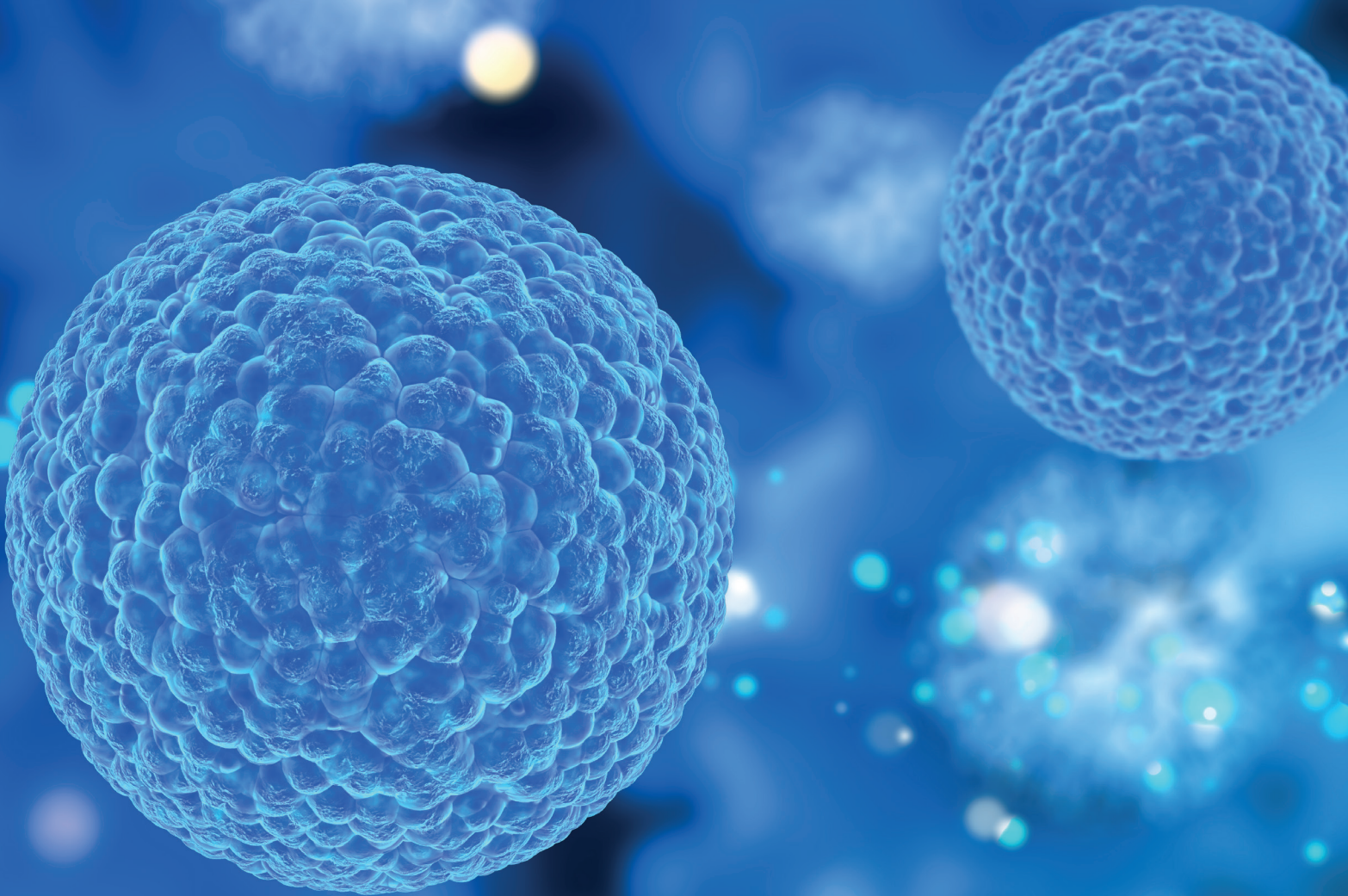


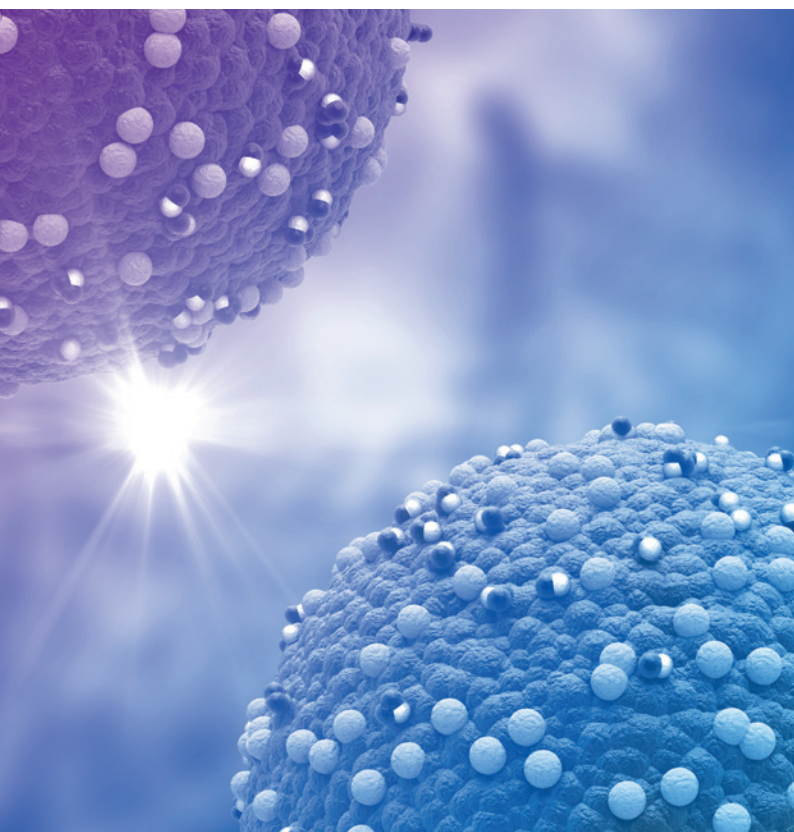
European Biotechnology

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Autoimmune & inflammatory diseases

SPECIAL



Europe takes cancer science into immunology

TECH TRANSFER Inspired by technology and insights gleaned from cancer research, Europe is leading the quest for a new generation of therapies in immunology and inflammation. Immunotherapy has revolutionised cancer therapy and become standard of care in many areas of oncology but it has also begun to change outcomes in inflammatory and autoimmune diseases.

Getting cancer immunotherapies approved and marketed took vast amounts of clinical trial research, which led to advancements in our knowledge of the immune system, how it works and how to manage it. Over the past few years, landmark research from European scientists has shown that CAR-T therapy – an immunotherapy first developed and approved in oncology – can induce remission in some patients with severe lupus.

The idea behind the research came from scientists such as Georg Schett and professor Ricardo Grieshaber-Bouyer, from the Uniklinikum Erlangen at Friedrich-Alexander-Universität Erlangen-Nürnberg. Scientists at University College London Hospital (UCLH) led by Claire Roddie and Maria Leandro have also been trialling the technology in humans to treat lupus.

The idea hinges around the way that CAR-T cells can be re-programmed to attack the B-cells that are the root cause of lupus, where the immune system begins to attack the patient's own body. Symptoms of the disease include joint pain, skin conditions and damage to organs such as the