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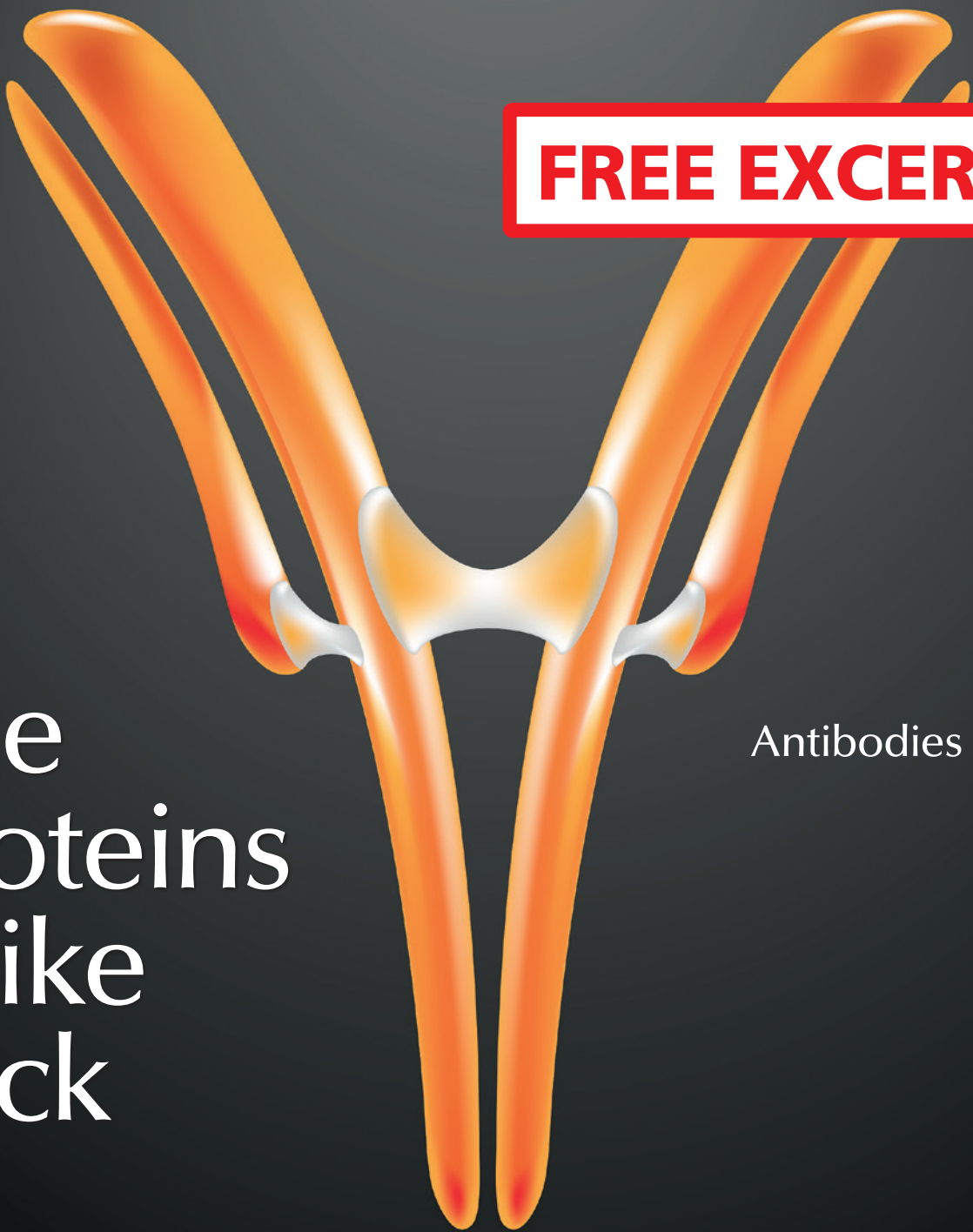
Interview

Thomas Lingelbach, CEO of French Valneva SE, on the vaccine maker's latest approval and his strategy.



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The proteins strike back

Antibodies & more

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NÜRNBERG MESSE

The golden age of engineered therapeutic antibodies

Therapeutic antibodies today represent a cornerstone of the treatment of various diseases including cancer, infectious, autoimmune, cardiovascular, haematological, metabolic, neurologic and ocular diseases, and make up a major proportion of blockbuster drugs with global sales of more than US$230bn in 2023.

