

## Biotechnology & Health:

Major developments in biotechnology and health on September 19, 2025, included a significant FDA approval for a rare genetic disease, new clinical trial results for a common inflammatory disease, and continued focus on the growing role of artificial intelligence (AI) in the healthcare sector.

### Biotechnology & Pharmaceutical News

**FORZINITY™ Approval for Barth Syndrome:** Stealth BioTherapeutics announced that the U.S. Food and Drug Administration (FDA) granted accelerated approval to FORZINITY™ (elamipretide HCl), the first-ever therapy for the ultra-rare and life-limiting genetic disease known as Barth Syndrome. The approval was supported by data from a clinical trial that showed improvements in muscle strength. This is a significant breakthrough for patients, as the disease is characterized by mitochondrial abnormalities, muscle weakness, and reduced life expectancy.

**TREMFYA® Approval for Ulcerative Colitis:** Johnson & Johnson received FDA approval for a subcutaneous induction regimen of TREMFYA® (guselkumab) for treating adults with moderately to severely active ulcerative colitis. This makes TREMFYA® the first and only IL-23 inhibitor to offer both subcutaneous and intravenous induction options for both ulcerative colitis and Crohn's disease, providing more flexibility and convenience for patients.

**New Findings on Ozempic®:** A new real-world study showed that Ozempic® (semaglutide), a once-weekly injectable, was associated with a 23% reduced risk of major adverse

**cardiovascular events** like heart attack, stroke, and death compared to a different drug, dulaglutide. This adds to the growing body of evidence supporting the cardiovascular benefits of Ozempic® for people with type 2 diabetes.

**Merck's KEYTRUDA QLEX™ Approved:** Merck's KEYTRUDA QLEX™ (pembrolizumab), a cancer immunotherapy, received FDA approval for a new subcutaneous administration in adults across most of its solid tumor indications. This new formulation allows for injection, offering a more convenient option compared to traditional intravenous infusions for many patients.

### Key Trends & Industry Developments

**AI in Drug Discovery and Healthcare:** Union Minister Dr. Jitendra Singh stated that India is poised for a bio-driven future economy driven by biotechnology. He highlighted the use of AI-driven mobile health clinics in India to provide hybrid medical consultations, showing the integration of AI in healthcare delivery. Other industry reports noted that AI is expected to drive 30% of new drug discoveries by 2025, helping to accelerate research and lower costs.

**India's Pharmaceutical Sector Outlook:** A rating agency, ICRA, projected that India's pharmaceutical sector will see healthy revenue growth of 7-9% in FY26. The growth is expected to be fueled by strong demand in domestic and European markets, despite anticipated moderation in the U.S. market.

**Gene and Cell Therapy Advances:** The field of gene and cell therapy saw notable updates, including Sanofi's gene therapy for neovascular age-related macular degeneration garnering FDA Fast Track Designation. This highlights the

continued progress and focus on developing advanced treatments for complex diseases.

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## MCQS

1. What rare genetic disease did the FDA grant accelerated approval for the first-ever therapy, **FORZINITY™**?

- a) Crohn's disease
- b) Barth Syndrome
- c) Ulcerative colitis
- d) Age-related macular degeneration

**Answer:** b) Barth Syndrome

The news report states that **FORZINITY™** was granted accelerated FDA approval as the first-ever therapy for the ultra-rare genetic disease known as Barth Syndrome.

2. Which pharmaceutical company's cancer immunotherapy, **KEYTRUDA QLEX™**, received FDA approval for a new subcutaneous administration?

- a) Stealth BioTherapeutics
- b) Sanofi
- c) Johnson & Johnson
- d) Merck

**Answer:** d) Merck

The report indicates that Merck's **KEYTRUDA QLEX™** received FDA approval for a new subcutaneous administration, providing a more convenient injection option for patients.

3. According to a new real-world study, by what percentage did **Ozempic®** reduce the risk of major adverse cardiovascular events compared to dulaglutide?

- a) 10%
- b) 15%
- c) 23%
- d) 30%

**Answer:** c) 23%





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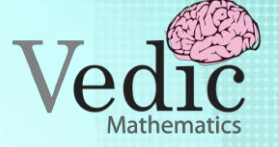
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The news mentions that a new real-world study showed Ozempic® was associated with a "23% reduced risk of major adverse cardiovascular events" when compared to dulaglutide.

**4. What is the projected revenue growth for India's pharmaceutical sector in FY26, according to the rating agency ICRA?**

- a) 5-7%
- b) 7-9%
- c) 9-11%
- d) 11-13%

**Answer:** b) 7-9%

The report cites the rating agency ICRA, which projected a "healthy revenue growth of 7-9%" for India's pharmaceutical sector in FY26.

**5. Which company's gene therapy for neovascular age-related macular degeneration received FDA Fast Track Designation?**

- a) Merck
- b) Stealth BioTherapeutics
- c) Johnson & Johnson
- d) Sanofi

**Answer:** d) Sanofi

The news mentions that Sanofi's gene therapy for neovascular age-related macular degeneration garnered FDA Fast Track Designation, highlighting progress in the field of gene and cell therapy.

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