Friday, 17 July 2026

CONTENT *(Highlights)*

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UPCOMING EVENTS

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DEALS AND FUNDING

Emcure Pharmaceuticals acquires final 12.05% stake in Gennova

PharmaBiz, 13 July 2026

Emcure Pharmaceuticals Limited announced the consolidation of its shareholding in biopharma subsidiary Gennova Biopharmaceuticals Limited, alongside a leadership transition, as it sharpens its focus as a biologics and biosimilars company. Emcure is acquiring the entire 12.05% minority stake in Gennova held by Dr Sanjay Singh and others, taking its ownership to 100% and making Gennova a wholly owned subsidiary.

Gennova will be led by Samit Mehta and will focus on its biologics franchise — Elaxim/TENECTASE, Vintor, Xgrast/PEGEX and Hamsyl — biosimilars development, and adjacent therapeutic platforms, leveraging its established mammalian and microbial biomanufacturing platforms.

Commenting on the announcement, Satish Mehta, managing director & CEO, Emcure Pharmaceuticals Limited, said: "We thank Dr. Sanjay Singh for his nearly two decades of exceptional scientific leadership at Gennova. His stewardship has built platforms, products, and a culture that will continue to fulfil Gennova's mission of transforming healthcare. With this stake acquisition, we simplify Gennova's ownership, sharpen its strategic focus, and position it under Samit Mehta's leadership for its next phase of growth in biologics and biosimilars."

Samit Mehta, whole time director & CEO, Gennova Biopharmaceuticals Limited, said: "As part of the One Emcure framework, Gennova will continue to anchor the Group's biologics and biosimilars capabilities. Our work will complement Emcure's broader R&D and pipeline priorities, with a focus on execution, quality and disciplined development across our chosen therapy areas."

The transaction is not expected to have a material impact on Emcure's consolidated financials or its capital allocation framework. The Company's deleveraging trajectory, capex plans and R&D investment plans remain unchanged.

Emcure Pharmaceuticals acquires final 12.05% stake in Gennova

★★★★★★★

AstraZeneca adds another Chinese asset, from Dizal

PharmaPhorum, 14 July 2026

AstraZeneca has continued its pipeline-boosting deal spree in China with a $1.5 billion agreement that gives it global rights to Dizal Pharma's lung cancer therapy Zegfrovy.

Zegfrovy (sunvozertinib) – an oral irreversible EGFR inhibitor – is already approved in China and the US as a second-line treatment for adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with exon 20 insertion mutations who have previously had platinum-based chemotherapy.

Shares in Shanghai-listed Dizal rose 20% on the announcement, which reveals that AZ is paying $600 million upfront for global development and commercial rights to Zegfrovy, along with additional payments of up to $900 million in development, regulatory and sales-related milestones and royalties on sales.

AZ's move on Zegfrovy follows a crucial readout for Zegfrovy from the WU-KONG28 study, which raises the prospect of moving the drug into first-line treatment of NSCLC with EGFR exon 20 insertion mutations – which would be new territory for the multibillion-dollar oral EGFR inhibitor class as a whole.

At the moment, the only drug approved in the frontline setting for this niche category of EGFR-mutated NSCLC is Johnson & Johnson's intravenously administered Rybrevant (amivantamab) in combination with chemo.

In WU-KONG28, Dizal's drug, given as a monotherapy, achieved a statistically significant improvement in progression-free survival (PFS) compared to frontline platinum chemo, offering the prospect of becoming the first oral, once daily, chemo-free, targeted therapy for these patients.

Armed with that data, Dizal has already filed to extend Zegfrovy's indications in China and the US to include first-line use in this form of NSCLC.

AstraZeneca adds another Chinese asset, from Dizal | pharmaphorum

★★★★★★★

Insilico signs on with CDMO Bora in $2.5B AI drug discovery deal

Fierce Pharma, 15 July 2026

Red-hot generative AI specialist Insilico Medicine has teamed up with another major biopharma player, this time linking up with CDMO Bora Pharmaceuticals.

