Bavarian Biotech News

March 2025





DEAR READER

Page 2

BAVARIAN START-UPS

Page 7 - 8

RECENT HEADLINES

Page 3 - 4

EVENTS & CONTACT

Page 10

BAVARIAN RESEARCHERS

Page 5

Dear reader,



spring has arrived in Bavaria. Nature's renewal can be observed everywhere, like at the beautiful Seealpsee in the Allgäu Alps on our cover picture.

Science also needs continuous renewal to ensure medical progress. The sustainable success of science and research depends not only on the latest technologies or the best ideas, but above all on the principles that make this success possible: Freedom and diversity.

Freedom and diversity are not opposites, but mutually dependent. Only by protecting the freedom of the individual, combined with the promotion of a diverse and open research landscape, can we create sustainable and fair science in order to develop sustainable innovations in biotechnology.

How research and progress can thrive under these conditions and what else there is to report from biotech in Bavaria, today in our newsletter.

We hope you enjoy reading it!

Your Bio^M team

Recent headlines

Matthias Tschöp elected as new president of LMU Munich

The University Council elected Prof. Matthias Tschöp as the new President of <u>Ludwig-Maximilians-Universität (LMU) Munich</u>. Matthias Tschöp is currently CEO and Scientific Director of <u>Helmholtz Munich</u> and holds the Chair of Metabolic Diseases at the <u>Technical University of Munich (TUM)</u>.

Matthias Tschöp will assume the presidency in October 2025, succeeding Prof. Bernd Huber, who has led Ludwig-Maximilians-Universität (LMU) Munich since 2002..



Matthias Tschöp, © Matthias Tunger, Photodesign

During his 23-year tenure, LMU has developed into one of the leading universities nationally and internationally.

Incoming LMU President Prof. Matthias Tschöp stated: "I am truly honored by the University Council's decision. As LMU President, I will dedicate all my efforts, together with all my colleagues, to ensuring a successful future for this exceptional university and all of its students."

Read more

Recent headlines



Helmholtz invests EUR 18 million in Al innovation ecosystems

The new 'HPC Gateway' initiative aims to open up access to the Helmholtz Association's world-leading HPC infrastructure for companies. The Helmholtz Association is investing EUR 18 million in this endeavour.

Artificial intelligence (AI) and high-performance computing (HPC) are crucial technologies for the competitiveness of companies. However, many companies, especially small and medium-sized enterprises (SMEs), face the challenge of gaining



access to high-performance computing resources and specialized data analyses. The Helmholtz Association addresses this challenge through the **HPC Gateway** initiative, investing EUR18 million in the program. The program aims to give companies access to the world-leading HPC infrastructure of the Helmholtz Centers and connect them with AI experts.

In the one-year pilot phase now underway, nine Helmholtz Centers at eight locations – including **Helmholtz Munich** – are opening their high-performance computing capacities to companies. The aim is to dovetail research and business more closely and to promote the formation of regional innovation ecosystems. Companies will receive hands-on support to advance Al-driven innovations, digital twins, and HPC-based developments. Read more

Formycon launches FYB202/Otulfi®, a biosimilar to Stelara®, in the United States and the European Union

Formycon AG and its commercialization partner Fresenius announced the commercial availability of Otulfi®, a biosimilar to Stelara®2 in the United States (U.S.) and the European Union (EU). FYB202/Otulfi® is now commercially available in both subcutaneous and intravenous formulations in the United States and the European Union. Classification as an interchangeable biosimilar in the USA is expected in the near future.



Ustekinumab is a **human monoclonal antibody** that targets the cytokines interleukin-12 and interleukin-23 which play an important role in inflammatory and immune responses. Otulfi® was approved by the <u>U.S.</u>

<u>Food and Drug Administration (FDA)</u> and the <u>European Medicines Agency (EMA)</u> in September 2024, having successfully met the agency's standards for biosimilarity to the reference product, including equivalent efficacy, safety and pharmacokinetics.

In the U.S., Otulfi® is indicated for the treatment of **Crohn's disease**, **ulcerative colitis**, **moderate to severe plaque psoriasis and active psoriatic arthritis**. The FDA has provisionally determined that Otulfi® will be interchangeable with the reference drug Stelara®, following the expiration of a competitor's interchangeability exclusivity. In the EU, Otulfi® has been launched to treat moderately to severely active Crohn's disease, moderate to severe plaque psoriasis and active psoriatic arthritis. Read more

Recent headlines



Bavarian Nordic receives approval for first Chikungunya vaccine in Europe for people aged 12 and over

Bavarian Nordic, with its subsidiary located in Planegg/Munich, has received marketing authorization from the European Commission for VIMKUNYA® for active immunization against Chikungunya virus disease in individuals aged 12 years and older in Europe. The company plans to launch the vaccine in key European markets during the first half of 2025.



