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Genentech History

Genentech was founded in 1976 by venture capitalist Robert A. Swanson and biochemist Dr. Herbert W. Boyer. In the early 1970s, Boyer and geneticist Stanley Cohen pioneered a new scientific field called recombinant DNA technology. After hearing about Boyer and Cohen's breakthrough, Swanson placed a call to Boyer and requested a meeting. Boyer agreed to give the young entrepreneur 10 minutes of his time. Swanson's enthusiasm for the technology and his faith in its commercial viability was contagious, and the meeting extended from 10 minutes to three hours; by its conclusion, Genentech was born.

Though Swanson and Boyer faced skepticism from both the academic and business communities, they forged ahead with their idea. Within a few short years, they successfully demonstrated the viability of using recombinant DNA technology to develop products with practical applications and, in so doing, launched a whole new industry.

- 1976** • Robert Swanson and Dr. Herbert Boyer founded Genentech on April 7.
- 1977** • Genentech produced the first human protein (somatostatin) in a microorganism (*E. coli* bacteria).
- 1978** • Human insulin cloned by Genentech scientists.
- 1979** • Human growth hormone cloned by Genentech scientists.
- 1980** • Genentech went public and raised \$35 million with an offering that leapt from \$35 a share to a high of \$88 after less than an hour on the market. The event was one of the largest stock run-ups ever.
- 1982** • First recombinant DNA drug marketed: human insulin (licensed to Eli Lilly and Company).
- 1984** • First laboratory production of Factor VIII, a clotting factor for bleeding in hemophiliacs. Genentech announced agreement to grant license of worldwide production and marketing of Factor VIII to Cutter Biological.
- 1985** • Genentech received approval from the U.S. Food and Drug Administration (FDA) to market its first product, Protropin[®] (somatrem for injection) growth hormone for children with growth hormone deficiency — the first recombinant pharmaceutical product to be manufactured and marketed by a biotechnology company.
- 1986** • Genentech's interferon alpha-2a — licensed to Hoffmann-La Roche, Inc. as Roferon[®]-A — received approval from the FDA for the treatment of hairy cell leukemia.

- Genentech instituted the Uninsured Patients Program, providing free growth hormone for financially needy, uninsured patients in the United States. The program was later expanded to include future products.

1987 • Genentech received FDA approval to market Activase® (Alteplase, recombinant), a tissue-plasminogen activator (t-PA), to dissolve blood clots in patients with acute myocardial infarction (heart attack).

1989 • Genentech opened its day-care center, Genentech's Second Generation, one of the largest corporate-sponsored day-care centers in the United States at the time.

1990 • Genentech and Roche Holding Ltd. of Basel, Switzerland completed a \$2.1 billion merger.

- Genentech's Hepatitis B vaccine — licensed to SmithKline Beecham Biologicals S.A. — received FDA approval.

- Genentech received FDA approval to market Activase for the management of acute massive pulmonary embolism (blood clots in the lungs).

1992 • Genentech opened the Founders Research Center, dedicated to founders Robert Swanson and Dr. Herbert Boyer in appreciation of their vision and determination to pursue the promise of biotechnology.

1993 • Genentech received FDA approval to market Nutropin® [somatropin (rDNA origin) for injection] for treating growth failure in children with chronic renal insufficiency before they undergo kidney transplantation.

- Genentech received approval to market Pulmozyme® (dornase alfa) for treating cystic fibrosis from regulatory agencies in the United States, Canada, Sweden, Austria and New Zealand.

- Genentech's Factor VIII — licensed to Miles Inc. (formerly Cutter Biological) in 1984 — received FDA approval for the treatment of hemophilia-A.

1994 • Genentech announced it would locate its new manufacturing facility in Vacaville, California.

- Genentech received FDA approval to market Nutropin for the treatment of children with growth failure due to inadequate levels of the natural growth hormone in their bodies.

1995 • Genentech announced an agreement with Roche Holding, Ltd. to extend for four years Roche's option to purchase the outstanding redeemable common stock of the company at a predetermined price that escalates quarterly up to \$82.50 a share. As part of the agreement, Genentech began receiving royalties rather than recording sales on European sales of Pulmozyme and Canadian sales of all Genentech products as Roche assumed responsibility for those sales.

- Genentech received FDA approval to market an accelerated infusion regimen of Activase for the management of acute myocardial infarction.

1996 • Genentech celebrated the 20-year anniversary of its founding.

- Genentech received FDA approval to market Nutropin AQ® [somatropin (rDNA origin) injection] for the treatment of growth failure in children with chronic renal insufficiency before they undergo kidney transplantation and for the treatment of growth hormone deficiency in children.