The collaboration, which could ultimately be worth $2.5 billion, the companies said, is another in a rush of drug discovery deals forged by Insilico. Others this year that have either joined forces or upped their ante with the 12-year-old Massachusetts biotech include Eli Lilly, Servier, Takeda and SK Biosciences.

The newest partnership, which covers multiple targets, combines Insilico's proprietary Pharma.AI drug development platform with Bora's development, manufacturing and commercialization capabilities to "explore a next-generation drug innovation model," the companies said.

Insilico's platform spans target discovery, generative chemistry and molecule optimization. By linking these capabilities with Bora's automation-driven operations, the companies are hoping to design novel molecules for diseases where unmet need remains.

Taipei-based Bora is also looking for the collaboration to enhance its "AI literacy across the organization," it said, seeking improved efficiency in its manufacturing, supply chain, distribution and corporate operations.

Bora CEO Bobby Sheng called the partnership an "important step" as the company evolves from a "leading pharmaceutical development and manufacturing partner into a broader drug innovation ecosystem."

Bora inks $2.5B deal with drug discovery AI specialist Insilico

★★★★★★★

Lilly enters psychedelic drug race with up to $3.8 billion AtaiBeckley deal

Reuterus, 16 July 2026

Eli Lilly will buy AtaiBeckley for up to $3.8 billion, the company said on Thursday, joining a race among pharma majors to develop psychedelic treatments for depression and other mental health disorders.

Interest in the sector received a boost after U.S. President Donald Trump in April directed health regulators to speed up reviews of certain psychedelic treatments and increased federal funding for research in the field.

Lilly will pay $6.75 per AtaiBeckley share in cash, a premium of about 26% to the stock's closing price on Wednesday. AtaiBeckley's shares rose more than 30% in premarket trading.

The offer consists of $2.8 billion upfront and additional up to $1 billion milestone-based payments.

The deal gives Lilly access to AtaiBeckley's lead candidate BPL-003, a psychedelic-based nasal spray in late-stage development for treatment-resistant depression, a severe form of the illness that does not improve after standard treatments.

"Millions of people are still searching for relief and desperately need a therapy that works," said Carole Ho, president, Lilly Neuroscience.

The companies expect the deal to close in the third quarter.

Drugmakers have shown growing interest in psychedelic-based treatments for depression and other mental health disorders.

AbbVie bought an experimental psychedelic-based depression drug from Gilgamesh Pharmaceuticals for up to $1.2 billion last year.

Lilly enters psychedelic drug race with up to $3.8 billion AtaiBeckley deal

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PHARMA & BIOLOGICS

SMALL MOLECULES

FDA Approves Revtorpyk (gedatolisib) for the Treatment of HR+/HER2-, PIK3CA Wild-Type Locally Advanced or Metastatic Breast Cancer

Drugs.com, 14 July 2026

Celcuity Inc., a biotechnology company focused on developing and commercializing targeted therapies for multiple solid tumor indications, today announced that the U.S. Food and Drug Administration ("FDA") approved Revtorpyk (gedatolisib) for the treatment of patients with hormone receptor positive ("HR+"), human epidermal growth factor receptor 2 negative ("HER2-"), locally advanced or metastatic breast cancer without a *PIK3CA* mutation detected following progression on or after treatment with at least one line of endocrine therapy in the metastatic setting. Revtorpyk is the only inhibitor of class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2 to receive FDA approval.

- *Revtorpyk is the first and only FDA-approved therapy that inhibits all class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2*
- *In the Phase 3 VIKTORIA-1 trial, Revtorpyk combined with palbociclib and fulvestrant and Revtorpyk combined with fulvestrant reduced the risk of disease progression or death by 76% and 67%, respectively, compared to fulvestrant among patients with PIK3CA wild-type advanced or metastatic breast cancer*

"The PI3K/AKT/mTOR, or PAM, pathway is one of the most important targets in cancer, but comprehensively inhibiting it has stymied researchers and drug developers for nearly two decades," said Brian Sullivan, CEO and co-founder of Celcuity. "Revtorpyk addressed this 20-year challenge by becoming the first pan-PI3K, mTORC1/2 inhibitor approved by the FDA. We are thankful for the opportunity to make this important new therapy available to patients with HR+/HER2- locally advanced or metastatic breast cancer."

