

Genentech

Overview

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines to treat patients with serious or life-threatening medical conditions. The company, a wholly-owned member of the Roche Group, has headquarters in South San Francisco, California.

Products

Genentech manufactures and commercializes multiple biotechnology products.

BioOncology

- Avastin® (bevacizumab) for use in combination with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment of patients with metastatic carcinoma of the colon or rectum and in combination with carboplatin and paclitaxel for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer
- Herceptin® (Trastuzumab)
For adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer:
 - As part of a treatment regimen containing doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel
 - With docetaxel and carboplatin
 - As a single agent following multi-modality anthracycline-based therapy

Also indicated:

- In combination with paclitaxel for the first line treatment of HER2-overexpressing metastatic breast cancer
- As a single agent for treatment of HER2-overexpressing breast cancer in patients who have received one or more chemotherapy regimens for metastatic disease
- Rituxan® (Rituximab) for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma (NHL) as a single agent; for previously untreated diffuse large B-cell, CD20-positive, NHL in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens; for previously untreated follicular, CD20-positive, B-cell NHL in combination with CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy; and for the treatment of non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent, after first-line CVP chemotherapy
- Tarceva® (erlotinib) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of at least one prior chemotherapy regimen; in combination with gemcitabine chemotherapy for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy

Immunology

- Rituxan® (Rituximab) for use in combination with methotrexate for the treatment of adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies
- Xolair® (Omalizumab) for Subcutaneous Use for adults and adolescents (age 12 or older) with moderate-to-severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids

Tissue Growth and Repair

- Activase® (Alteplase, recombinant), a tissue-plasminogen activator to dissolve blood clots, for treating patients with acute myocardial infarction (heart attack), patients with acute massive pulmonary embolism (blood clots in the lungs), and for treating patients with acute ischemic stroke (brain attack) within the first three hours of symptom onset
- Cathflo® Activase® (Alteplase), a thrombolytic agent for the restoration of function to central venous access devices in both pediatric and adults patients
- Lucentis® (ranibizumab injection), a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD).
- Nutropin® [somatropin (rDNA origin) for injection] and Nutropin AQ® [somatropin (rDNA origin) injection] human growth hormone for treating growth hormone deficiency, for the treatment of growth hormone deficiency in children and adults, growth failure associated with chronic renal insufficiency prior to kidney transplantation, short stature associated with Turner syndrome, and long-term treatment of idiopathic short stature
 - Nutropin AQ Pen® for use with Nutropin AQ Pen® Cartridge, a delivery device for Nutropin AQ®
- Pulmozyme® (dornase alfa, recombinant) Inhalation Solution, for the management of cystic fibrosis patients to improve pulmonary function
- TNKase® (Tenecteplase), a modified form of t-PA for use in mortality reduction associated with acute myocardial infarction; treatment should be initiated as soon as possible after the onset of AMI symptoms

Medicine Development at Genentech

Genentech has an extensive track record in all phases of bringing new disease treatments to patients – from discovery research through clinical development, manufacturing, and commercialization. With multiple protein-based products on the market for serious or life-threatening medical conditions, Genentech has experience taking a drug from A to Z, transforming the seed of an idea in a lab into a novel therapy for a patient in need.

Discovery Research

Research is the wellspring of potential products, and Genentech's research organization is among the world's finest. Genentech's approximately 1,100 researchers, scientists and postdocs consistently publish important papers in prestigious peer-reviewed journals and are among the top researchers in the world in terms of total citations. In addition, Genentech's scientists have secured approximately 7,400 current, non-expired patents worldwide and have approximately 6,250 patent applications pending worldwide. Discovery research at Genentech focuses primarily on three areas of medicine: oncology, immunological disease, and disorders of tissue growth and repair, including angiogenic disorders. In March 2008, the research organization also announced the initiation of early efforts in two new therapeutic areas:

neuroscience and infectious disease.

To ensure continued scientific excellence, in October 1992 Genentech opened the Founders Research Center, a 275,000 square-foot, \$85 million research facility devoted solely to biotechnology. It was dedicated to Bob Swanson and Dr. Herbert Boyer in honor of their pursuit of the promise of biotechnology when they established Genentech in 1976. In April 2001, the company celebrated its 25th anniversary by breaking ground on a 280,000 square foot expansion of the Founders Research Center. Completed in 2003, the complex houses specialized laboratories and state-of-the-science equipment in several interconnected buildings.

Product Development

Genentech uses an extensive set of criteria, including scientific rationale and medical need, to determine which projects to move from discovery research into development. Our clinical scientists and medical professionals then perform the essential role of translating basic science into patient benefit. They help Genentech determine which potential new drugs are tested against specific diseases in the clinic and guide chosen drug candidates through the many phases of clinical testing. Genentech is dedicated to evaluating its therapies in rigorous randomized trials. Our approach is to put a drug candidate through tough clinical testing in order to demonstrate its potential benefit as a therapeutic. Genentech's development pipeline includes multiple projects targeting a range of disease areas across all phases of clinical development.

