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Interview

How companies will benefit from the first fund for circular bio-economy – ECBF head Michael Brandkamp explains.



FREE EXCERPT

THE VOID

COVID-19 Therapeutics

The Green Deal

How biotechnology can change industry in the post-COVID age

Diagnostics

Building a common European framework for antigen tests

Antibodies & Jobs

Industry pipelines full with candidates to ease pandemics

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Urgent need for medical data network across borders



JAANUS PIKANI has been surgical practitioner in head and neck oncology, hospital manager, secretary general of the Ministry of Social Affairs of Estonia and chief of staff of the President of Estonia. He was among the initiators of the Estonian Genome Project, a population-based health and genome databank representing as of now app. 20% of the adult population of the country. Currently, he is active as an entrepreneur and healthcare consultant for the World Bank and WHO. Dr Pikani is the chairman of life and health science meta-cluster organisation ScanBalt and board member in Tartu Biotechnology Park.

The COVID-19 pandemic is putting our health systems in Europe to the test. Capacity bottlenecks are becoming apparent, as are long-neglected investments in modern infrastructure. As the pandemic does not stop at national borders, cross-border healthcare solutions are more urgent than ever. Healthcare is a crucial point of European unification policy, but it is precisely here that the nation states have retained their autonomy - which is now taking a bitter revenge.

If Europe is to become once again a continent of freedom of movement and prosperity, we urgently need a common digital infrastructure to solve the mammoth tasks ahead. The current and future pandemics can only be solved with joint European research efforts, coordinated cross-border health care and modern digital tools such as interoperable tracing apps.

Even though a common European health data space is still in the future, the annual conference of the health clusters organised in the ScanBalt network has identified a number of promising local and regional digital health solutions for the current crisis. Three examples illustrate the diversity of solutions:

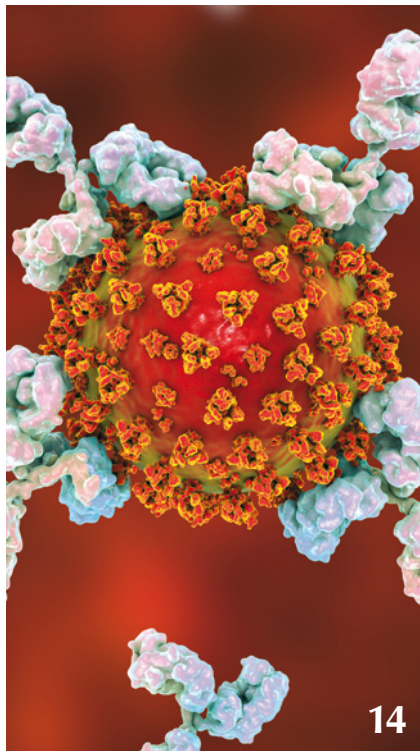
- *The training and organisation of the staff of the COVID-19 emergency hospital in Hanover were carried out using digital tools from a private Norwegian company.*
- *The “Supercomputing Project” of the University Hospital of Barcelona brings together the data of COVID-19 patients from private and public clinics for research purposes (and has identified considerable backlog demand for uniform data standards).*
- *In the Italian research region of Milan – which was particularly hard hit by the first wave of coronavirus – the existing biobank cooperation between the university hospital, research institutions and private pharmaceutical companies was also used for basic COVID-19 research within a short time.*

With the jointly formulated ScanBalt Declaration, 30 cluster organisations from 15 European countries are demanding that these promising individual solutions finally receive a common legal framework to be applied throughout Europe. Industrial development must be involved as an important strategic partner from the very beginning. The public sector alone is not capable of taking the necessary innovation and investment steps.

Please sign up to this joint pan-European innovation initiative: <https://scanbalt.org/eu-health-data-space/support-the-declaration/>. The ScanBalt Declaration will be handed over to the German EU Council Presidency as the voice of civil society for a common European Data Space.

FREE EXCERPT

COVER STORY



A jab, but no Plan B

A licensed vaccine for COVID-19 could soon be a reality, but therapy options remain limited, while deaths in the ongoing pandemic continue to mount by the day. In early November, BioNTech SE and marketing partner Pfizer Inc. provided proof-of-concept that their mRNA vaccine candidate BNT162b2 could effectively prevent infection with SARS-CoV-2. Emergency personnel, however, remain desperate for new therapeutics to help limit the spread of the new coronavirus and treat patients who have a potentially deadly host immune response.

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GREEN MONEY

EU at a turning point

In October, ECBF Management GmbH announced the first closing of its European Circular Bioeconomy Fund. The European Investment Bank (EIB) has committed to contributing €100m to the fund's target of €250m. ECBF Head Michael Brandkamp explains how it will be a financial instrument for achieving Europe's Green Deal goals.