HR+/HER2- breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of all breast cancers.[1] Among this breast cancer subtype, approximately 60% have *PIK3CA* wild-type disease.[2]

"For patients with HR+/HER2- locally advanced or metastatic breast cancer, there is an urgent need for new treatment options that can meaningfully increase the likelihood of survival without disease progression or death," said Sara Hurvitz, MD, Senior Vice President, Clinical Research Division, Fred Hutchinson Cancer Center, Smith Family Endowed Chair in Women's Health and Professor and Head, Division of Hematology and Oncology, University of Washington, School of Medicine and co-principal investigator for the VIKTORIA-1 trial. "With the approval of Revtorpyk, oncologists now have an effective new treatment option for these patients."

FDA Approves Revtorpyk (gedatolisib) for the Treatment of HR+/HER2-, PIK3CA Wild-Type Locally Advanced or Metastatic Breast Cancer

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FDA Approves a First-Of-Its-Kind Pill to Cut Cholesterol in High-Risk Patients

US News, 16 July 2026

The Food and Drug Administration has approved a first-of-its-kind pill that can drastically reduce cholesterol in a way that's previously only been available with expensive, injectable drugs.

The drug from Merck was OK'd on Thursday for patients with artery-clogging cholesterol that persists even after taking statins, the standard medications for cutting heart attack risk. Merck will market its pill under the brand name Lipfendra.

It's the first noninjectable medication that works by blocking a liver protein called PCSK9. That protein limits the body's ability to clear cholesterol from the blood, and biotech injectables targeting it have been available from Amgen and other drugmakers for more than a decade. But patient access has been stymied for years by high prices, insurance restrictions and limited prescribing by doctors.

Statins block some of the liver's production of cholesterol and are the cornerstone of treatment. But even at the highest doses, many people need additional help lowering their LDL, or bad, cholesterol enough to meet medical guidelines.

Merck, which has headquarters in Rahway, New Jersey, won approval based on two studies in high-risk patients who added the company's pill to their standard treatment, including statins. In one study of 3,000 patients, those taking Lipfendra saw their levels of LDL cholesterol drop more than 55% after six months. In a second study, patients averaged a reduction of 59% compared with patients who received a dummy pill.

That benefit dropped only slightly over a year, and side effects — including dizziness and diarrhea — were similar between those taking the pill or a placebo, researchers found. One caveat: The pill must be taken on an empty stomach.

The FDA reviewed the drug under its program that promises ultra-fast reviews for promising medications that serve the public interest. The pathway was created by then-FDA chief Dr. Marty Makary, who resigned from the agency in May after months of pressure from drugmakers, patients and other outside groups.

FDA Approves a First-Of-Its-Kind Pill to Cut Cholesterol in High-Risk Patients

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LARGE MOLECULES

India's Sun Pharma wins South Africa approval to launch generic Ozempic

Reuters, 15th July 2026

India's Sun Pharmaceutical Industries (SUN.NS), has received approval from South Africa's health regulator to manufacture and sell a generic version of semaglutide, the active ingredient in Novo Nordisk's top-selling diabetes and obesity drugs.

Novo's (NOVOb.CO), patent on semaglutide - used in diabetes drug Ozempic and weight-loss treatment Wegovy - expired in March, prompting expectations of a wave of cheaper generics from local and international drugmakers.

The entry of generics also poses a challenge to U.S. company Eli Lilly (LLY.N), which has launched blockbuster diabetes and obesity drugs in South Africa as well.

The approval from the South African Health Products Regulatory Authority makes South Africa the second market, after India, where Sun Pharma has secured clearance for a generic semaglutide injection, the company said in a statement.

The approval is for adults with inadequately controlled type 2 diabetes.

Sun Pharma said it plans to launch the product in South Africa in the coming days. The drug will be sold as a pre-filled, multi-dose injectable pen in two strengths — 2 mg and 4 mg — for once-weekly use.

https://www.reuters.com/legal/litigation/indias-sun-pharma-wins-south-africa-approval-launch-generic-ozempic-2026-07-15/

★★★★★★★

Oxford begins first human trial of Bundibugyo Ebola vaccine

Reuters, 13th July 2026

The University of Oxford has launched the first human trial of a vaccine against Bundibugyo ebolavirus, seeking to accelerate efforts to combat an outbreak spreading in the Democratic Republic of Congo and Uganda.