- Genentech received FDA approval to market Activase for the treatment of acute ischemic stroke or brain attack.

- Genentech received FDA approval to market Pulmozyme for treating cystic fibrosis patients with advanced disease.

1997

- Genentech and partner IDEC Pharmaceuticals (now Biogen Idec Inc.) received FDA approval to market Rituxan® (Rituximab) for the treatment of patients with relapsed or refractory low-grade or follicular, CD20 positive, B-cell non-Hodgkins lymphoma.

- Genentech received FDA approval to market Nutropin AQ for the treatment of short stature associated with Turner syndrome.

- Genentech received FDA approval to market Nutropin and Nutropin AQ for the treatment of growth hormone deficiency in adults.

- Genentech launched a service for patients and their physicians called SPOC – Single Point of Contact – to provide customer-focused reimbursement assistance. The program became Genentech Access Solutions in 2008.

- In recognition of the importance of Genentech in establishing the biotechnology industry in South San Francisco, the city renamed the 400 block of Point San Bruno Boulevard to DNA Way, giving Genentech the new street address 1 DNA Way.

1998

- Genentech received approval from the FDA to market the humanized antibody Herceptin® (Trastuzumab) as a first-line therapy in combination with paclitaxel and as a single agent in second- and third-line therapy for patients with metastatic breast cancer who have tumors that overexpress the HER2 (human epidermal growth factor receptor2) protein.

- Genentech dedicated its new \$250 million manufacturing facility in Vacaville.

1999

- Genentech co-founder Robert Swanson was awarded (posthumously) the National Medal of Technology for his foresight and leadership in recognizing the commercial promise of recombinant DNA technology and his seminal role in the establishment and development of the biotechnology industry.

- Genentech reached a settlement agreement with the U.S. Attorney for the Northern District of California regarding Genentech's promotion of human growth hormone in the late 1980s and early 1990s.

- Roche exercised its option to cause Genentech to redeem all of its outstanding special common shares not owned by Roche. Roche announced its intent to publicly sell up to 19 percent of Genentech shares and continue Genentech as a publicly traded company with independent directors.

- Genentech received FDA approval of additional efficacy results for its growth hormone products – Nutropin and Nutropin AQ – on the effects of growth hormone replacement therapy on spine bone mineral density in young adults with childhood-onset growth hormone deficiency (GHD).

- On July 20, after about a month-long hiatus due to the Roche redemption, Genentech returned to the New York Stock Exchange (NYSE) with a public reoffering of 22 million shares by Roche, in what is considered the largest public offering in the history of the U.S. health care industry. The stock closed the first day of trading at \$127, over 31 percent above the public offering price of \$97. This was also the first introduction of Genentech's new NYSE trading symbol, DNA.
- Roche conducted a secondary offering of 20 million Genentech shares on October 20. The shares were priced at \$143.50 per share, making it the largest secondary offering in U.S. history.
- Genentech and the University of California (UC) agreed to a settlement of the patent infringement lawsuit brought by UC relating to the company's human growth hormone product, Protropin. Both parties agreed that this settlement was not an admission that Genentech infringed UC's patent or used the genetic material in question.
- Genentech and partner Alkermes, Inc. received FDA approval to market Nutropin Depot® [somatropin (rDNA origin) for injectable suspension] for the long-term treatment of growth failure due to a lack of adequate endogenous GH secretion.

2000

- Roche conducted a third offering of up to 19 million shares of Genentech stock at \$163 per share.
- Genentech announced the purchase of a cell culture manufacturing facility in Porriño, Spain. Genentech sold the facility to Lonza in 2006.
- Genentech's state-of-the-art manufacturing facility in Vacaville, California, received FDA licensure as a multi-product facility.
- Genentech received FDA approval of TNKase® (Tenecteplase), a modified form of t-PA, for use in mortality reduction associated with acute myocardial infarction (AMI), or heart attack; treatment should be initiated as soon as possible after the onset of AMI symptoms.

2001

- Genentech celebrated the 25th anniversary of its founding.
- Cathflo® Activase® (Alteplase) was approved by the FDA for the restoration of function to central venous access devices (CVADs).

2002

- The FDA approved Nutropin AQ Pen® for delivery of Nutropin AQ recombinant growth hormone.
- A Los Angeles County Superior Court jury voted to award the City of Hope (COH) \$300 million in additional royalties and \$200 million in punitive damages in the retrial of a contract dispute lawsuit brought by COH against Genentech. Genentech announced it would appeal the judgment in the case to the California Court of Appeal.
- Genentech received FDA approval to include HER2 gene detection test in Herceptin product labeling.

