Patient Wellness First

Issue: 15 June 2025

BioSciTech biweekly NEWS

NEWS & COMMENTARIES

Saudi Food and Drug Administration (SFDA) Release Regulatory Guidance for Literature Based Support of Efficacy and Safety of Medicines

by Dr. Jehad Alghamdi, *Executive Director https://www.linkedin.com/in/jahad7/*

SFDA has released the Regulatory Guidance for Literature-Based Support of Efficacy and Safety of Medicines. It provides a structured pathway for improving the quality of clinical data to support market authorization requests for new medicines, particularly in cases where applicant-sponsored trials are unavailable, such as for generic (multisource) products and known active substances, when the reference innovator is not registered by the SFDA. This guidance aims to strengthen the regulatory framework by enabling the use of existing scientific evidence to support timely access to safe and effective medicines.

https://www.sfda.gov.sa/sites/default/files/2025-05/RGLBSESM.pdf

Adjuvant Immunotherapy Ups Survival in dMMR Colon Cancer

— Adding atezolizumab to chemotherapy reduced the risk of recurrence or death by 50%. After 3 years of follow-up, 86% of patients treated with atezolizumab (Tecentriq) and chemotherapy remained alive without evidence of disease. That compared with 76.6% of patients who received chemotherapy only after surgery. A subgroup analysis showed a consistent benefit across patients, including low- and high-risk patients and those older than age 70.

https://www.medpagetoday.com/meetingcoverage/asco/115839

Almac Discovery and Formosa

Pharmaceuticals announce global licensing agreement for development and commercialisation of ALM-401, a first-in-class EGFRxROR1 Bispecific Antibody-Drug Conjugate), addressing the high unmet needs of cancer patients worldwide suffering with intractable and aggressive solid tumours.

https://hubs.li/Q03lfJvh0

ASCO: AstraZeneca's oral SERD tied to 56% PFS benefit in phase 3 breast cancer trial

AstraZeneca has produced some fresh data to back up its blockbuster ambitions for camizestrant, tying the oral SERD to a 56% improvement in progression-free survival (PFS) in a phase 3 breast cancer study. The Serena-6 study had a novel design that reflected an unmet need in individuals with HR-positive, HER2-negative advanced breast cancer. All 315 patients received an aromatase inhibitor and a CDK4/6 inhibitor—either Eli Lilly's Verzenio, Novartis' Kisqali or Pfizer's Ibrance—as their first-line treatment.

https://www.fiercebiotech.com/biotech/asco-astrazenecas-oral-serd-tied-56-pfs-benefit-phase-3-breast-cancer-trial?utm_medium=email&utm_source=nl&utm_campaign=LS-NL-FierceBiotech&oly_enc_id=1227H3695790A1V

SELECTED PUBLICATIONS

Exercise Cuts Colon Cancer Recurrence and Boosts Survival, Study Finds

The Brief

A large Canadian study found that regular exercise after colon cancer treatment reduces the risk of cancer returning. Patients who followed a structured exercise program had higher survival rates than those who only received health education. After eight years, the exercise group had a 37% lower risk of death and better long-term outcomes.

Key Takeaways

- A three-year exercise plan cut colon cancer recurrence by 28%
- Patients also had 37% fewer deaths from any cause
- Coaching helped survivors stay active long-term

https://www.vtcng.com/state_and_world/health_news/exercise-cuts-colon-cancer-recurrence-and-boosts-survival-study-finds/article_f19abb57-9a46-54a4-a6b2-3b0c5dc35372.html

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Humour uncovers the wide landscape of life: From laughter to freedom

