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Biotechnology & Health:

Drug Major **Approvals** I. and Breakthrough Therapies (July 2025)

The FDA has been active in approving several new drugs and biosimilars this month. highlighting advancements various in therapeutic areas:

Diabetes:

Kirsty (insulin aspart-xjhz) Injection: Approved on July 15, 2025, as an interchangeable biosimilar to NovoLog. It's a rapid-acting human insulin analog for glycemic control in adults and pediatric patients with diabetes mellitus. (Drugs.com, July 15, 2025)

Hereditary Angioedema (HAE):

Ekterly (sebetralstat) Tablets: Approved on July 8, 2025, this is the first and only oral on-demand treatment for HAE attacks in adults and pediatric patients aged 12 years and older. (Drugs.com, July 8, 2025)

Oncology:

Lvnozvfic (linvoseltamab-gcpt) Injection: Granted accelerated approval on July 2, 2025, for the treatment of relapsed or refractory multiple myeloma. It's a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager. (Drugs.com, July 2, 2025)

Zegfrovy (sunvozertinib) Tablets: Granted accelerated approval on July 2, 2025, for nonsmall cell lung cancer with EGFR Exon 20 Insertion Mutations. (Drugs.com, July 2, 2025)

Datopotamab deruxtecan-dlnk (Datroway): Approved January 17, 2025, for unresectable or metastatic, HR-positive, HER2-negative breast cancer. (HCPLive, July 2, 2025)

Other notable approvals from late June 2025 (relevant for ongoing impact):

Harliku (nitisinone) Tablets: Approved June 19, 2025, for alkaptonuria.

Arynta (lisdexamfetamine dimesylate) Oral Solution: Approved June 16, 2025, for ADHD and binge eating disorder.

Zusduri (mitomycin) for Intravesical Solution: Approved June 12, 2025, for recurrent lowgrade intermediate-risk non-muscle invasive bladder cancer.

(amlodipine, Widaplik indapamide and telmisartan): Approved June 9, 2025, as a single-pill, triple combination therapy for hypertension.

Xifyrm (meloxicam) Injection: Approved June 10, 2025, for moderate-to-severe pain. (Drugs.com)

II. Advances in Gene Therapy and CRISPR **Technology**

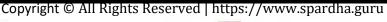
The field of gene editing continues to see rapid progress, offering potential cures for previously untreatable diseases:

Hearing Restoration: An AAV-based gene therapy has shown full recovery in all 10 participants in a trial for children with congenital deafness, marking a significant breakthrough. (LucidQuest Ventures, July 10, 2025)

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Friedreich Ataxia: The **FDA** granted Breakthrough Therapy designation to LX2006 Friedreich Ataxia, accelerating development. (LucidQuest Ventures, July 10, 2025)

Custom CRISPR Gene Editing: The American Society of Gene & Cell Therapy (ASGCT) highlighted the debut of the first-ever custom CRISPR gene editing treatment for an infant known as "baby KJ." This treatment involved base editing to correct a specific genetic disorder, with promising early efficacy signs. (ASGCT, June 25, 2025)

CRISPR and Cancer: Scientists have uncovered that a gene called SDR42E1 is crucial for vitamin D absorption and metabolism. Disabling this gene using CRISPR/Cas9 in colorectal cancer cells crippled their survival, opening new avenues for targeted cancer therapies by either cutting off vitamin D supply to tumors or enhancing the gene's activity. (ScienceDaily, July 18, 2025)

CRISPR Market Growth: The global CRISPR gene editing market is projected to reach USD 4.77 billion in 2025 and is expected to grow significantly, driven technological by advancements and increasing investments for disease treatment. (GlobeNewswire, July 8, 2025)

Retinal Diseases: Gene therapy applications for inherited retinal diseases (IRDs) continue to advance, with ongoing clinical trials for conditions like Leber Congenital Amaurosis (LCA), Retinitis Pigmentosa (RP), Choroideremia showing promising results in visual improvement. (MDPI, July 20, 2025)