Since the first approval of monoclonal antibodies more than 25 years ago, the field has seen the emergence of engineered antibodies, e.g. Fc-engineered antibodies, antibody drug conjugates (ADCs) and bispecific antibodies (bsAbs). Notably, as of today, 13 ADCs and 17 bsAbs have been approved by health authorities and already account for more than US$10bn and US$8bn in global sales, respectively.

DR CHRISTIAN KLEIN, CXO in residence and drug hunter at the early-stage VC specialist Curie.Bio, has 22 years of industry experience in the field of therapeutic antibodies, co-authored 220 publications and is co-inventor of 240 patent families. The biochemist joined Roche pRED in 2002 and co-led teams pioneering the development of CrossMabs, 2+1 TCBs, 4-1BB/CD28 costimulators and PD1-cis immunocytokines. He contributed to 32 clinical NMEs for Roche of which four are approved and to numerous collaborations with biotech companies.

It is important to note that bsAbs are increasingly being applied for the treatment of diseases beyond oncology. Based on the recent therapeutic progress, ADCs and bsAbs represent the fastest growing class of therapeutic antibodies in (pre-)clinical development and have been a major driver of deal-making in the biopharmaceutical industry in the past years. Interestingly, the first bispecific antibodies approved, catumxomab and blinatumomab, were originally developed by academic start-ups in Munich, Germany.

ADCs and bsAbs continue to be an attractive area of research for innovative biotech companies due to the availability of technologies allowing a comparably rapid identification and optimisation of development candidates, the progress made with the manufacturing of complex molecules, and the generally favourable clinical development success rates for therapeutic antibodies.

BsAbs are particularly attractive from a conceptual point of view, as they allow the mediation of completely novel mechanisms of action for the therapy of various diseases that cannot be achieved with conventional monospecific antibodies. This includes, for example, the recruitment and engagement of immune cell subsets for tumour cell killing, e.g., with T-cell engagers, mimicking of blood coagulation factors, dual-targeted bispecific ADCs with selectivity for defined cancer types, cis-targeting of T-cell subsets with dual checkpoint inhibitors or cytokines, degradation of cell surface proteins, transport of antibodies across the blood-brain-barrier, triggering of cytokine receptors with cytokine mimetics or activation mechanisms that can switch bsAbs on/off in the tumour microenvironment to prevent undesired peripheral toxicities, and many more.

It is amazing to see how researchers after 50 years of antibody engineering continue to come up with novel and ingenious solutions to tackle therapeutic challenges and to observe how novel methods like single-cell sequencing, proteomics, cryo-EM, machine learning and artificial intelligence help to further accelerate therapeutic innovation. Given all this progress and the diversity of ideas pursued in biotech companies and biopharmaceutical industry, I firmly believe that the golden age of engineered antibodies and their use for synthetic biology is only about to start. Their potential is beyond our imagination. ■

Picture: © Curie.Bio

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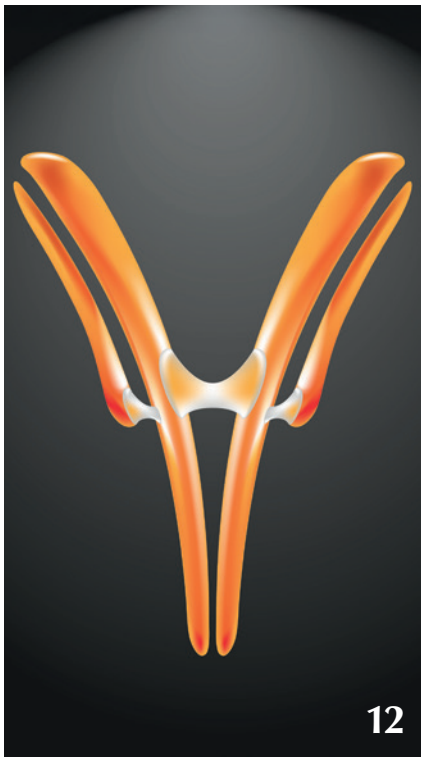
COVER STORY



A Golden Age for protein engineering

Monoclonal antibodies laid the foundation for precision medicine, and still dominate the US$417bn biologics market. However, after decades of development, new treatments are now hitting the market. Among them: improved versions of artificial bispecific antibodies, antibody-drug conjugates and other engineered proteins used in immunoreceptor-based therapies such as CAR-T and TCR-T cell therapies. We took a deep dive into what bioengineers were talking about at the most recent iteration of the PEGS Europe summit.