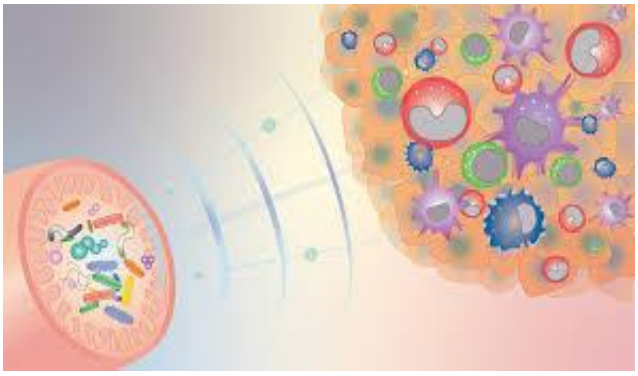
Vladimir Leksa 2025

https://doi.org/10.1038/s44319-025-00494-6

"Of all the bodily movements which at once shake the body and soul, laughter is the healthiest, because it promotes digestion, circulation, evaporation, and refreshes the vital sap in all the organs." Thus wrote Christoph Wilhelm Hufeland, personal physician of Johann Wolfgang Goethe and Friedrich Schiller. A hundred years later, comedian Groucho Marx said the same in different words: "A clown is like aspirin, only he works twice as fast." They were both right. Similar to the physician and the comedian, science has concluded that humour has indeed a profoundly positive effect on the physical and mental health of a laughing individual (Savage et al, 2017).

"A clown is like aspirin, only he works twice as fast."

- Grand consilium on the compelling questions of humour
- Are there genes for humour?
- Absence of humour as a sign of totalitarianism
- There is always someone who gets offended
- A sense of humour as a condition for living in truth



Cancer microbiota: a focus on tumor-resident bacteria

Vella and Rescigno, 2025

https://doi.org/10.1038/s44319-025-00482-w

Tumor-resident bacteria (TRB) are emerging as key influencers of cancer growth, immunity, and treatment response. This review explores their origins, dual roles in tumors, and potential as therapeutic targets. Advances in detection and modulation of TRB may pave the way for innovative cancer therapies.

Assessing the health of the gut microbial organ: why and how?

DeLeon and Chang, 2025

https://doi.org/10.1172/JCI184313

The gut microbiome, a diverse community of microbes, plays a vital role in human health. It is now considered as significant as other organs due to its systemic effects. This review series highlights microbiome impacts across body systems and life stages. Topics include diet, neonatal health, immunity, cancer, and the vaginal microbiome.

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Microbiota mechanisms in cancer progression and therapy

Xing Zhang et al., 2025

DOI: 10.1016/j.chembiol.2025.04.005

The microbiota influences cancer progression and therapy response, offering new avenues for patient care. This review explores recent advances in uncovering the chemical mechanisms by which specific microbial species, enzymes, and metabolites affect cancer and immunotherapy. Understanding these pathways could lead to better diagnostics and treatments, though many mechanisms remain unknown and call for innovative chemical genetic tools.

Gut microbial metabolite 4-hydroxybenzeneacetic acid drives colorectal cancer progression via accumulation of immunosuppressive PMN-MDSCs

Qing Liao et al., 2025

https://doi.org/10.1172/JCI181243

The microbial metabolite 4-HPA fosters colorectal cancer by attracting immunosuppressive cells. It enhances PMN-MDSC infiltration via the JAK2/STAT3-CXCL3 axis, weakening CD8+ T cell response. Blocking CXCL3 or reducing 4-HPA through chlorogenic acid reversed immune suppression. These findings support targeting microbe–tumour–immune interactions to improve cancer therapy.

Oligomerised RIPK1 is the main core component of the CD95 necrosome

Ivanisenko et al., 2025

https://doi.org/10.1038/s44318-025-00433-0

Researchers have mapped the composition and structure of the necrosome, a key driver of necroptotic cell death and inflammation. Using mass spectrometry and AlphaFold modeling, they identified RIPK1 as the core component, with critical type-II death domain interactions driving complex formation. These findings deepen our understanding of necroptosis and offer new targets for therapies aimed at controlling inflammation and cell death–related diseases.

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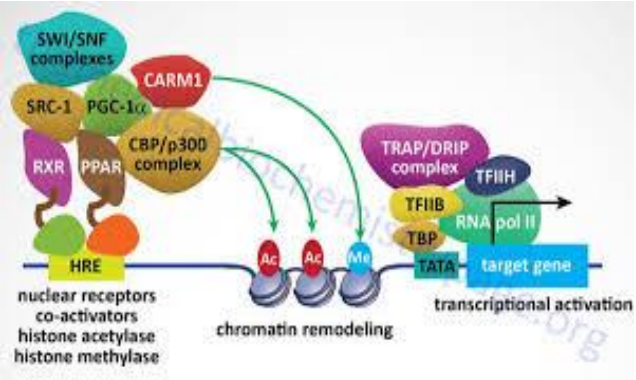