Manufacturing

Genentech was the first biotechnology company to scale up protein manufacturing successfully from the small quantities used for research to the much larger quantities needed for clinical trials and marketing. Genentech is a world leader in biotech manufacturing, with more FDA-approved manufacturing capacity for the production of biotech medicines than any other company. Over the last two decades, Genentech has built world-class production facilities, developed expertise in commercially viable manufacturing processes and also attracted and retained key personnel with experience in all aspects of large-scale biologics manufacturing. Genentech's manufacturing expertise and capacity (approximately 330,000 liters of installed fermentation capacity) provide important competitive advantages in the maturing biotechnology industry and position the company well to meet the demands of its promising product pipeline. Genentech currently has three manufacturing facilities in California (South San Francisco, Vacaville and Oceanside). In 2004, Genentech began construction on an expansion to its Vacaville site, which, when completed, will be the largest biotechnology manufacturing facility of its kind in the world. Genentech acquired an Oceanside, California biologics manufacturing facility in June 2005 and received U.S. Food and Drug Administration (FDA) licensure in April 2007. In March 2006, Genentech announced the purchase of property in Hillsboro, Oregon, for the construction and development of a fill/finish facility. Construction is progressing at the location for a fill/finish facility, and the warehouse and distribution center became operational in July 2008. In November 2006, Genentech and Lonza entered into a supply agreement for the manufacture of Avastin at Lonza's facility currently under construction in Singapore. When completed, the 80,000-liter facility will be the first large-scale bulk biologics manufacturing plant in Singapore, with FDA licensure expected in 2010.

Commercialization

The commercial group plays a crucial role in bringing Genentech's therapies to our customers by transforming our scientific innovations into changes in the practice of medicine that enhance and extend patients' lives. The group's primary focus is to market and sell novel, targeted therapies for disease areas with unmet needs. The development and implementation of

commercial strategies involves collaboration across a variety of teams with dedicated expertise. These dialogues are supported by intensive market planning to ensure thoughtful understanding of each therapeutic area and customer group and by ongoing examination of broad healthcare marketplace trends.

Product Pipeline

In 2008, Genentech invested \$2.8 billion, or 21 percent of operating revenues on a GAAP basis, into research and development — significantly more than the pharmaceutical industry average. To balance resource use with the strongest likelihood of success, Genentech continuously evaluates its pipeline products in order to determine which are the most promising projects to move through the many phases of clinical testing.

Genentech's development pipeline continues to grow, now numbering more than 100 projects in the following therapeutic focus areas: oncology, immunology, disorders of tissue growth and repair, and neuroscience. The pipeline includes both breakthrough innovations and new indications for existing, well-understood products that may fight more than one disease or more than one form of a disease.

Oncology

Genentech is taking part in the fight against cancer by continuously studying and developing therapies for a variety of cancers. At present, we are studying our marketed products Avastin, Herceptin, Rituxan and Tarceva in numerous new oncology indications as well as investigating a number of new molecules as cancer therapies. We are also conducting combination trials of some of our cancer therapies, such as Avastin plus Tarceva in lung and pancreatic cancer and Avastin plus Herceptin in breast cancer.

Immunology

Immunology is a growing area of expertise and emphasis for Genentech, and we are developing several potential therapies for immune-related diseases. Two of our marketed products are approved for treatment of immunological conditions: Xolair for moderate-to-severe persistent asthma and Rituxan for use in adult patients with moderately-to-severely active rheumatoid arthritis who have had an inadequate response to one of more tumor necrosis factor antagonist therapies. We are continuing to investigate Rituxan in a variety of immune disorders as well as Xolair in pediatric asthma.

Disorders of Tissue Growth and Repair

An example of our investigational work in disorders of tissue growth and repair is our anti-angiogenesis drug, Lucentis, which was approved in June 2006 for the treatment of neovascular (wet) age-related macular degeneration (AMD). We are also studying Lucentis in diabetic macular edema and retinal vein occlusion.

Neuroscience

In March 2008, Genentech announced neuroscience as a new focus area, building on existing internal expertise and interest in neurodegeneration, neurophysiology and restoration. Since December 2006, we have had a research collaboration with AC Immune for the development of anti-beta-amyloid antibodies for the potential treatment of disease, and in the first quarter of 2008 we filed an IND for an anti-beta antibody in Alzheimer's disease.

Employees

Genentech employees consistently cite the opportunity to make a difference in the lives of patients as the primary reason they enjoy working at the company. We place great value on our approximately 11,000 dedicated and mission-driven employees and reward them accordingly with a comprehensive and diverse set of benefits and services. The company has consistently been recognized as a top employer by such publications as FORTUNE, Working Mother, and Science. In January 2009, FORTUNE named Genentech to its annual list of the “100 Best Companies to Work For” for the eleventh consecutive year.

About Genentech Access Solutions

Genentech is committed to people having access to our medicines. Genentech Access Solutions is a team of 350 Genentech employees who help those who need Genentech medicines. This team works with patients and doctors to resolve reimbursement and insurance issues and provides assistance to eligible patients in the United States who do not have insurance coverage or who cannot afford their out-of-pocket co-pay costs.

Since its first medicine was approved in 1985, Genentech has donated approximately \$1.3 billion in free Genentech medicine to the uninsured through the Genentech® Access to Care Foundation (GATCF) and other product donation programs. The household income limit to receive free medicine through GATCF is \$100,000 per year. Since 2005, Genentech has also donated approximately \$250 million to various independent, non-profit organizations that provide financial assistance to those who cannot access needed medical treatment due to co-pay costs.