kidneys. Harvested from a patient's own body, genetically modified, expanded and then reintroduced through infusion, the CAR-T cells reset the immune system by destroying all B cells in the body, both healthy and disease-causing. Once the treatment is over, the healthy B cells grow back, and the patient's immune system is reset, without the symptoms of lupus.

The drawbacks: the therapy is expensive and takes a long time to make as it is tailored to each individual patient. Side

effects in the Phase 1 CARLYSLE trial at UCLH were more manageable, however. Researchers observed no cases of immune effector cell-associated neurotoxicity syndrome (ICANS), a serious neurological side effect associated with some CAR-T cell therapies. Cytokine release syndrome (CRS), another common side effect of CAR-T therapy where the immune system becomes overstimulated, was limited to only low levels.

As of November 2025, nine adults with severe, treatment-resistant lupus had received the treatment, obecabtagene autoleucel, developed by London-based Autolus. All had highly active disease despite multiple previous therapies, and most had lupus nephritis, a serious form of the disease that affects the kidneys. Researchers found that five of the first six patients treated at the lower dose achieved remission according to standard lupus criteria, with improvements emerging within months of treatment. Patients also experienced rapid reductions in disease activity. For patients whose kidneys had been affected by the disease, several achieved complete or partial renal responses, with reductions in proteinuria and stabilization or improvement in kidney function over time.