INSIGHT EUROPE

ECONOMY

REGIONAL NEWS

SCIENCE & TECHNOLOGY

PICK & MIX

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CLIMATE CHANGE

Stress test for Council

Germany, Denmark and 19 supporting states have called on the EU Commission to adopt a protein strategy that prominently includes cultured protein for food and feed, but Hungary is likely to contest the idea. It holds the EU Council presidency and leads a blocking minority calling for rules on banning and approving laboratory foods similar to those in place for medicines.


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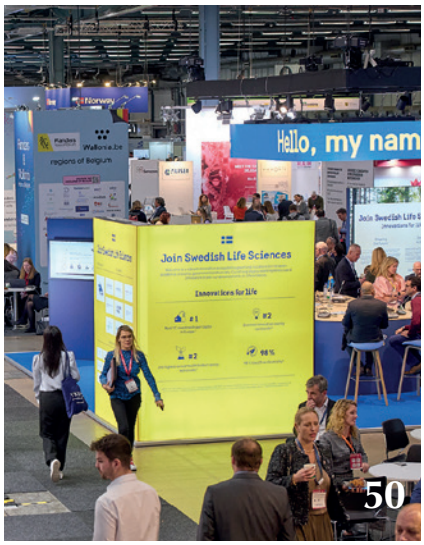
BIO-EUROPE



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Spotlight Scandinavia

In the latest BIO-Europe in Stockholm, representatives from Sweden, Denmark, Norway and Lithuania grabbed the chance to step out of the shadows. The positive messaging came through loud and clear, along with a load of impressive data about the power of the region's innovation motor.

SPECIAL

Biofairs Compass

Pictures: Freepik - Consilium (left above); Informa/EBD Group (middle); BIOCOM AG (right)