Long-term histone lactylation connects metabolic and epigenetic rewiring in innate immune memory

Ziogas et al., 2025

DOI: 10.1016/j.cell.2025.03.048

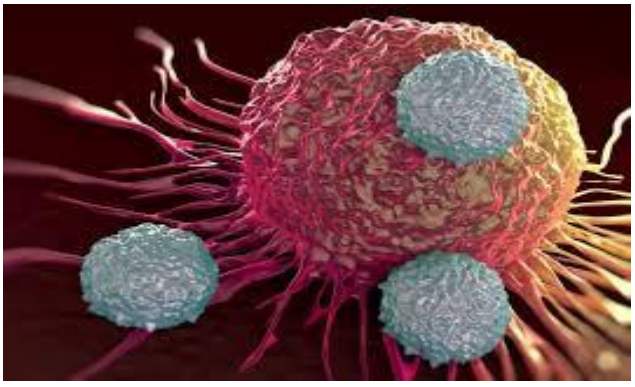
A new study reveals that histone lactylation, specifically H3K18la, is a lasting epigenetic mark underlying trained immunity. In BCG-vaccinated individuals, increased lactate production drives proinflammatory cytokine responses through H3K18la at active chromatin sites. This modification persists long after the training stimulus and is essential for enhanced immune responses. Blocking lactate production or lactylation disrupts trained immunity, while genetic variants in LDHA and EP300 influence its strength. These findings position histone lactylation as a key regulator(and potential target) of innate immune memory.

Engineering a protease-stable, oral single-domain antibody to inhibit IL-23 signaling

Ota et al., 2025

DOI:10.1073/pnas.2501635122

Researchers have developed a highly stable, orally administered VHH antibody that targets IL-23R, an important therapeutic target in inflammatory bowel disease (IBD). Engineered for enhanced affinity and resistance to gut proteases, the VHH remains active in intestinal conditions and achieves strong anti-inflammatory effects in preclinical models. A single oral dose sustained IL-23 pathway inhibition in primates for over 24 hours, offering a cost-effective, non-invasive alternative to injectable biologics for IBD treatment.



Targeted apoptotic immune modulator for the treatment of metastatic EGFR-positive solid tumors

Derrick Broka et al., 2025

DOI:10.1073/pnas.2500489122

TAR001, a novel nanoparticle-based therapy, offers a powerful new approach for treating EGFR-overexpressing solid tumors. By delivering polyIC selectively to cancer cells, TAR001 triggers apoptosis, activates innate and adaptive immunity, and reshapes the tumor microenvironment. Tested in multiple cancer models, it significantly extended survival and suppressed tumor growth. This multimodal treatment shows promise for hard-to-treat metastatic cancers, including head and neck, lung, colorectal, renal, and triple-negative breast cancers.

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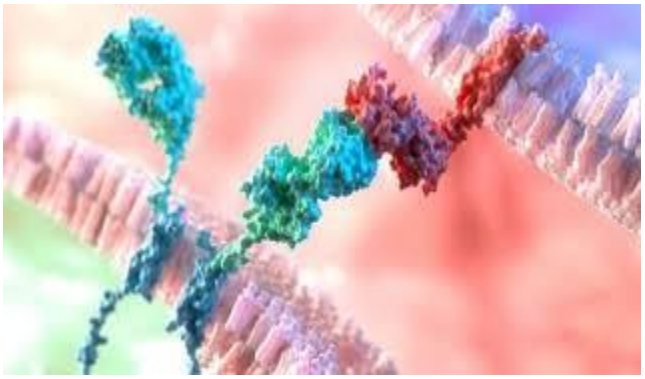


Engineering sonogenetic EchoBack-CAR T cells

Longwei Liu et al., 2025

DOI: 10.1016/j.cell.2025.02.035

EchoBack-CAR T cells are activated by ultrasound to maintain strong, localised anti-tumour effects. Using heat-shock promoters and feedback signalling, these cells outperformed traditional CAR T cells. In glioblastoma and prostate cancer models, they showed durable response with minimal toxicity. Single-cell RNA analysis confirmed better T cell persistence and lower exhaustion rates.