It's just one example of how expertise in cancer has begun to inform the treatment of autoimmune diseases such as rheumatoid arthritis, psoriasis, Crohn's disease and ulcerative colitis. Iain Kilty, CEO of UK-based biotech Sitryx, described results from CAR-T therapy in lupus as "phenomenal." "We are

seeing sustained remission as it kills the cells that are driving the disease,” he added.

However, Kilty noted that the same drawbacks that applied to CAR-T in cancer apply in immunology. While early autoimmune studies have suggested that some familiar CAR-T toxicities may be manageable, safety remains a major question, alongside a manufacturing process that is still cost- and labor-intensive. That question gained new urgency in August, when Novartis paused eight studies of its CD19 CAR-T rapcabtagene autoleucel in autoimmune and neurological diseases after three patients died from immune effector cell-associated hemophagocytic syndrome (IEC-HS), a severe inflammatory complication. The company is reviewing the cases with regulators and independent safety boards.

Pawel Szczepanski, CEO of Poland’s JJP Biologics, added: “Looking at a purely scientific perspective, the boundary from oncology and autoimmunology is increasingly porous. In cancer, immune response may be insufficient, exhausted and depressed. In autoimmune disease, responses may be persistent and misdirected toward healthy tissue. This creates a degree of target or platform symmetry – a pathway strengthened in oncology may be inhibited in immune disease.”

Technology and platforms can be transferred from oncology to autoimmune diseases, along with the knowledge and technical know-how required to discover, manufacture drugs and bring them to market. Szczepanski added: “Expertise in antibody, T-cell therapy, biomarkers and immune monitoring can be transferred. Oncology tech cannot be transferred unchanged, but the synergies exist there. I would dare to say the synergies between target platforms and portfolios are quite evident. We see examples of going from oncology into inflammation and immunology and there is also a portfolio rationale. It creates opportunities to reuse platforms in multi-indication markets.”

A growing demand

Driving the research is the demand for new drugs in autoimmune diseases and inflammation. The first generation of blockbuster autoimmune disease drugs, such as AbbVie’s Humira (adalimumab), is encountering biosimilar competition; and while they redefined treatment of many diseases, they were not perfect. They superseded medicines such as methotrexate, which are effective but come with a long list of side effects. Even with biologic therapies, remission only occurred in a fraction of patients depending on the disease area, with considerable unmet need.

Between 10% and 30% of patients fail to respond to treatment with anti-TNFs such as Humira, Kilty noted, adding that patients are also looking for convenience with either less frequent injections or medicines administered in pill form.

Inflammation and immunology continue to tick the right boxes for big pharma investment in research, according to JJP Bio’s Szczepanski. He said: “Immunology as an area has a few



Treatment convenience is a growing priority in immunology

characteristics that large pharma tend to appreciate, the substantial disease burden, treatment demand, specialist care infrastructure and the possibility to apply one mechanism across multiple indications. Those are the characteristics that make it attractive to big pharma.”

JJP Biologics is part of a biotech ecosystem that is becoming established in Poland. The company’s most advanced clinical asset is nebaprubart, a CD89 inhibitor that is in Phase 1b development in autoimmune diseases. Research has been slowed in this receptor because it is not expressed in mice, meaning that the drug had to be proven in several different preclinical models before it was cleared for human trials. The company’s focus is not only on IgA-driven renal conditions but also on the “big four” inflammation areas: rheumatoid arthritis, inflammatory bowel disease, psoriasis and systemic lupus. Szczepanski said: “We clearly see that despite the general perception that those are crowded markets, the deeper you look, the more you challenge that perception.”

Kilty’s work at Sitryx was informed by research originally done by professor Luke O’Neill of Trinity College, Dublin, which suggested PKM2 serves as a critical metabolic switch not only in cancer, but also in chronic inflammation. In the case of diseases such as atopic dermatitis, Sitryx aims to modulate the pathway to normalize the activity of the immune system. The company’s lead drug SYX-5219 is heading for Phase 2 in atopic dermatitis, with an itaconate mimetic SYX-1042 also ready for Phase 2 in psoriasis and psoriatic arthritis.

Both Kilty and Szczepanski agree that there is a promising decade for European research into inflammatory and autoimmune diseases, driven by demand for new products and a supply of R&D know-how in academic institutions and the biotech sector. Kilty concluded: “It’s important to focus on those areas where we are differentiated. There’s lots of competition in America and China, and the speed at which they can develop drugs. We have that expertise in Europe, we have people who have progressed assets from idea to approval.”