EDITORIAL

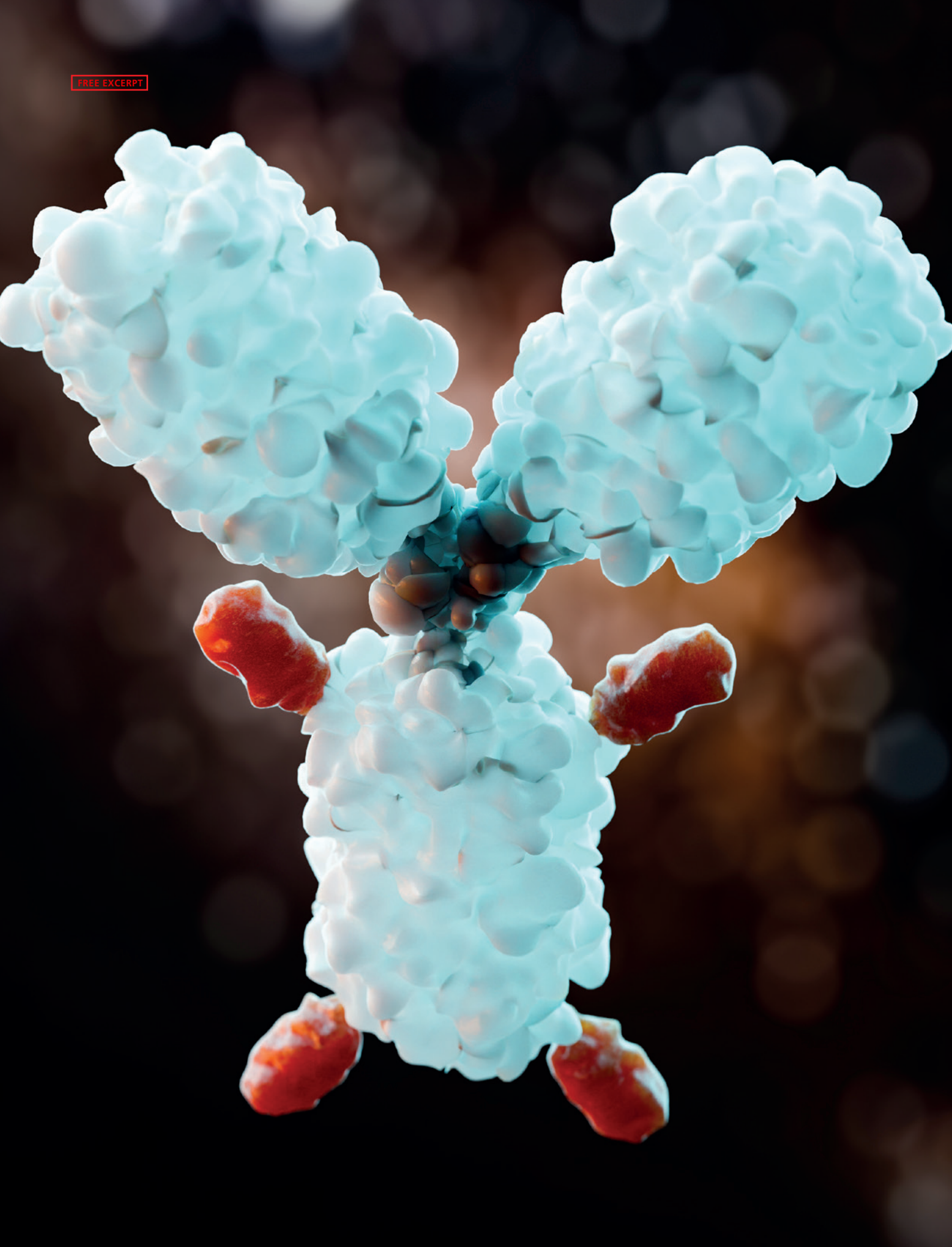
No will to zero

The fight against climate change and species extinction is a popular topic among politicians. It is becoming increasingly difficult to deny the consequences of global inaction, and looking the other way no longer helps. A lot of money was promised in Montreal back in 2022. At the UN COP15 Biodiversity Conference, negotiators agreed to set up a provisional fund to help heal environmental damage by protecting 30% of land and marine areas and pushing back invasive species. To date, only 2% of the promised cash has been raised. At the follow-up conference in Cali (COP16), further negotiations on the US$200bn biodiversity fund by 2030 agreed in Montreal failed.

At the same time, climate diplomats at COP29 in Baku argued about the financing of climate protection funds (p. 8). Estimates say around US$2,400bn is needed per year to limit global warming to 2°C by 2100. The countries of the Global South, which are responsible for just 5% of greenhouse gas emissions (CHG), called for US$1,300bn. But wealthy nations only countered with an offer of US$300bn. Since the Paris Agreement, CHG emissions have risen by 9% instead of falling by 67.5% as agreed.

Collective action – like that sometimes seen during the pandemic – is critical. Now that the potential of biotechnology in medicine has grown clear, the biologisation of industry is next. It's the only way for us all to win in the end.

Thomas Gabrielczyk
Editor-in-Chief



FREE EXCERPT

New proteins on the block

PEGS EUROPE 2024 Monoclonal antibodies still dominate the US$417bn biologics market. After decades of development, however, improved antibodies and protein formats with better target selectivity and safety profiles are now hitting markets and pipelines. A range of bispecific antibodies and antibody-drug conjugates – along with CAR-Ts, TCR-RTs and NK cell-based immunoreceptor constructs – were in focus at the PEGS Europe Summit.

Since the first antibody drug (muromonab-CD3) was approved back in 1986, monoclonal antibodies (mAbs) have emerged as the dominant class in the global US$417bn market for biologics. At the end of 2023, sales stood at more than US$230bn. However, as tumours – in addition to autoimmune diseases still one the most important application fields of mAbs – are moving targets, newly engineered antibody and engineered protein formats that unite complementary cell-killing mechanisms in a single molecule have been developed, approved and are increasingly leaving clinical pipelines for the market. They include refined bispecific antibodies, antibody drug conjugates (ADCs) and targeted radiopharmaceuticals, as well as immune-receptor-based cell therapies such as CAR-T and TCR-T cell therapies.

Every year at the PEGS Europe Summit, the CSOs of bio/pharma companies provide a detailed overview of newly developed therapeutic modalities, and thus an outlook for the future. This year in Barcelona, the 16th summit helped clarify why the approval of bispecific antibody formats has increased dramatically (13 out of 18 approvals in the past three years) and why improved ADCs, CAR-Ts, TCR-Ts and new modalities are entering the market. The freshly engineered formats promise to reduce current problems of bispecific antibody and T-cell therapies such as cytokine release syndrome (CRS), neurotoxicity, and on-target/off-tumour toxicity. In addition, targeting two targets simultaneously increases selectivity, and allows drug developers to combine complementary cancer-killing mechanisms that could reduce resistance to cancer therapies and improve efficacy.

YEMI ONAKUNLE Founding Director and CEO, Mabswitch Inc., Cambridge, USA

? How can toxicities and T-cell exhaustion that occur in all T-cell-based therapies be avoided?