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CIRCULAR BIOECONOMY



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Greening the bloc

Surveys show that despite COVID-19, climate change and sustainability still matter to consumers – perhaps even more than ever before. The European Commission has proposed investing more than €250bn earmarked for its post-COVID-19 recovery programme into building a sustainable economy. Biotech companies stand to benefit significantly.

EDITORIAL

EU opportunity

BioNTech is the first European biotech company to show what EU companies can achieve compared to leading US competitors (see cover story, p. 14) – and that without any government aid or subsidies. The global enthusiasm over the proof-of-concept that a vaccine against the pandemic coronavirus could be effective has also had an impact on European and international financial markets.

That's particularly important for European biotech companies, which on average raise just 20% of the funding that US counterparts usually achieve in Series A financings – either because the regulatory environment is hostile, or because European investors tend to be more averse to risk.

EU Commission President Ursula von der Leyen gave the sector something of a tailwind with a lively speech on Europe's Green Deal, and has promised heavy investment in a sustainable bioeconomy (see p. 44). At least in speeches, she sees the biologisation of industry in Europe as an opportunity for the bloc's economy to make up lost ground in a post-COVID era.

Given the upsurge in innovation on the continent, let's hope the EU will open up to foreign investment and not get bogged down in protectionism. To promote European biotechnology, it's now essential to build on positive perceptions of biotech, and foster better conditions for investment in the field.