Richard Staines

“We want to understand MS patients better than anyone”

MULTIPLE SCLEROSIS Immunic is preparing to transition from a late-stage development biotechnology company into a fully integrated commercial organization focused on multiple sclerosis (MS). At the center of its strategy is vidofludimus calcium, an oral therapy being developed for relapsing and progressive MS. EUROPEAN BIOTECH spoke with Immunic’s CEO Erik Lundgren about the company’s clinical trials and commercial ambitions, the role of neuroprotection and why he believes the next major opportunity in MS may lie beyond relapse control.

EuroBiotech: Mr. Lundgren, this year marks Immunic’s 10th anniversary, coinciding with what could be a decisive period in the company’s history. How would you describe Immunic’s position today?

Erik Lundgren: *This is a particularly exciting time for Immunic. As we celebrate our 10th anniversary this year, we are entering what could be one of the most transformative phases in the company’s history. Over the past decade, we have built a differentiated pipeline focused on chronic inflammatory and autoimmune diseases such as MS, and generated data that reinforces our confidence in our scientific approach. Today, we are not only advancing our late-stage clinical asset vidofludimus calcium in MS, but are also preparing to become a fully integrated commercial organization. In addition to research and clinical development, we have started thinking beyond and positioning the company for long-term success. Importantly, we have assembled a highly talented and experienced team and believe that our focused strategy, combined with disciplined execution, puts us in a strong position for the months and years ahead.*

EB: You came to Immunic at a pivotal time in its development. What persuaded you to join the company?

Lundgren: *I have spent much of my career in MS, so I have always been fascinated by the science behind the disease. Over the years, we have seen our under-*



ERIK LUNDGREN Chief Executive Officer, Immunic Inc., has more than two decades of biopharmaceutical leadership experience, with deep expertise in commercialization, commercial strategy and BD. Before Immunic, he led the commercial portfolio organization at Genentech.

standing of MS evolve significantly. First, T cells were the primary focus, then B cells and their antibody repertoire became central to how we think about the disease. I was fortunate to be part of some of those shifts at companies like Genentech and Roche, which initially were not regarded as major players in MS but ultimately helped reshape the treatment landscape.

What attracted me to Immunic is its unique scientific approach and the oppor-

tunity to address one of the field’s most significant unmet needs: the progression of disability and the neurodegenerative component of MS. When I joined the company, I saw, and continue to see, tremendous potential in the science, the lead program, and the highly talented team striving to bring this vision forward.

A truly outstanding factor is the global, multinational team. At Immunic, we have more than 20 different nationalities among roughly 100 people. That is remarkable for a company of this size and supporting our growth phase.

EB: From your years of experience in the MS field, what differentiates Immunic’s approach from previous waves of innovation?

Lundgren: *Having witnessed several waves of innovation in MS throughout my career, what excites me about Immunic is that we are focused on some of the most important unresolved challenges in the disease: progression, safety and tolerability, and patient choice.*

One of the reasons I joined Immunic was the insight I gained through many conversations with MS physicians and experts. While tremendous progress has been made in treating MS, significant unmet needs remain, creating opportunities for the next generation of therapies.

The first relates to disease progression. For many years, reducing relapses and controlling inflammation were the primary goals of treatment. Today’s reality is different. Many patients experience few



Erik Lundgren in discussion with ...

or no relapses, yet they continue to accumulate disability over time. This progression independent of relapse activity, or PIRA, remains one of the most important challenges in MS.

The second unmet need is long-term safety and tolerability. Currently approved therapies have transformed MS patient care, but prolonged treatment can be associated with serious side effects such as infections, gastrointestinal or cardiovascular risks. As a result, therapies with favorable, well-tolerated safety profiles continue to be highly relevant.

The third unmet need is patient choice. In the U.S. alone, approximately 125,000 people diagnosed with relapsing MS remain untreated, while around 45,000 patients switch therapies each year. The reasons vary, ranging from access and reimbursement challenges to concerns about tolerability, adherence and the suitability of available treatment options at different stages of the disease. These numbers underscore that many patients and physicians continue to look for therapies that better meet their individual needs.

We believe vidofludimus calcium has the potential to address these challenges in a differentiated way, which is what makes the program so exciting.

EB: How does vidofludimus calcium address the unmet needs you have identified in MS?