The early-stage trial, known as BD-Ebov, will evaluate the safety and immune response of the ChAdOx1 BDBV vaccine in 50 healthy adults aged 18 to 55 in Oxford, the university said on Monday.

Here are the details:

- Recruitment has begun, with vaccinations expected to start in the coming weeks pending regulatory approval.
- The vaccine was developed by scientists at Oxford's Vaccine Group and Pandemic Sciences Institute using the same viral vector platform as the Oxford/AstraZeneca (AZN.L), COVID-19 shot.
- Serum Institute of India, which is partnering on the programme, said it manufactured and stockpiled about 620,000 doses of the vaccine candidate within two weeks and supplied 4,000 investigational doses for the early-stage study.
- In May, the World Health Organization recommended prioritising ChAdOx1 BDBV vaccine, alongside a single-dose candidate known as rVSV Bundibugyo, being developed by the International AIDS Vaccine Initiative, for clinical evaluation as part of the response to the ongoing outbreak.
- The Coalition for Epidemic Preparedness Innovations said it would initially invest up to $8.6 million for the development of the shot.

https://www.reuters.com/business/healthcare-pharmaceuticals/oxford-begins-first-human-trial-bundibugyo-ebola-vaccine-2026-07-13/

★★★★★★★

Sanofi opens new chapters in Pfizer, Moderna mRNA patent litigation sagas

Fierce Pharma, 15th July 2026

As Pfizer and Moderna have tied off certain threads in their separate webs of mRNA patent litigation, Sanofi has opened a new front to challenge the companies' blockbuster COVID-19 vaccines.

In separate complaints filed in the U.S. District Court for the District of New Jersey this week, attorneys for Sanofi took aim at the lipid nanoparticle (LNP) tech undergirding the delivery of mRNA in Pfizer's COVID-19 shot Comirnaty, plus two versions of Moderna's mRNA coronavirus prophylactic—Spikevax and mNexpsike—and its respiratory syncytial virus (RSV) vaccine mResvia.

LNPs have been a frequent point of contention in the mire of patent litigation that has sprung up around mRNA vaccine technology following the approvals of Pfizer's and Moderna's products.

Sanofi's legal team specifically argues that Pfizer's and Moderna's LNP technologies have infringed related patents developed by Translate Bio. Sanofi shelled out $3.2 billion to acquire Translate Bio back in 2021, signaling continued commitment to the field despite the company's failure to muster its vaccine expertise behind an approved mRNA COVID-19 shot.

https://www.fiercepharma.com/pharma/sanofi-opens-new-chapters-pfizers-modernas-mrna-patent-litigation-sagas

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Novo gains head start on Lilly with European Commission approval of Wegovy pill

Fierce Pharma, 15th July 2026

In Novo Nordisk and Eli Lilly's competition to launch their respective GLP-1 obesity pills in the United States, the Danish company got a three-month head start earlier this year, which has proven to be crucial as Lilly is still playing catch-up.

Now it appears Novo will gain a similar advantage across the Atlantic, as the European Commission has granted marketing authorization for the Wegovy pill for adults with obesity or who are overweight.

Novo could gain an even greater advantage over Lilly in Europe, as it remains unclear when the Indianapolis drugmaker will begin selling its GLP-1 pill, Foundayo, there.

European regulators are still reviewing the company's application.

Three weeks ago, Lilly's International President Patrik Jonsson told Reuters that the launch could come by the end of the year or in early 2027 and added that U.S. President Donald Trump's most favored nations (MFN) pricing policy "will play a role for all launches."

In addition to endorsing the Wegovy pill, the European Commission also approved the high-dose, 7.2-mg version of Wegovy, which could produce greater weight loss than the standard maximum dose of 2.4 mg. Under its national priority voucher program, the FDA approved the high-dose Wegovy pen in March.