Autoimmune Diseases: Researchers have developed a new CRISPR-Cas9 guided gene editing approach to effectively deplete the autoantigen protein SP3, offering a potential for alternative treatment anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitides (AAVs). (CRISPR Medicine News, July 4, 2025)

III. Personalized Medicine and ΑI Integration

The convergence of biology, technology, and data is driving a shift towards hyperpersonalized and predictive healthcare:

AI in Drug Discovery: The generative AI in drug discovery market is experiencing rapid growth, projected to reach USD 318.55 million in 2025. Al models are accelerating drug discovery by simulating compounds, predicting biological activity. and optimizing formulations, significantly reducing development time and costs. (Towards Healthcare, July 7, 2025)

AI for Enhanced Diagnostics and Treatment: AI machine learning are transforming healthcare by improving diagnostic accuracy (e.g., in radiology and pathology), powering predictive analytics to flag at-risk patients, and streamlining clinical trials. (Lifebit, June 8, 2025; Los Angeles Times, July 21, 2025)

Multi-Omics Expansion: Precision medicine is increasingly leveraging multi-omics data (genomics, transcriptomics, proteomics, metabolomics) for deeper insights individual patient biology, enabling real-time clinical decisions. (Lifebit, June 8, 2025)

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Digital Health **Ecosystems:** Wearables. telehealth, and digital therapeutics are creating personalized care pathways, allowing for realtime health monitoring and early detection of conditions. (Global IMI, January 28, 2025)

AI in Traditional Medicine: A new report by WHO, ITU, and WIPO showcases how AI is enhancing traditional medicine practices globally, including AI-powered diagnostics in Ayurgenomics and machine learning models for identifying medicinal plants. This highlights efforts to combine ancient healing systems with modern technology. (WHO, ITU, WIPO, July 11, 2025)

IV. Other Notable Developments

Sustainable **Biotechnology:** Biotechnology continues to offer solutions for global challenges, including climate-resilient crops, cleaner biofuels, and bioremediation for environmental pollutants. (Mahindra University, June 20, 2025)

Protein Discovery for Drought Resistance: Scientists discovered that the motor protein myosin XI helps plants close their pores to potential conserve water. offering for developing drought-resistant crops. (ScienceDaily, July 16, 2025)

Aging Research: Starving and refeeding worms has revealed secrets about aging, particularly the role of a gene called TFEB in recovery from fasting. (ScienceDaily, July 4, 2025)

Natural Cancer-Fighting Substances: Scientists found a unique sugar in sea cucumbers that can block Sulf-2, an enzyme cancer cells use to spread. (ScienceDaily, June 11, 2025)

MCQS

1.Which newly approved interchangeable biosimilar to NovoLog for diabetes mellitus?

- a) Ekterly
- b) Kirsty
- c) Lynozyfic
- d) Zegfrovy

Answer: b) Kirstv

The text states, "Kirsty (insulin aspart-xjhz) Injection: Approved on July 15, 2025, as an interchangeable biosimilar to NovoLog."

2. What is unique about Ekterly (sebetralstat) Tablets, approved on July 8, 2025?

- a) It's a new treatment for multiple myeloma.
- b) It's the first and only oral on-demand treatment for Hereditary Angioedema (HAE) attacks.
- c) It targets EGFR Exon 20 Insertion Mutations in lung cancer.
- d) It's an insulin analog for glycemic control.

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Answer: b) It's the first and only oral ondemand treatment for Hereditary Angioedema (HAE) attacks.

The text says, "Ekterly (sebetralstat) Tablets: Approved on July 8, 2025, this is the first an only oral on-demand treatment for HAE attacks in adults and pediatric patients aged 12 years and older."

3.Lynozyfic (linvoseltamab-gcpt) Injection received accelerated approval for the treatment of which condition?

- a) Non-small cell lung cancer
- b) Hereditary Angioedema
- c) Relapsed or refractory multiple myeloma
- d) Breast cancer

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Answer: c) Relapsed or refractory multiple myeloma

The text states, "Lynozyfic (linvoseltamab-gcpt) Injection: Granted accelerated approval on July 2, 2025, for the treatment of relapsed or refractory multiple myeloma."