Lundgren: What makes vidofludimus calcium particularly interesting is its dual mechanism of action. In preclinical studies, the molecule has demonstrated activation of the transcription factor Nurr1, which is believed to play an important role in maintaining neuronal health. At the same time, vidofludimus calcium is a selective DHODH inhibitor, modulating the activity of overactive immune cells involved in the MS disease process. This combination is especially relevant as it has the potential to target both the neurodegenerative and inflammatory drivers of the disease.

We believe this dual approach has the potential to address some of the key unmet needs in MS today: controlling inflammatory disease activity, maintaining a favorable safety and tolerability profile and potentially influencing the mechanisms underlying disability progression.

Today, vidofludimus calcium is being evaluated in Phase 3 trials in relapsing MS, which are expected to read out by the end of this year. We also plan to initiate a Phase 3 trial in progressive MS. That setting may ultimately be particularly important, as it could provide a broader dataset on the drug's impact on neurodegenerative processes.

EB: Ultimately, these hypotheses need to be confirmed in the clinic. What are the key questions the ENSURE Phase 3 trials are designed to answer?

Lundgren: The trials are designed to provide a comprehensive assessment of relapse activity. The primary objective of the ENSURE program is to demonstrate that vidofludimus calcium can significantly reduce the risk of relapses in patients with relapsing MS, as measured by time to first relapse.

Key secondary endpoints include MRI measures such as new or enlarging T2 lesions and gadolinium-enhancing T1 lesions, as well as annualized relapse rate. Together, these endpoints give us a detailed picture of how effectively the treatment can control inflammatory disease activity.

The program also evaluates confirmed disability improvement and confirmed

disability worsening in pooled analyses as part of the secondary and exploratory endpoints. While the studies are not specifically designed to measure disability and therefore the relevant signals may be limited, these endpoints can provide additional insights into the treatment's potential impact on long-term patient outcomes.

Taken together, the ENSURE trials are designed to assess whether vidofludimus calcium can deliver meaningful clinical benefit across multiple dimensions of MS disease activity, with the primary focus on relapse reduction, while continuing to generate safety and tolerability data, which we hope will be in line with the favorable profile observed to date.

EB: What could positive ENSURE data mean for the future of vidofludimus calcium?

Lundgren: If the ENSURE trials deliver positive results, our immediate next step would be to finalize the preparations and submit a New Drug Application (NDA). We have already engaged extensively with regulators and continue to maintain an ongoing open dialogue.

From a commercial perspective, we believe vidofludimus calcium could be well positioned in the relapsing MS market if we are able to reproduce the efficacy, safety and tolerability results observed in our Phase 2 program. As we discussed earlier, patients and physicians continue to need new treatment options that combine efficacy with a favorable safety and tolerability profile.

An oral route of administration, combined with strong relapse control and the favorable safety profile observed to date, could represent a differentiated value proposition for relapsing MS patients. We believe that would provide a meaningful opportunity in the market, even in a treatment landscape with multiple approved drugs.

EB: Looking beyond the initial relapsing MS opportunity, where do you see the greatest long-term potential for vidofludimus calcium?

Lundgren: We see several opportunities beyond the relapsing MS market. MS is a

chronic disease in which patients cycle through different therapies over time. For example, around 10% of patients discontinue anti-CD20 treatment each year, creating an ongoing need for additional treatment options. We believe vidofludimus calcium could be relevant for several patient groups, including newly diagnosed patients, patients looking for an oral alternative to switch to and those seeking a treatment with a favorable safety and tolerability profile.

We are also seeing an aging MS population. As patients age, immune senescence becomes increasingly relevant. You cannot continue intensifying immune suppression indefinitely, which is why treatment goals and patient needs evolve over time.

At the same time, the progressive component of the disease becomes increasingly important. This is where we see a particularly compelling long-term opportunity. Significant unmet needs remain in progressive MS, and our planned progressive MS Phase 3 program will help us further explore the potential of vidofludimus calcium in this setting. If successful, it could provide an important point of differentiation for the drug.

EB: You mentioned progressive MS as an important future development area for vidofludimus calcium. Why is progression such a critical challenge in MS, and why has it proven so difficult to address?

Lundgren: One of the key learnings in MS over the past decade is that the traditional distinction between relapsing and progressive disease becomes less clear. Current therapies have transformed the treatment landscape, and the waiting rooms are no longer full of patients in wheelchairs, which is a remarkable achievement.

At the same time, we have come to recognize that progression remains a fundamental part of the disease. Many patients eventually enter a progressive phase, where relapses become less prominent or stop altogether, but disability continues to worsen. In other words, while the inflammatory component of

the disease may decline over time, the progressive component remains and often increases over time.