In the 72-week Step Up trial, which paved the way for the high-dose Wegovy approvals, patients receiving the 7.2-mg dose lost an average of 20.7% of their body weight, compared with 17.5% among patients receiving the 2.4-mg dose and 2.4% among those receiving a placebo.

https://www.fiercepharma.com/pharma/novo-gets-head-start-lilly-europe-ec-approval-wegovy-pill-0

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REGULATORS AND REGULATORY ACTIONS

Alembic Pharma gets warning letter from USFDA for Vadodara facility

Pharmabiz, 14th July 2026

Alembic Pharmaceuticals Limited announced that the United States Food and Drug Administration (USFDA) has issued a Warning Letter, dated 10 July 2026, to the Clinical Investigator associated with a bioequivalence (BE) study conducted at the company's Bioequivalence Facility in Vadodara.

The USFDA inspection was carried out from 3 March to 7 March 2025. According to the company, the Warning Letter pertains to observations related to the Informed Consent Form (ICF) used in the bioequivalence study. The company further clarified that the observations are procedural in nature and do not involve any data integrity concerns. Based on its preliminary assessment, the Warning Letter does not impose any restrictions on the operations of the Bioequivalence Facility, and the company is coordinating with the Clinical Investigator submits an response to the USFDA within the stipulated timeline.

https://www.pharmabiz.com/NewsDetails.aspx?aid=187140&sid=2

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Maharashtra FDA seizes Cadila Pharma's Rs 2.45 cr worth Aciloc stock; orders market recall over "deceptive" branding

Bignewsnetwork, 12th July 2026

In a major crackdown under the 'Safe Food, Safe Medicines, Safe Maharashtra' campaign, the Food and Drug Administration (FDA) of Maharashtra has seized stocks of Aciloc 150+ and Aciloc 300+ worth approximately Rs 2.45 crore and ordered a total market recall of the brand over deceptive labelling and branding concerns.

According to an official press note on Saturday, the action follows a routine inspection in Amravati, where it was observed that Cadila Pharmaceuticals Ltd., Ahmedabad, had long been licensed to manufacture and market Aciloc 150 and Aciloc 300, which contain Ranitidine as their Active Pharmaceutical Ingredient (API).

However, the company recently introduced Aciloc 150+ and Aciloc 300+, in which Ranitidine has been replaced with Famotidine, an entirely different active pharmaceutical ingredient. Despite this major change, the company retained nearly identical branding and label artwork, merely adding a '+' (Plus) sign to the product name before marketing the medicines.

https://www.bignewsnetwork.com/news/279182316/maharashtra-fda-seizes-cadila-pharma-rs-245-cr-worth-aciloc-stock-orders-market-recall-over-deceptive-branding

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Medicines containing over 12% alcohol will now require prescription in India

Moneycontrol, 10th July 2026

The Centre has withdrawn the licensing exemption for medicinal formulations containing more than 12 per cent of ethyl alcohol and brought them under stricter regulatory oversight, including mandatory licensing and prescription-only sale, to curb misuse and prevent diversion for intoxication, officials told PTI.

Certain medicinal products, including tinctures of cardamom, ginger and other aromatic preparations, have been exempted from licensing requirements under Schedule K of the Drugs Rules, 1945, the ministry said.

https://www.moneycontrol.com/news/india/medicines-containing-over-12-alcohol-will-now-require-prescription-in-india-13970974.html

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MEDTECH

Newronika's adaptive deep brain stimulation system, aDBS receives CE Mark

PharmaBiz, 15 July 2026

Newronika S.p.A., a Milan-based medtech company redefining deep brain stimulation therapy, has received CE Mark certification for the latest commercial release of aDBS, its adaptive deep brain stimulation system, now including full integration with WebBioBank, Newronika's proprietary cloud-based neural data platform.

This regulatory milestone marks the first approval for an adaptive DBS system that continuously senses neural activity and automatically adjusts stimulation according to patient-specific adaptive therapy settings, transmitting the data into a fully integrated neural data cloud platform.

Built on more than 20 years of advanced research and development, Newronika's platform understands the brain's signals and is designed to deliver better outcomes with fewer side effects, fewer clinical visits, and a reduced burden on both patients and clinicians.

