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Global Breakthrough Therapies Market Growth (Status and Outlook) 2025-2031

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Abstracts

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The global Breakthrough Therapies market size is predicted to grow from US$ 17950 million in 2025 to US$ 41620 million in 2031; it is expected to grow at a CAGR of 15.0% from 2025 to 2031.

Breakthrough therapy is a new drug review channel created by the U.S. Food and Drug Administration (FDA) in July 2012 to accelerate the development and review of new drugs to treat serious or life-threatening diseases. A breakthrough therapy designation is for a drug that treats a serious or life-threatening condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies.

United States market for Breakthrough Therapies is estimated to increase from US$ million in 2024 to US$ million by 2031, at a CAGR of % from 2025 through 2031.

China market for Breakthrough Therapies is estimated to increase from US$ million in 2024 to US$ million by 2031, at a CAGR of % from 2025 through 2031.

Europe market for Breakthrough Therapies is estimated to increase from US$ million in 2024 to US$ million by 2031, at a CAGR of % from 2025 through 2031.

Global key Breakthrough Therapies players cover F. Hoffmann-La Roche, Merck & Co., Bristol-Myers Squibb, Novartis, AstraZeneca, etc. In terms of revenue, the global two largest companies occupied for a share nearly % in 2024.

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LPI (LP Information)' newest research report, the “Breakthrough Therapies Industry Forecast” looks at past sales and reviews total world Breakthrough Therapies sales in 2024, providing a comprehensive analysis by region and market sector of projected Breakthrough Therapies sales for 2025 through 2031. With Breakthrough Therapies sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US$ millions of the world Breakthrough Therapies industry.

This Insight Report provides a comprehensive analysis of the global Breakthrough Therapies landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyses the strategies of leading global companies with a focus on Breakthrough Therapies portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms’ unique position in an accelerating global Breakthrough Therapies market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Breakthrough Therapies and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Breakthrough Therapies.

This report presents a comprehensive overview, market shares, and growth opportunities of Breakthrough Therapies market by product type, application, key players and key regions and countries.

Segmentation by Type:

Targeted Therapy

Immunotherapy

Gene Therapy

Cell Therapy

Other

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Segmentation by Application:

- Cardiovascular
- Central Nervous System and Neurology
- Rare Diseases
- Oncology
- Others

This report also splits the market by region:

- Americas
  - United States
  - Canada
  - Mexico
  - Brazil
- APAC
  - China
  - Japan
  - Korea
  - Southeast Asia
  - India
  - Australia

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Europe

Germany

France

UK

Italy

Russia

Middle East & Africa

Egypt

South Africa

Israel

Turkey

GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analyzing the company's coverage, product portfolio, its market penetration.

F. Hoffmann-La Roche

Merck & Co.

Bristol-Myers Squibb

Novartis

AstraZeneca

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Johnson & Johnson

Pfizer

AbbVie

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(2020-2025)

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