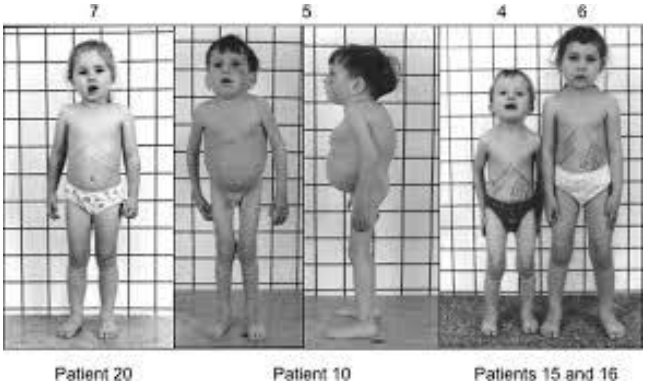
Prognostic model for predicting recurrence in breast cancer patients in Saudi Arabia

Ousman Khan et al., 2025

https://doi.org/10.1038/s41598-025-94530-z

A predictive model was developed using clinical data from Saudi breast cancer patients.

Logistic and Cox regression identified key recurrence risks including tumour size and treatment. Chemotherapy and surgery significantly lowered recurrence odds in both training and test cohorts. The model achieved strong predictive accuracy and is freely accessible for clinical use.



FLT201, a novel liver-directed AAV gene therapy candidate for Gaucher disease type 1

Comper et al., 2025

DOI:10.1016/j.ymthe.2025.05.003

FLT201 is an AAV-based gene therapy delivering a long-lasting GCase enzyme variant. The engineered GCase85 shows increased stability at both serum and lysosomal pH. Preclinical results suggest improved treatment durability over standard enzyme therapy. FLT201 aims to better manage Gaucher disease by reducing harmful substrate buildup.

RECOMMENDED EVENTS

The Science & SciLifeLab Prize for Young Scientists
Recent PhD?

How about US$30,000, having your essay published in Science magazine, and being celebrated with a week of festivities in Stockholm, Sweden?
A global award aimed at young researchers
In addition, all four winners are published in Science, and at the end of the year, invited to visit SciLifeLab in Stockholm.

Questions: scilifelabprize@aaas.org
About the Prize: scienceprize.scilifelab.se
Application deadline: July 15, 2025
Eligibility: applicants must have received their PhD between January 1, 2023 and December 31, 2024.

Eppendorf & Science Prize for Neurobiology

The international Eppendorf & Science Prize for Neurobiology is awarded annually to one young scientist who is not older than 35 years for the most outstanding neurobiological research based on methods of molecular, cellular, systems, or organismic biology conducted by him/her during the past three years.
Prize money: US$ 25,000
Deadline for Submissions: June 15, 2025
https://corporate.eppendorf.com/en/company/scientific-awards/global-award/

AACR Special Conference in Cancer Research: Advances in Ovarian Cancer Research

September 19-21 • Grand Hyatt Denver • Denver, CO
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https://www.aacr.org/meeting/aacr-special-conference-in-cancer-research-advances-in-ovarian-cancer-research/

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From Skepticism to Opportunity: Building Investor Confidence in First-in-Class and First-in-Disease Drug Innovation

June 16, 2025

1:45 PM - 2:45 PM

Business Development and Investment Business Development and Investment

210A

King's College London:Lecturer (AEP) in Pharmacology Education

The post holder is responsible for delivering and enhancing the content of modules delivered by the Department of Pharmacology & Therapeutics, eg. running modules and facilitating their delivery and contributing to the strategic vision of Pharmacology education within the Faculty's School of Bioscience Education. In addition, there may be opportunity to deliver short term (6 weeks) Pharmacology teaching at our partner University in Shenzhen, China.

https://www.kcl.ac.uk/jobs/115085-lecturer-aep-in-pharmacology-education

The ASCI's job board provides visibility of your professional opening to a community of physician-scientists who are active researchers and clinicians across academic medical centers and corporations in the US and elsewhere. The board is promoted across:

https://beta.the-asci.org/job-board/

https://scienceprize.scilifelab.se/about-young-scientist-prize/

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