited for these patients. This drug combines the targeting power of monoclonal antibodies with the cell killing ability of radioactive atoms, and is the first radioimmunotherapy to be approved by the FDA.**

Millenium Pharmaceuticals **Velcade** **13 May 2003/2003**

- **A treatment for multiple myeloma, that works by specifically inhibiting an enzyme complex known as the proteosome. Under an accelelerated approval program, the FDA has allowed the use of Velcade in patients who have failed two prior therapies. The selectivity and manageable side-effect profile of this boronic dipeptide compound makes it an exciting new cancer drug. NIH researchers made a critical contribution by developing stable, pharmaceutically acceptable compositions of these important compounds. Indeed, as the first proteosome inhibitor to be approved by the FDA, Velcade opens the door for a new class of useful drugs.**