This single-dose, virus-like particle (VLP) vaccine is the first **Chikungunya vaccine** approved in Europe

for individuals aged 12 and above. The authorization, which applies across all EU member states as well as Iceland, Liechtenstein, and Norway, marks the second approval of VIMKUNYA® following its recent approval by the <u>U.S. Food and Drug Administration (FDA)</u> earlier this month.

Bavarian Nordic has also recently submitted a marketing authorization application to the UK's
Medicines and Healthcare products Regulatory Agency (MHRA), with approval anticipated in the first half of 2025. Simultaneously, VIMKUNYA® will be introduced in key European markets within the same timeframe.

Read more

Formycon receives regulatory approval for FYB203 (aflibercept) in the UK

Formycon AG and its licensing partner Klinge Biopharma GmbH have been granted marketing authorization by the UK Medicines and Healthcare Products Regulatory Agency (MHRA) for FYB203 (aflibercept), a biosimilar to Eylea®, under the brand name AHZANTIVE®.

The approval covers the treatment of Age-Related Neovascular (wet) Macular Degeneration (nAMD) and other serious retinal conditions, including Diabetic Macular Edema



O Unsplash

(DME), visual impairment due to Myopic Choroidal Neovascularization (CNV) and Macular Edema following Retinal Vein Occlusion (RVO). Aflibercept is an inhibitor of the **vascular endothelial growth factor (VEGF)**, which plays a key role in the abnormal formation of blood vessels in the retina, leading to vision impairment.

The **UK market authorization** follows successful regulatory approvals by the <u>U.S. Food and Drug Administration (FDA)</u> and the <u>European Comission</u> for FYB203. The U.S. Food and Drug Administration (FDA) had already granted marketing authorization for FYB203 in June 2024, followed by European Commission's approval in January 2025. <u>Read more</u>

Bavarian researchers



Erlangen University Hospital receives USD 600,000 in funding for translational study on CAR-T cell therapy for lupus erythematosus

More than 45 people with autoimmune diseases have been successfully treated with a novel CAR-T cell therapy at the <u>University Hospital Erlangen</u>, part of <u>Friedrich-Alexander University Erlangen-Nürnberg</u> (FAU). Among them, over 15 patients with systemic lupus erythematosus – who had previously not responded to any other treatments – are now symptom-free. A new study, supported by a USD 600,000 grant from the U.S.-based <u>Lupus</u> <u>Research Alliance</u>, will now investigate the underlying mechanisms of this therapy.

In lupus, immune cells known as B cells produce antibodies against the body's own tissues. As part of



Prof. Ricardo Grieshaber-Bouyer
© Friedrich-Alexander-Universität-Erlangen-Nürnberg

the **CAR-T cell therapy** developed in Erlangen, patients' own immune cells (T cells) are extracted and equipped with a special artificial receptor (CAR). These CAR-T cells are then returned to the patient, where they bind to harmful B cells in the blood and tissues and destroy them.

The result is a **reboot** of the immune system. However, the disease lupus is not only driven by B cells; other immune cells such as T cells and macrophages also play an important role.

In a new study, **Prof. Ricardo Grieshaber-Bouyer** wants to investigate the **underlying mechanisms** of the therapy. Read more

Researchers from Bayreuth create hyrdogel with self-healing properties

A research team from the <u>Universität Bayreuth</u> and <u>Aalto University</u> in Finland has, for the first time, succeeded in developing a hydrogel with a unique structure that combines strength, flexibility and self-healing properties of natural skin.

This breakthrough opens up new possibilities for applications such as targeted drug delivery, wound healing, sensors in soft robotics, and artificial skin. Read more



TUM scientists develop efficient method to purify proteins with light

Scientists at the <u>Technical University of Munich</u> (<u>TUM</u>) have developed a method that relies on physics rather than conventional chemistry to obtain proteins.

Using short-wave, UV light invisible to humans, they have succeeded in purifying proteins from cell extracts or cultures. This method is more efficient and gentler than existing techniques and could be used in the future for high-throughput drug development in pharmaceutical or biotechnology companies. Read more



Sabrina Bauer / TUM



1 - 2 July 2025 | Munich

Design Offices München Macherei







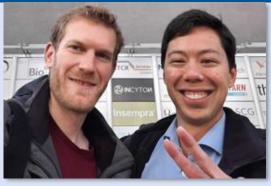
Bavarian start-ups



m⁴ Awardee Invitris wins EIC Accelerator funding

The Martinsried-based start-up Invitris, winner of the m⁴ Award coordinated by Bio^M, has been selected as one of 71 companies in the latest funding round of the EIC Accelerator. The biotech start-up impressed with its platform technology for the production of bacteriophages for the treatment of antibiotic-resistant infections and will receive a combination of grants and equity funding.