That is why neuroprotection is emerging as one of the most important areas of innovation in MS today, and why we believe approaches that can potentially address both inflammation and neurodegeneration warrant close attention.

EB: As Immunic prepares for commercialization, how do you envision bringing vidofludimus calcium to patients globally?

Lundgren: Our ambition is to build a successful commercial organization and bring vidofludimus calcium to patients ourselves in the core MS markets, first in North America. At the same time, we will carefully evaluate the opportunities and requirements of different healthcare systems and regions around the world.

We have already begun preparing for this next phase of growth. Earlier this year, we completed a tranched financing backed by strong institutional investors and designed to support our transformation into a fully integrated biotechnology organization. In addition, a second tranche of up to \$200 million could become available following ENSURE data. Our current cash position allows us to continue executing on our development priorities.

Ultimately, our focus remains on delivering strong Phase 3 data and preparing the organization to capitalize on the opportunities that could follow.

EB: What else is in Immunic's pipeline beyond vidofludimus calcium?

Lundgren: We have additional work ongoing around the Nurr1 target with the goal to understand this mechanism and biology even better. While some of its aspects are still a hypothesis, we continue to drive preclinical work to better understand and prove it. Both the preclinical work and the clinical trials will tell us more and we are eager to learn.

EB: As Immunic enters this next phase of its development, what is your vision for the company?



... editor Georg Kääh

Lundgren: What motivates me every day is the opportunity to disrupt MS once again and ultimately improve the quality of life for patients. Over the past decades, tremendous progress has been made, but significant unmet needs remain, particularly when it comes to disability progression and long-term safety. The possibility of making a meaningful difference for patients is what drives me and our team every day.

My vision is for Immunic to become the company that understands MS patients better than anyone else. That should be our superpower. Patients' needs evolve throughout the course of the disease, and our responsibility is to understand those needs and develop solutions that truly address them.

We are evolving from a science-driven biotechnology company into a fully integrated organization. But I do not see science and commercialization as competing priorities. Commercialization is the natural extension of great science. Scientific innovation only achieves its full value when it reaches patients.

If we can combine scientific excellence with a deep understanding of patients and execute successfully as a commercial organization, I believe Immunic has the opportunity to become a true disruptor in MS.

Georg Kääh

What's next for argenx, Europe's autoimmune breakthrough?

LEADERSHIP Over the past few years, Belgium's argenx has become a biotech force to be reckoned with, driven by the success of its autoimmune drug Vyvgart (efgartigimod alfa) in diseases such as generalised myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP). We caught up with CEO Karen Massey to discuss how she plans to build on this success after joining argenx in March 2023 and taking up the role of CEO at the start of this year.

European Biotechnology: What attracted you to the job at argenx?

Karen Massey: All over the world, people are living with debilitating autoimmune diseases. Many endure diagnostic odysseys that last for years, going from doctor to doctor as they try to work out what condition they have. And when they do eventually find out, treatment options – often unchanged for decades – can be incredibly limited, and also burdensome. I wanted to be part of a dynamic company – one that is grounded in science and focused on addressing these significant unmet needs. I wanted to be part of a team that is building a different type of biotech.

This combination of scientific ambition and patient focus really stood out to me when I first met Tim Van Hauwermeiren, one of the co-founders of argenx and now our Chairman. Having worked across commercial teams and at earlier stages of the value chain during my career, I felt I could bring a broader perspective that would complement the expertise already within the company and help contribute to its next stage of growth.

argenx is a company that not only responds to the needs of patients today but is continually anticipating what patients – and other stakeholders – will need in the future. The company combines a listening- and understanding-first approach to the development of medicines with a real spirit of co-creation and scientific entrepreneurship. We work closely with clini-



KAREN MASSEY joined argenx in March 2023. After serving as chief operating officer, she was appointed chief executive officer in May 2026. Karen has over 20 years of experience in the biopharma industry, including as senior vice president of product development and global clinical operations at Genentech (part of Roche). Karen started her biopharmaceutical career in marketing at Pfizer and has held leadership positions in corporate strategy, sales and as a commercial lead in Latin America.

cians and patients to learn what they really need in order to achieve better outcomes. Through our Immunology Innovation Program (IIP) – a program that

integrates leading biologists from academic centres across the world into argenx research teams – argenx is building a deep understanding of the underlying biology driving autoimmune conditions.