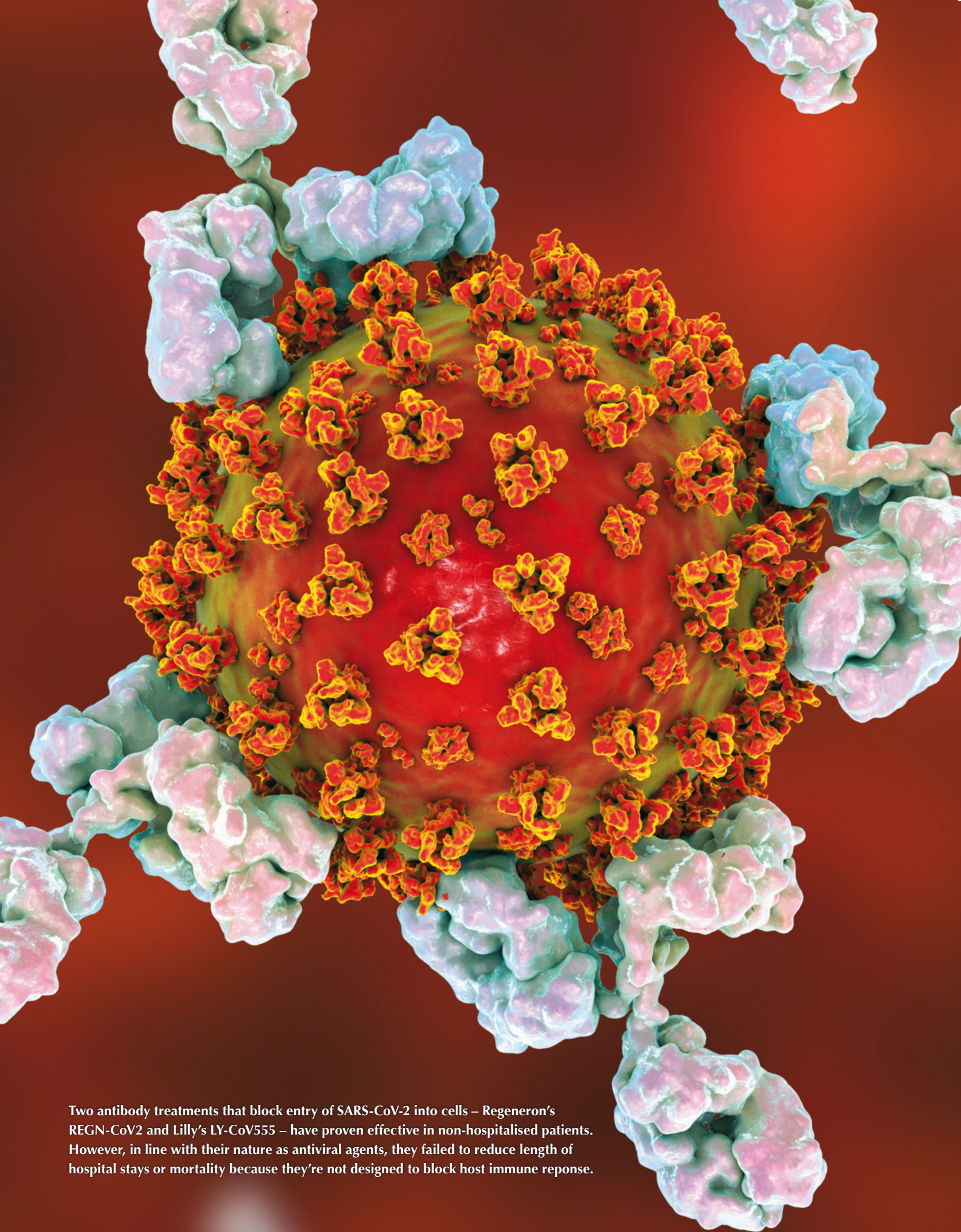
Thomas Gabrielczyk
Editor-in-Chief

SPECIAL

EU Event Compass

- 51 We very much hope that with the availability of COVID-19 vaccines and therapeutics, we'll be able to return to in-person events soon, and continue to offer the EU Event Compass in its usual scope!
- 52 Renewable Materials Conference, Cologne, Germany, hybrid event
- 54 euroPLX-75, Cascais, Portugal, hybrid event
- 56 Bio-Europe Spring, fully digital





Two antibody treatments that block entry of SARS-CoV-2 into cells – Regeneron’s REGN-CoV2 and Lilly’s LY-CoV555 – have proven effective in non-hospitalised patients. However, in line with their nature as antiviral agents, they failed to reduce length of hospital stays or mortality because they’re not designed to block host immune response.

Still no treatments

COVID-19 Even though a licensed vaccine for COVID-19 is nearing reality, therapy options remain limited, so that deaths in the ongoing pandemic are continuing to mount by the day. In early November, BioNTech/ Pfizer provided proof-of-concept that their mRNA vaccine candidate BNT162b2 could effectively prevent infection with SARS-CoV-2. Emergency personnel, however, are also calling for new therapeutics to help limit the spread of the coronavirus and dampen the potentially deadly host immune response.

In early November, what we've all been waiting for finally appeared to happen. "The first interim analysis of our global Phase III study provides evidence that a vaccine may effectively prevent COVID-19," said Ugur Sahin, co-founder and CEO of German BioNTech, which is nearing study completion of its mRNA vaccine candidate BNT162b2. "This is a victory for innovation, science and a global collaborative effort," commented Sahin. "While we are all in the midst of a second wave and many of us in lockdown, we appreciate even more how important this milestone is on our path towards ending this pandemic and for all of us to regain a sense of normality".

What exactly has been accomplished, and what does the announcement mean? The results of an interim analysis by an independent Data Monitoring Committee (DMC) demonstrated that BioNTech/ Pfizer's mRNA-based jab was more than 90% effective at preventing COVID-19 in healthy volunteers. The result is based on unblinded data determining the case ratio between volunteers who received the placebo and vaccinated individuals. No data were published on antibody titres or T-cell-dependent immunity. However, experts have previously suggested the experimental mRNA jab may give protection for about a year. Data from other vaccine trials will show to what extent antibody titres or T-cell titres determine prevention of infection with the new coronavirus.

The DMC conducted the first interim analysis after 94 confirmed cases of COVID-19 had occurred in the study population more than seven days af-

ter the second of two vaccinations with BNT162b2. That's more than half of the 164 cases required for completion of the study. Following a safety analysis scheduled for the third week in November, the



Philippe Pouletty, Ph.D.
CEO Abivax SA,
Founder Truffle Capital, Paris

? Is COVID-19 therapy development adequately supported at an EU level?

! On April 22, the EU's COVID-19 scientific committee published guidelines. The EIB called for submissions to its €5bn program, and hired 50 experts for fast review to support 100 COVID-19 projects. But none of this 'dream' happened. Countries worked on their own. There was a small EIB programme with slow review. Meanwhile the US had clear guidelines, billions in grants, and one reviewing agency – the FDA. Another missed opportunity for Europe's leadership! If not for the second, let's get ready for the third wave!

company will apply for an FDA Emergency Use Authorisation (EUA) while long-term safety and efficacy will be investigated for a total of two years.

The companies, which did not receive any state funding for the development of BNT162b2, said they didn't observe any serious adverse events among the 43,538 enrolled participants. As the trial continues, the final determined vaccine efficacy percentage may vary. However, for the moment, the efficacy is significantly above the minimum 60% efficacy set by the FDA. For unknown reasons, the EMA decided not to set a minimum efficacy level. According to Cowen Inc, BNT162b2 is among the higher-price vaccines (\$19.50/dose). Experts, however, stress that there is still high unmet medical need for those who are already infected, or who will be in the coming months and perhaps years.