<u>Invitris</u> utilizes **bacteriophages** to treat **antibiotic-resistant infections** and has developed a unique technology that enables, for the first time, the in vitro production of genetically optimized



Co-founder & CEO Dr. Patrick Grossmann and cofounder and CTO Dr. Kilian Vogele (left) of Invitris © Invitris

bacteriophages for therapeutic use. The spin-off from the <u>Technical University of Munich</u> had already received **funding through INCATE in 2022**.

Winners of the <u>EIC Accelerator</u> receive up to **EUR 2.5 million** in grants, with some also benefiting from equity investments. Nearly 80% of the companies opt for blended finance, combining grants and equity investments.

Read more

Caire.ai secures EUR 850,000 for smart Al based health monitoring

Munich-based healthtech start-up <u>Caire.ai</u> has raised EUR 850,000 in a pre-seed round. The company is developing technology that uses video recordings of a person's face to determine vital parameters such as heart rate, blood pressure, oxygen saturation, and stress levels. Lead investor is <u>VC YZR Capital</u>. <u>Bayern Kapital</u>, <u>capacura</u>, <u>online pharmacy DocMorris</u>, and healthcare angel investor <u>Martin</u> <u>Blüggel</u> also participated in the round.



The Caire.ai team. © Caire.ai

The smart Al-based health monitoring solution

operates completely contactless and is compatible with almost any standard camera. With its technology, Caire.ai aims to provide the clinical sector with faster ways to capture patients' vital signs. Hospitals could thus implement rapid, contactless, and fully digital triage systems.

Beyond clinical applications, the technology can also be used in the automotive industry or consumer technology—envisioning, for instance, vehicles that monitor drivers' health or smartphones offering enhanced, continuous health monitoring features.

Read more

Bavarian start-ups



ONVY HealthTech Group raises over USD 2 million in seed funding for Al-powered health coaching

ONVY HealthTech Group GmbH, a Munich-based pioneer in Al-driven precision health, has successfully raised over USD 2 million in a seed extension financing round. The round was led by Voloridge Health, LLC an affiliate of Voloridge Investment Management, LLC a quantitative hedge fund manager renowned for his use of data science and predictive modeling to develop sophisticated systematic investment strategies. This investment will accelerate ONVY's expansion as it scales its Al-driven health coaching platform to power hyper-personalized health engagement at scale.



© ONVY HealthTech Group

The health and wellness industry is shifting towards **data-driven personalization**, yet it remains fragmented, reactive, and heavily siloed, limiting user engagement and long-term health impact.

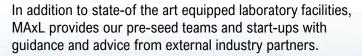
ONVY is closing this gap by delivering an Al-powered platform that processes and interprets biometric and behavioral data in real time, guiding users towards better health decisions through instant, tailored recommendations.

ONVY's platform - **an Al health coach** - transforms raw health data into instant, customized advice - empowering users to act when it matters most, according to **Adrian Kochsiek**, founder and CEO of ONVY. Read more

Become a partner of Munich Accelerator Life Sciences & Medicine - MAxL

Do you want to be part of the next generation of biotech success?

As part of the programming at the Munich Accelerator Life Science and Medicine – MAXL we are looking to expand our partner portfolio.



Would you like to support our start-up teams with your unique services and expertise? There are several packages available to suit potential partners – do not hesitate to reach out!

Contact the us to learn more about becoming a MAxL partner.







Bio^M Biotech Cluster Development GmbH

Regina Abendroth
Program & Community Manager
E-Mail Abendroth@bio-m.org

MAXL – MUNICH ACCELERATOR LIFE SCIENCES & MEDICINE

Perfect conditions for successful start-ups



Events



BioVaria 2025

28 - 29 April 2025 I Munich, Germany

LSX World Congress 2025

29 - 30 April 2025 I London, Great Britain

Swiss Biotech Day 2025

5 - 6 May 2025 I Basel, Switzerland

BIO International Convention

16 - 19 June 2025 I Boston, USA

BayOConnect Forum for Biotech & LifeScience

1 - 2 July 2025 I Munich, Germany





Nordic Life Science Days

13 - 14 October 2025 I Gothenburg, Sweden

Please find current event information on our website www.bio-m.org/en/events

Contact

Bio^M Biotech Cluster Development GmbH Am Klopferspitz 19a 82152 Martinsried, Munich, Germany

Follow us on: in







www.bio-m.org

+49 (0) 89 89 96 790

info@bio-m.org

Editorial staff



Gabriele Klingner klingner@bio-m.org



Dr. Christina Grimm grimm@bio-m.org

International Affairs



Ariane Doischer. doischer@bio-m.org

Founders & Investors, MAxL



Dr. Petra Burgstaller, burgstaller@bio-m.org



Christina Enke-Stolle enke-stolle@bio-m.org