! *Mabswitch's remote-controlled antibodies offer a novel approach to enhance the efficacy of antibody-redirected therapies – such as CAR-T cells, T-cell engagers, and ADCs – for treating devastating diseases like cancer, autoimmune disorders and chronic infectious diseases, all while minimising side effects.*

"Based on recent therapeutic progress, ADCs and bispecific antibodies (bsAbs) represent the fastest-growing class of therapeutic antibodies in development and have been a major driver of dealmaking in the biopharmaceutical industry in the past years," emphasised Dr Christian Klein at the PEGS summit, which took place from 5-7 November. The patent champion (240!) in protein engineering, who moved to early-stage investor Curie.Bio in the summer after 22 years at Roche pRED (see p. 3, p. 38) started with a brief summary of the 14 bispecifics (and 17 – still monospecific – ADCs on the market) approved until December 2023. But he quickly turned to what's new, interesting and probably a business case. And there is a lot of ground to cover, as around 50% of bispecific antibodies are already in late phase testing (Phase II or III, see Fig. 1, p. 14).

New age for bispecifics

According to Klein, T-cell engagers (TCEs), together with cancer immunotherapies, now account for almost 80% of the bispecific antibodies clinically developed to

›› **Read the full story in the printed issue.**

Things got busy around the cubicles for partnering at BIO-Europe 24.

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Scandinavia's gangbuster biotech

BIO-EUROPE It was the 30th anniversary for the largest pharmaceutical sector partnering event on the European continent, and this year's programme saw a colourful mix of veterans, first-timers and absolute newcomers. The Nordic countries and host Sweden in particular made quite a splash.

What began three decades ago as the mother of all partnering events has turned both participants and organisers into professionals and veterans. BIO-Europe is all about the repetition of participation and routine reunions for relationships that may have been established years ago. It's about the friendly handshake hinting that unfortunately you have to leave immediately for the next meeting, or really lingering over small talk. Maybe followed by a lunch appointment at a less draughty location in the exhibition hall in Stockholm or elsewhere in the city, because there are so many interesting topics to discuss. Those and many other ways of approaching people in the industry are all part of the job.

MC Services – a communications agency and long-time partner in crime with the organisers – collected examples of necessary, cultivated small talk into a little booklet called "The Stockholm Pocket Phrase Book", with the standard introductory chit-chat in Swedish. It also revealed that about five questions are sufficient to sail through the event without peril. The first should be:

What's new in your drug pipeline?

Veteran observer Mike Ward, a true trendsetter who was himself celebrating 40 years in the communications industry, echoed the 'Groundhog Day' feeling that the event at times inspires: a kind of 'been there, done that, got the t-shirt' attitude. Like Donald Trump's re-election after four years out of office, which dominated discussions on the second day of the fair, but also the industry's ritualised annual meeting to find partners in general. Repetition is a constant companion at BioEurope, and no one is particularly bothered by it, regardless of where the event's entourage sets up camp. This time it took place in Stockholm, outside the German-speaking core of Europe. The choice was a nod to Nordic dynamism, which has given the world league of large pharmaceutical players a new North Star with Copenhagen-based pharma heavyweight Novo Nordisk.

Sweden and Denmark can also be mentioned in one breath and considered together, as industry savants in Copenhagen refer to the Øresund region as Medicon Valley, which includes nearby Lund (Sweden) across a watery border. While the Danes make waves around the world and have a giant pharmaceutical tanker at anchor with Novo, Sweden likes to present more as a hotbed of innovation benefiting both neighbouring countries and Europe as a whole. Both regularly top the innovation and patent league tables in the life sciences, especially in relation to their populations. But even without that kind of caveat, Sweden is second only to Switzerland in global innovation rankings. In early October and then again at their presentation in December, the country radiates scientific excellence with the Nobel Prizes, still viewed as the top global award for the international research elite.

Considered a partnership?

At this year's showcase event, Sweden didn't just want to bask in the glow of other successes, it also wanted to highlight its own strengths. With around 4,000 life sciences companies in a country of around 10.5 million, there is plenty to brag about. By comparison, Austria – which has a similar population – is home to just over 1,000 life sciences companies (biotech, pharma and medtech).

In Sweden, medical technology is the largest sector within the life sciences in terms of number of companies, while lab technology and diagnostics are the smallest sectors. Swedish companies though are often active in several different industries. For example, there is a large overlap between laboratory equipment and diagnostics and medical technology. The Swedish innovation agency Vinnova tried to illustrate these overlaps in a very unique 3D graphic.

In 2022, the Swedish life sciences sec-

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