No time to relax

In the intensive care unit at Munich Schwabing Clinic, the medicine cabinet is empty – at least of drugs that could help COVID-19 patients. "Apart from dexamethasone, we're empty-handed," says Head of Infectiology at the clinic Clemens Wendtner. "The resources we have are not sufficient to save patients in the late stages of the disease. We have to watch them die because the standard of care is far from adequate. And this despite the fact that there are so many promising [...]"

» Read the full story in the printed issue.

GREEN DEAL



Investors and politicians are increasingly focusing on sustainable biotechnology. Rising demand for products like cultured meat could be accompanied by major EU investments in the biotech sector.

The post-pandemic biotech opportunity

GREEN DEAL Surveys show that despite COVID-19, climate change and sustainability still matter to consumers – perhaps even more than ever before. The European Commission has proposed investing more than a third of the €750bn earmarked for its ‘NextGenerationEU’ post-COVID-19 recovery programme into building a sustainable economy. Along with the well-established ‘red’ biotech sector in healthcare, green biotech companies also stand to benefit significantly.

There’s been a lot written recently about how the pandemic, while sounding the death knell in many industries, is driving biotech to new heights. This is especially true for developers of vaccines and therapeutics, of course, but less is said about the opportunities also opening up for young companies in other areas, particularly those involved in the food industry and the circular economy. In the shadow of economic decline during the pandemic, policymakers are mobilising billions to support the bioeconomy and biotechs in a range of fields across Europe in a post-pandemic world.

Back in 2019, the European Commission (EC) headed by President Ursula von der Leyen declared climate protection and sustainability to be among the EU’s core concerns, and with the Green Deal presented in December, the EU is meant to become a role model for the world. The Commission formulated ambitious goals, among others to make the EU climate-neutral by 2050. According to EC estimates, this will require around a trillion euros in investment over the next decade. The money is to come from the EU, its member states and private companies. The EC President chose big words for the policy, saying the Green Deal aims to become Europe’s “man on the moon moment”.

The COVID-19 pandemic is now being billed as a trigger for the EC to push

forward Green Deal plans for billions in green investments. In her September State of the Union address, von der Leyen first tightened up the climate target. By 2030, the bloc now wants to reduce greenhouse gas emissions by up to 55% instead of 40%. She also announced a huge reconstruction plan to mitigate the economic consequences of the pandemic that will provide €750bn for the NextGenerationEU programme. And 37% of that, or around €278bn, is to go towards financing the Green Deal. The Commission also wants to raise 30% of the money for NextGenerationEU with the help of green bonds. Plans envision €14.6bn from the programme flowing into the Horizon Europe research programme, which would have a total budget of €91.1bn. The European Council originally proposed just €5.4bn and €85.5bn respectively. The final decision was to be taken after we go to press in mid-November.

The European Green Deal is much more than just a programme to reduce emissions.

However, the Green Deal is not only intended to be an environmental or climate protection programme. In her speech, von der Leyen said: “The European

Green Deal is much more than just a programme to reduce emissions. It is about the systematic modernisation of our entire economy, society and industry. It is about creating a better, stronger world.” The Commission has defined nine policy areas for the Green Deal: climate action to achieve climate targets, measures to protect ecosystems (biodiversity), clean energy, an environmentally friendly construction sector (buildings and renovation), the promotion of environmentally friendly means of transport, combating pollution, sustainable production cycles in industry, a sustainable food chain (‘from farm to fork’) and sustainable agriculture. The biotech sector is well placed to drive most of the fundamental transformations from the current system. The opportunities are huge.

But how will the funding be distributed to and among biotech companies? One instrument that the EU wants to employ to make its economy more sustainable is the European Circular Bioeconomy Fund (ECBF) – the first venture fund focusing on bioeconomy and circular bioeconomy in Europe. It kicked off operations in October with a financing round for a Dutch and a German start-up. To date, the ECBF has raised €82m, with the main investor the European Investment [...]

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Save the date!

SWISS BIOTECH DAY

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20 April 2021
Congress Center Basel

The Swiss Biotech Day has become the leading biotechnology conference in Europe and is a fixed date in the community's calendar. While the event could not take place this year due to the worldwide COVID-19 pandemic, we plan to bring the Swiss Biotech Day back on stage on 20 April 2021.

What you can expect:

- › Meet senior experts from the life science industry from across Europe
- › Exhibition throughout the day
- › Delegations from various countries
- › Presentation of the Swiss Biotech Report
- › Swiss Biotech Success Stories Awards
- › Innovative biotech start-ups and medium-sized biotech companies
- › Thematically focused panel discussions
- › Pre-scheduled one-to-one partnering meetings

Should it not be possible to hold the event by this date due to the further development of the pandemic, we are planning to postpone it until autumn 2021.

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