- 4.What significant breakthrough in gene therapy for congenital deafness was reported on July 10, 2025?
- a) A new drug to manage symptoms
- b) Full recovery in all 10 participants of an AAVbased gene therapy trial for children
- c) A surgical procedure to implant cochlear devices
- d) Development of a new hearing aid technology

Answer: b) Full recovery in all 10 participants of an AAV-based gene therapy trial for children The text mentions, "An AAV-based gene therapy has shown full recovery in all 10 participants in a trial for children with congenital deafness, marking a significant breakthrough."

- 5. What genetic editing technique was used in the first-ever custom gene editing treatment for infant "baby KJ"?
- a) RNA interference
- b) Base editing (a form of CRISPR gene editing)
- c) Viral vector delivery without CRISPR
- d) Stem cell transplantation

Answer: b) Base editing (a form of CRISPR gene editing)

The text states, "This treatment involved base editing to correct a specific genetic disorder, with promising early efficacy signs." Base editing is a type of CRISPR technology.

6. Scientists have found that disabling which gene using CRISPR/Cas9 crippled the survival of colorectal cancer cells by affecting vitamin D? a) TFEB

- b) SP3
- c) Sulf-2
- d) SDR42E1

Answer: d) SDR42E1

The text says, "Scientists have uncovered that a gene called SDR42E1 is crucial for vitamin D absorption and metabolism. Disabling this gene using CRISPR/Cas9 in colorectal cancer cells crippled their survival."

- 7. What is the projected market size for generative AI in drug discovery in 2025?
- a) USD 4.77 billion
- b) USD 318.55 million
- c) USD 6.93 billion
- d) USD 1.78 billion
- Answer: b) USD 318.55 million

The text states, "The generative AI in drug discovery market is experiencing rapid growth, projected to reach USD 318.55 million in 2025."

- 8. Which of the following is not explicitly mentioned as a way AI and machine learning are transforming healthcare?
- a) Improving diagnostic accuracy
- b) Powering predictive analytics
- c) Designing new surgical instruments
- d) Streamlining clinical trials

Answer: c) Designing new surgical instruments While AI might contribute indirectly to instrument design, specifically the text highlights "improving diagnostic accuracy (e.g., radiology and pathology), predictive analytics to flag at-risk patients, and streamlining clinical trials."

- 9. What is "multi-omics" in the context of precision medicine?
- a) A single type of genetic data for diagnosis.

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- b) The integration of various biological datasets like genomics, transcriptomics, proteomics, and metabolomics.
- c) The use of traditional medicine practices exclusively.
- d) A system for tracking drug supply chains.

Answer: b) The integration of various biological genomics, datasets like transcriptomics, proteomics, and metabolomics.

The text defines it as "Precision medicine is increasingly leveraging multi-omics (genomics, transcriptomics, proteomics, metabolomics) for deeper insights individual patient biology."

- 10.A new report by WHO, ITU, and WIPO showcases AI enhancing traditional medicine practices. Which of the following is an example
- a) AI-powered robotic surgery in traditional
- Machine learning models identifying medicinal plants.
- c) Al for manufacturing traditional herbal landia Private Limited remedies at scale.
- d) AI for direct patient consultations in traditional medicine.

Answer: b) Machine learning models identifying medicinal plants.

The text states, "It includes examples such as how AI-powered diagnostics are being used in Ayurgenomics; machine learning models identifying medicinal plants in countries including Ghana and South Africa."

- 11. What motor protein was discovered to help plants close their pores to conserve water, offering potential for drought-resistant crops?
- a) Myosin II
- b) Myosin V
- c) Myosin XI

d) Kinesin

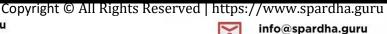
Answer: c) Myosin XI

The text says, "Scientists discovered that the motor protein myosin XI helps plants close their pores to conserve water, offering potential for developing drought-resistant crops."



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