By combining these insights with argenx's antibody-engineering expertise, argenx has been able to move at pace to develop and deliver efgartigimod, a precision therapy that is changing the treatment paradigm in generalised myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP), two rare neuromuscular autoimmune conditions. We're now very hopeful we'll be able to do the same for other IgG-mediated autoimmune rheumatological conditions, including autoimmune myositis.

EB: You worked almost a decade at Roche's Genentech before joining argenx. What's the difference between working for a large pharma group and argenx?

Massey: What is consistent at both companies is the patient focus. Roche and argenx put the patient at the center of everything they do. Having worked directly with physicians earlier in my career, I have seen first-hand the difference bringing innovative medicines can make to patients' lives. This is something that motivates me on a very personal level, and seeing that same sense of purpose reflected across argenx is incredibly powerful.

The key difference at argenx is that we have an opportunity to build something much earlier in its lifecycle. The world is

changing rapidly, and as a younger company, we can respond to this more quickly. We are able to take advantage of the latest technologies to help us develop better medicines. We can look for the partnerships that will help us accelerate novel science. We can look at other modalities, such as oral formulations of FcRn medicines or next-generation FcRn molecules that offer different dosing intervals, and we can take a really fresh approach to the way in which we develop our digital and AI strategies. Older companies have a lot of legacy infrastructure and systems, whereas we have the opportunity to take a blank sheet of paper and design purpose-built solutions. We have far less organizational drag. We really do have a golden opportunity to build a company that is fit for the future.

EB: Can you tell us more about your research into oral drug technology; is it clearly aligned with what you said about patient focus?

Massey: Patients are looking for serial innovation. Thanks to our strong partnerships with leading disease biologists and our autoantibody engineering expertise, we were the first company to launch an FcRn inhibitor, a precision therapy designed to target the underlying biology of severe autoimmune conditions. But we wanted to go further than simply providing an innovative molecule that needed to be administered intravenously. We understand that, for patients living with chronic conditions, the way in which they take their medicines is very important. So, within just a few years, we will have brought three new modes of administration to market: a subcutaneous formulation administered by doctors, a pre-filled syringe that patients can administer themselves without having to come into a clinic, and next year, an autoinjector. And as already mentioned, we have an oral FcRn molecule in development. Our job is to deliver a best-in-class experience for patients, and that is what we are committed to doing.

EB: Earlier this year, argenx acquired Forte Biosciences for \$2.2 billion. Tell us

how this acquisition fits into your drug pipeline?

Massey: Our ambition is to be an immunology innovation company. We want to transform lives, treating 50,000 patients across ten different diseases, with five molecules in late-stage development by 2030. As we continue to grow, we are always looking out for compelling, novel science in areas of unmet need. As we assess these molecules, we ask ourselves whether the science is truly novel, whether there is an elegant antibody or delivery approach, and whether it has the potential to treat diseases in areas of high unmet need. Aligned with our cultural pillar of humility, we understand that not everything has to come from argenx – there is a lot of value being created outside of our company. Indeed, much has come through our IIP. With Forte, we found a molecule that fits our formula: novel science addressing autoimmune diseases with high unmet need. We thought, ‘that looks like an argenx molecule,’ so we moved quickly to secure it.

EB: It must be a good time to be in charge of a company that has pivoted from a biotech burning through cash to one generating income with a drug on the market?

Massey: It is, and with our success comes a responsibility and a duty to patients and society to invest where we can have the most impact and where there is high unmet need. We do not want to be bringing the tenth medicine to market in an indication that already has multiple treatment options. The success we have with efgartigimod gives us choices and enables us to invest in innovation that can make a meaningful difference to patients, many of whom are having to rely on outdated technologies.

EB: In your opinion, how will the European biotech sector develop over the next 10 years?

Massey: Whether you look at Europe, China, the US biotech ecosystem or Australia, where I’m from, we are seeing remarkable scientific progress. The key question is how regions can structure

their ecosystems to ensure they are able to bring important innovations to patients without unnecessary delay. For example, is it possible to conduct first-in-human studies quickly? How are clinical trial systems set up? How are medicines evaluated in terms of the benefits they deliver to patients? Different regions are doing some things better than others. The region that will be the most successful will be the one that brings all the key pieces together.

Europe is a strong hub and has all the right ingredients: great science, a strong ecosystem and good healthcare infrastructure. Going forward, Europe needs to learn from what is working well in other regions and ensure it has a model in place that incentivizes innovation.

EB: What’s next for argenx?