2003

- Genentech received FDA approval for Xolair® (Omalizumab) for Subcutaneous Use in 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. Xolair is the first humanized therapeutic antibody for the treatment of asthma and the first approved

therapy designed to target the antibody IgE, a key underlying cause of the symptoms of asthma that has an allergic component.

- Genentech received FDA approval for Raptiva® (efalizumab) for the treatment of chronic moderate-to-severe plaque psoriasis in adults age 18 or older who are candidates for systemic therapy or phototherapy. In April 2009, Genentech announced the voluntary withdrawal from the U.S. market of Raptiva.

2004

- Genentech received FDA approval for Avastin® (bevacizumab) for use in combination with 5-Fluorouracil-based chemotherapy in the treatment of first-line metastatic cancer of the colon or rectum. Avastin is the first FDA-approved therapy designed to inhibit angiogenesis, a process fundamental to cancer growth and metastasis.

- Genentech broke ground on an expansion of the Vacaville site. When completed, the new facility will be configured with an additional eight 25,000-liter fermentation tanks and, when combined with our existing facility, will be the largest biotechnology cell culture manufacturing site of its kind in the world.

- OSI Pharmaceuticals and Genentech announced that the FDA approved, after priority review, Tarceva® (erlotinib) for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failure of at least one prior chemotherapy regimen. Tarceva is an oral tablet indicated for daily administration.

2005

- Genentech purchased Biogen Idec's Oceanside, California, biologics manufacturing facility.

- Genentech received FDA approval for Tarceva (100 mg) in combination with gemcitabine chemotherapy for the treatment of locally advanced, inoperable or metastatic pancreatic cancer in patients who have not received previous chemotherapy.

2006

- Genentech celebrated the 30th anniversary of its founding.

- Genentech received approval from the FDA for Lucentis® (ranibizumab injection) for the treatment of neovascular (wet) age-related macular degeneration.

- Genentech received FDA approval for Rituxan 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.

- Genentech received FDA approval for Herceptin as part of a treatment regimen containing doxorubicin, cyclophosphamide and paclitaxel, for the adjuvant treatment of patients with HER 2-positive, node-positive breast cancer.

- Genentech received FDA approval for Avastin in combination with carboplatin and paclitaxel for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous NSCLC.

- Genentech and Lonza finalized an agreement for Lonza to purchase Genentech's manufacturing facility in Porriño and to continue to supply Avastin for Genentech under a supply agreement. Concurrently, Genentech entered into a supply agreement for the manufacture of certain Genentech products at Lonza's facility currently under construction in Singapore, with the right to exercise an exclusive option to purchase the facility between 2007 and 2012.

- 2007**
- Genentech finalized its acquisition of Tanox, enabling Genentech to improve the Xolair business and acquire Tanox's product pipeline.
- 2008**
- Genentech was one of the "100 Best Companies for Working Mothers" by Working Mother Magazine for the 16th year.
 - Genentech received FDA approval for Herceptin as a single agent, for the adjuvant treatment of HER2-overexpressing node-negative (ER/PR-negative or with one high-risk feature) or node-positive breast cancer, following multi-modality anthracycline-based therapy.
 - In April 2008, The California Supreme Court overturned the award of \$200 million in punitive damages resulting from the contract dispute lawsuit brought by City of Hope against Genentech.
 - In July 2008, Genentech received a proposal from Roche to acquire all of the outstanding shares of Genentech stock not owned by Roche.
- 2009**
- In March 2009, Roche and Genentech announced that they have signed a merger agreement under which Roche will acquire the outstanding publicly held interest in Genentech for US\$95.00 per share in cash, or a total payment of approximately US\$46.8 billion to equity holders of Genentech other than Roche.
- 2010**
- FORTUNE named Genentech one of the "100 Best Companies to Work For" for the 12th consecutive year. Genentech is the only biotech/pharmaceutical company since 2000 to be ranked among the top 20.
 - Genentech received FDA approval for ACTEMRA® (tocilizumab) to treat adults with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a tumor necrosis factor (TNF) antagonist has been used and did not work well.
 - Genentech received FDA approval for Rituxan® (Rituximab) in combination with fludarabine and cyclophosphamide (FC) for people with previously untreated and previously treated CD20-positive chronic lymphocytic leukemia (CLL).
 - Genentech was named "top employer in the biopharmaceutical industry" by Science magazine. This is the eighth number one ranking for the company.

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