"This certification validates our vision of a fully connected, data-driven approach to neuromodulation therapy, and opens a new era in personalized treatment for patients living with Parkinson's disease and other neurological conditions," said Lorenzo Rossi, PhD, co-founder, CEO & CTO of Newronika.

Conventional Deep Brain Stimulation delivers fixed stimulation, regardless of how a patient's brain state changes throughout the day. aDBS is different by design.

Powered by a patented Adaptive Therapy Stim Engine, aDBS continuously senses local field potential (LFPs), reading the brain's signals in real time and adjusting the stimulation to keep each patient within their optimal therapeutic window.

The aDBS system includes an implantable pulse generator (IPG), a physician interface, and a patient remote that enables seamless at-home data collection. Together, these components enable a connected care model where patient data is transmitted continuously, and clinicians gain longitudinal data that may support ongoing therapy optimization over time.

Newronika's adaptive deep brain stimulation system, aDBS receives CE Mark

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INTERESTING MEDICAL NEWS

Popular 'good' gut bacteria may signal higher diabetes risk years in advance

Medical News Today, 13 July 2026

- Researchers identified 6 bacterial species in the gut microbiome associated with an increased risk of type 2 diabetes, with these changes detectable years before diagnosis.
- The findings suggest changes in the gut microbiome may occur before the disease develops, rather than being a consequence of it.
- The researchers highlight how diet may influence gut bacteria's effects on health, with low dietary fiber potentially altering the effects of a usually beneficial bacterium.
- While the findings require further validation, gut microbiome analysis could

  complement existing risk factors, such as obesity, family history, and blood glucose levels, to help identify those at high risk of type 2 diabetes and support earlier preventive interventions.

Type 2 diabetes is estimated to affect more than 460 million people worldwide. Cases have continued to rise over recent decades, with projections suggesting that more than 1 billion people will be living with the condition by 2050.

While researchers have established certain risk factors for type 2 diabetes, such as having overweight or obesity, or having a family history of the condition, growing evidence is highlighting the potential role of the gut microbiome.

The gut microbiome refers to the trillions of bacteria and other microorganisms that naturally live in the digestive tract. Previous studies have noted a link between the gut microbiome and certain health conditions, including type 2 diabetes.

However, it remains unclear whether changes in the gut microbiota occur before the disease develops or result from it.

Now, a large Swedish study suggests that changes in the gut microbiome could help identify people at increased risk of developing type 2 diabetes years before symptoms appear.

The study, published in Cell Reports Medicine, found that several bacterial species were associated with a higher likelihood of developing type 2 diabetes.

This means it may be possible to detect type 2 diabetes years before it develops by analyzing gut bacteria, helping identify people who would benefit from earlier preventive interventions.

6 bacterial species in gut microbiome linked to risk

As part of the European research project HealthFerm, researchers at Chalmers University of Technology led a large epidemiological study involving 4,685 Swedish adults whose microbiomes were examined in stool samples.

Of the study participants, 383 developed diabetes after an average follow-up of 5 years, and early common denominators were observed in their gut microbiota.

Because this study followed participants over time, the researchers were able to observe changes to the microbiome several years before the disease developed.

Comparing the microbiomes of those who went on to develop the condition with those who remained diabetes-free, the researchers identified 9 bacterial species associated with future diabetes risk. Of these, 6 were linked to increased risk, while 3 were linked to decreased risk.

These findings indicate that the composition of the gut microbiome may play a role in the development of diabetes, rather than the other way around. Because this study followed participants over time, it strengthens the case that certain bacteria may be involved earlier in the disease process.

Study author Gaël Toubon, PhD, a postdoctoral researcher in food science at Chalmers' Department of Life Sciences was not surprised that changes in the gut microbiome could be detected several years before a diagnosis of type 2 diabetes:

"Previous studies had suggested that the gut microbiome is linked to T2D, but most of them have compared people who already have T2D with those who do not," he explained to *Medical News Today*.

"Finding microbial signatures years before diagnosis strengthens the idea that the gut microbiome may play a role early in disease development, rather than simply reflecting established diabetes."

— Gaël Toubon, PhD

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