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Science in Europe is world class, the challenge is turning that strength into impact for patients and society

03.12.2025

Tags:

France, argenx, Biotech, Antibodies, Immunology, Strategy

*argenx has moved from an antibody engineering start-up to one of Europeâ??s most closely-watched biotechs, advancing a pipeline that spans multiple autoimmune diseases. In this interview, FranÃ§ois Rauch reflects on argenxâ?? growing position in France, , the lessons drawn from navigating Franceâ??s evolving access landscape and the broader policy conditions required to keep the country competitive for clinical research, investment and innovation. His perspective offers a clear view of how a young biotech builds momentum in a complex ecosystem while preparing for its next wave of launches.*

**How did argenx originate, and how has this scientific foundation influenced the way your R&D model and pipeline have evolved?**

argenx began in 2008 in Ghent, Belgium, grounded in antibody engineering research carried out by scientists associated with Ghent University. From the start we set out to build a robust platform able to generate antibodies with a high level of precision and durability, particularly for complex autoimmune diseases where unmet need remains significant. What began as a focused scientific ambition has grown into a mature engine that now supports several clinical programmes across multiple autoimmune indications.

Our R&D approach is built on two complementary pillars. The first is our internal antibody engineering capability, which brings together Fc engineering, target specificity work and proprietary technologies that allow us to shape potency and half-life in a controlled way. The second is our Immunology Innovation Program (IIP), which creates long-term partnerships with leading academic groups. These collaborations give us early visibility on disease biology, help us validate promising targets and allow us to integrate academic insight directly into our discovery and engineering work.

This structure gives us continuous access to high quality science while retaining a strong in-house platform, and it explains the breadth of our pipeline for a company of our size. Ghent remains our core R&D hub. It is where much of our scientific expertise sits and where the antibody engineering work that anchors argenx continues to progress.

**How did your journey with argenx begin, and what led you to take on the task of establishing its presence in France, Belgium and Luxembourg?**

I joined argenx almost five years ago, at the moment when we had decided to build a direct commercial presence in Europe. I already knew argenx well from my time working in the Belgian ecosystem, so the move felt like a natural continuation of conversations that had started earlier. The role involved creating the commercial entity for France, Belgium and Luxembourg, which was an opportunity to help shape the foundation of our regional organisation from the ground up. I did not approach the decision with scepticism, even though building a commercial infrastructure is always demanding for a young biotech. I had spent close to fifteen years in another European biotech and had already experienced the challenges and rewards of scaling a company in this way. That background gave me confidence that, with the right scientific base and a clear long term vision, the model could work.

What makes such a build-up viable is the strength and breadth of the pipeline. It is difficult to sustain a full regional organisation with a single asset in one indication. At argenx we have several late stage assets, each with the potential to support multiple diseases. Efgartigimod spans a wide range of autoimmune indications, empasiprubart covers complement mediated neuropathies and other conditions, and ARGX 119 addresses neuromuscular diseases. This depth gives us a solid rationale to invest in a long-term European structure.

Our first launch in France involved an injectable therapy administered in the hospital setting, which can be complex. The key was to engage early with the national rare disease ecosystem. France has built a strong framework through successive rare disease plans, creating reference and competence centres that allow patients to access specialised care across the country. By working closely with this network, we identified the most effective route into the system.

We then moved through the French market access process, including the Early Access pathway (AccÃ¨s PrÃ©coce). This mechanism allows innovative therapies for serious or rare conditions to reach patients ahead of full marketing authorisation or final reimbursement. It enabled us to make the treatment available while progressing regulatory, pricing and organisational steps in parallel. Managing this required careful judgement on timing and risk, yet it allowed us to build the affiliate while ensuring patients could benefit from the therapy without unnecessary delay.

**How would you assess the current positioning of your lead neuromuscular therapy in France, and what experience from the first launch is guiding your approach to the next indication?**

Our portfolio is anchored by our first-in-class neuromuscular therapy, which carries several approved indications globally. In France we hold the authorisation for adult patients with generalised myasthenia gravis who are AChR antibody positive. We first entered the market through the Early Access system, moving from the AP1 route before marketing authorisation to AP2 afterwards, while the pricing and reimbursement process was being completed. We now have full reimbursement, and patients can access the treatment through standard pathways. A second indication, chronic inflammatory demyelinating polyneuropathy (CIDP), was approved by the European Commission in June 2025 and has already been introduced in Germany. We are now progressing through the national steps in France so that patients here can benefit from it as well. Both diseases fall within the rare neuromuscular field and have a profound impact on quality of life.

Our first launch came at a moment of regulatory transition in France. The country had just replaced the Temporary Authorisation for Use (ATU) framework with the new Early Access model, and many operational elements were still being clarified. We were among the early therapies to navigate this shift, which required a close partnership with the rare disease ecosystem, strong clinical data and a clear focus on unmet need. At the same time we were building our organisation in parallel, which added another layer of complexity and required careful sequencing of each step.