Massey: Our second molecule, empasiprubar, is being investigated in patients with Multifocal Motor Neuropathy (MMN), a neurological condition that results in muscle weakness and where there is high unmet need. The topline results from our Phase 3 MMN study are expected in the fourth quarter of this year.

We’re also evaluating empasiprubar in CIDP, and we have a combination study running in MG. Just like efgartigimod, we believe empasiprubar, which is a C2 inhibitor targeting a very specific part of the immune system, could be a pipeline-in-a-product-medicine for us.

We’re also advancing adimanebart, a first-in-class MuSK agonist antibody, in congenital myasthenia syndromes and other neuromuscular diseases, including spinal muscular atrophy.

Of course, our recent acquisition of Forte Biosciences further strengthens our pipeline. The lead candidate, FB102, which is currently being trialled in vitiligo and celiac disease, has the potential to be a pipeline-in-a-product asset that addresses multiple autoimmune diseases where there are few treatment options available.

The pipeline is looking very strong and we’re making great progress towards broadening our immunology pipeline. ■

Richard Staines

AATec is pioneering a new approach to lung diseases

ADVERTORIAL AATec is advancing ATL-105, a new recombinant version of alpha-1 antitrypsin for inhalation, into clinical development for chronic respiratory diseases. Rüdiger Jankowsky, CEO, and Gabriele Matschiner, Chief Development Officer, explain the development program, the choice of bronchiectasis and the upcoming Phase 1b/2a trial.

European Biotechnology: AATec is developing a new class of therapeutics for respiratory diseases. What makes you so excited about the program?

Rüdiger Jankowsky: *What excites us is the idea of creating a new platform for respiratory diseases with a high unmet need. Because our approach is based on a human molecule with broad activity and an established safety profile, it could be relevant not only for our lead indication non-CF bronchiectasis, but also for COPD and other lung diseases, as well as rare diseases of the airways.*

Gabriele Matschiner: *The key for us is that we combine this broad activity with delivery to the lungs. We can target several disease drivers directly where they occur and limit drug exposure elsewhere in the body.*

EB: Why is ATL-105 a promising approach for chronic respiratory diseases, and what sets it apart?

Jankowsky: *ATL-105 is based on alpha-1 antitrypsin (AAT), a naturally occurring human protein that helps protect the lung from excessive inflammation and tissue damage. That is key in chronic respiratory diseases, where inflammation, damaging proteases and infection often come together. ATL-105 addresses several disease drivers at once through its combined anti-inflammatory, antiprotease and anti-infective activity.*

EB: Why did you choose non-cystic fibrosis bronchiectasis as the first clinical indication?

Matschiner: *Bronchiectasis still comes with a high unmet medical need. One of its hallmarks is neutrophilic inflamma-*



RÜDIGER JANKOWSKY, CEO and co-founder of AATec, has more than 25 years of leadership experience in biotech, with a focus on product development, regulatory approval and corporate development.



GABRIELE MATSCHINER, CDO, brings more than 20 years of experience in translational and early clinical development, particularly in respiratory diseases and inhaled biologics.

tion, which drives damaging proteases and airway damage. This gives us a very clear way to test the mechanism of ATL-105 in patients. And because the disease mainly affects the larger airways, it is also readily accessible to inhalation treatment.

EB: Which preclinical findings gave you the confidence to move ATL-105 into the clinic?

Matschiner: *The key moment was seeing that ATL-105 reduced neutrophilic inflammation in vivo when we delivered it directly to the lungs. In addition, we saw a clear, dose-dependent effect in lung samples from patients, and it was well tolerated even at high local concentrations in our toxicology studies.*

EB: What would success look like in the first clinical trial?

Matschiner: *We will conduct a randomized, placebo-controlled Phase 1b/2a study directly in patients, testing different doses of ATL-105. Success would mean*

showing safety and tolerability together with a dose-dependent reduction in protease activity. That would provide clinical proof of concept and help us select the dose for the next stage of development.

EB: Was there a moment when you realized ATL-105 could become more than an interesting scientific concept?

Jankowsky: *The in vivo data were an important turning point. But what finally transformed the concept into a product-development program was the full package: the biological activity, the excellent product quality and the fact that we could nebulize ATL-105 while completely maintaining its activity. That confidence is reinforced by strong interest from international clinical experts, investors and global pharmaceutical companies, as well as by the backing in our pre-series A financing round of SPRIN-D, the German federal agency for breakthrough innovation.*