

Genentech Secures FDA Approvals, Advances Pioneering Therapies Across Multiple Therapeutic Areas, and Reinforces Its Leadership in Biopharmaceutical Innovation

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Genentech Achieves Key Clinical Milestones in Oncology, Neurology, and Metabolic Disorders in H1 2024

Genentech

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Between January and June 2024, Genentech, a leading biotechnology company, made significant strides across multiple therapeutic areas, underscoring its commitment to advancing medical science and improving patient outcomes. The company's achievements during this period reflect groundbreaking progress in oncology, neurology, metabolic disorders, and more, with several pivotal clinical trials and regulatory approvals marking key milestones.

Oncology Breakthroughs and New Treatments

Genentech's oncology division made headlines with the Phase III STARGLO study results, where the combination of Columvi® (glofitamab-gxbm) and chemotherapy demonstrated a significant extension in overall survival for patients with relapsed or refractory diffuse large B-cell lymphoma. The treatment reduced the risk of death by 41%, providing new hope for patients battling this aggressive cancer. Additionally, the FDA granted Breakthrough Therapy Designation and Priority Review to Genentech's inavolisib-based regimen for PIK3CA-mutated HR-positive HER2-negative metastatic breast cancer. This designation followed promising results from a Phase III trial, positioning the regimen as a potential new standard of care for this challenging cancer subtype.

Advancements in Neurology and Rare Diseases

In the realm of neurology, Genentech reported encouraging long-term data for Evrysdi® in the treatment of Type 1 spinal muscular atrophy (SMA). An impressive 91% of children treated with Evrysdi® over five years survived, with significant motor function improvements, showcasing the drug's potential to transform the lives of those affected by this debilitating disease.

Genentech also continued to lead in the treatment of multiple sclerosis (MS), with its subcutaneous injection of Ocrevus® proving nearly as effective as the intravenous version in suppressing relapses and brain lesions. This development offers patients a more convenient treatment option without compromising efficacy, further solidifying Ocrevus® as a cornerstone of MS management.

Innovations in Metabolic Disorders

The company made significant progress in addressing obesity and type 2 diabetes through its novel dual GLP-1/GIP receptor agonist, CT-388. In a Phase Ib trial, CT-388 demonstrated substantial weight loss and glucose normalization, highlighting its potential as a transformative treatment in the fight against these pervasive metabolic disorders.

Lung Cancer and Beyond

Alecensa, another of Genentech's groundbreaking therapies, received FDA approval as the first adjuvant treatment for

ALK-positive early-stage lung cancer. A Phase III study revealed that Alecensa reduced the risk of disease recurrence or death by 76%, marking a significant advancement in early cancer intervention.

Innovative Treatments and Discontinuations

Further expanding its portfolio, Genentech achieved FDA approval for Xolair® as the first treatment for IgE-mediated food allergies. This approval is particularly impactful as it addresses allergic reactions across multiple foods, offering a new therapeutic option for children and adults with life-threatening food allergies.

Meanwhile, Genentech announced the planned discontinuation of Nutropin AQ® NuSpin® formulations in the U.S. by the end of 2024. The company has committed to supporting patients through the transition to alternative growth hormone treatments, ensuring continuity of care.

Ophthalmology Successes

In ophthalmology, Genentech’s Vabysmo® continued to demonstrate its efficacy, particularly in treating retinal vein occlusion. Data from Phase III studies showed that Vabysmo® provided prolonged treatment intervals and significant vision improvements, reinforcing its global approval for various retinal conditions.

The first half of 2024 was marked by substantial achievements for Genentech, as the company continued to drive innovation across multiple therapeutic areas. From oncology to neurology and metabolic disorders, Genentech’s advancements reflect its unwavering commitment to improving patient outcomes through cutting-edge science and pioneering treatments. As the company looks ahead, these milestones reinforce Genentech’s position as a leader in biopharmaceutical innovation, dedicated to transforming the future of medicine.

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