As we prepare for the second indication, we do so with a more established structure, although the broader environment remains challenging. The current discussions around the Social Security Financing Bill (PLFSS) highlight the importance of maintaining Franceâ??s competitiveness for innovative therapies. The speed at which clinical trials are set up, the design of sector specific taxes and the way innovation is valued all shape long term investment decisions. Companies work on horizons of ten to fifteen years, so stability and predictability matter. France has strong scientific foundations and an excellent rare disease ecosystem. Preserving those advantages requires a regulatory and fiscal environment that supports sustained investment over time.

**How do you view the role of France within argenx today, and how is Franceâ??s rare disease ecosystem evolving as new diagnostic technologies emerge?**

France holds a central place in our European activities. It is a major market with a large population, strong academic institutions and a rare disease network that has been built and refined over several national plans. These elements make the country an important contributor to clinical research and patient access. The real question, in my view, is not whether France is important, but how we ensure that it remains attractive for biotech investment in the long term. Sustaining that position requires a stable environment that supports innovation and allows companies to plan confidently.

The rare disease infrastructure in France continues to provide a strong foundation. The French system remains effective because it is built around networks of competence or reference centres. These networks operate through a hub and spoke model, with regional reference centres partnering with competence centres and local hospitals as well as with European reference networks (ERNs). This ensures that patients suspected of having a rare disease can be routed to specialist teams without losing the link to their main treating clinician.

Many clinicians see this system as one of Europeâ??s stronger frameworks for rare disease care. It supports earlier diagnosis, offers clarity for patients and provides clinicians with a connected structure. As genomic tools become more prevalent, the challenge will be to make sure the system adapts at the right pace so that it continues to serve patients effectively.

**How are you approaching real world evidence generation in France, and how do the national registries support this work?**

Real world evidence is an area where collaboration is essential for us, and we apply the same partnership driven approach in France that guides our wider R&D model. We work closely with FILNEMUS, the national neuromuscular disease network, which operates a dedicated registry covering patients across the country and supporting both clinical and epidemiological research. This work builds on the BNDMR, the national rare disease data bank, where certified reference centres are required to enter their diagnosed patients using the national Minimum Data Set. Their accreditation and access to budgets depend on this contribution, which ensures a solid national view of prevalence and patient profiles. Alongside that, the SNDS, Franceâ??s national health data system, covers almost the entire population and provides a complete picture of a patientâ??s journey through the healthcare system. When the SNDS, the BNDMR and disease specific registries such as FILNEMUS are combined, they create a uniquely powerful dataset for rare disease research. These sources help us understand when and where patients are diagnosed, how long diagnosis takes, how care pathways function and how patients move between institutions.

The issue today is not the availability of data, but the time required to access it. Administrative procedures are slow, and it can take more than a year between initiating a request and receiving usable data. Privacy protections are essential, yet faster processing would greatly increase the value of these datasets for research and patient care. When we speak about access, we do so through certified trusted third parties rather than handling patient level information ourselves, but even within that framework the timelines remain long. In rare diseases, where timely insight can make a real difference, these delays represent a clear opportunity cost.

**How is France contributing to argenxâ??s recent momentum, and what role will the affiliate play as you look ahead to the next phase of growth?**

France has become an important engine for us. When argenx chose to build a direct presence in Europe, it did so with the intention of anchoring long-term growth. Our commitment is to bring meaningful innovation to French patients while establishing a durable footprint across the continent, as we are doing in other territories. France adds particular value because of its clinical research strength. The countryâ??s academic institutions, established networks and rare disease expertise give us an environment that supports faster and more robust development of our programmes in autoimmune and neuromuscular diseases.

Our collaborations reflect this approach. We work closely with centres across the country and maintain both early-stage research partnerships and clinical trial activity. One example is our research prize with the â??Fondation Maladies Raresâ?•, which helps uncover promising antibody-based projects and positions us to support them over the long term. Alongside this, several clinical studies are underway at different sites in France, reinforcing a solid and growing R&D presence in the country. These efforts underscore why France matters for argenx and why we continue to invest in building a strong and sustainable role here.

**How are you preparing for next yearâ??s launches, and to what extent could the current French environment influence your timelines?**

Our main priority for next year is the introduction of the new formulation of VYVGART. We began with the intravenous infusion administered in hospital, and we are now moving toward a prefilled

syringe that allows patients to self-inject at home. This brings a convenient subcutaneous form that will reach French patients at the beginning of 2026. It represents a natural evolution of the therapy and reflects how we see patient needs changing.

In parallel, we are progressing the CIDP indication. The European Commission granted approval in June 2025, and we are now going through the French steps for pricing, reimbursement and launch.

**How would you describe the long-term vision and values that guide argenx as the organisation grows?**

We operate with a clear horizon for 2030, which gives the entire organisation a shared sense of purpose. By the end of the decade we aim to have more than fifty thousand patients benefiting from our therapies, compared with roughly fifteen thousand today. We have also set two further goals for ourselves, to secure at least ten approved indications and to advance five molecules into phase three. These goals provide structure and help guide the choices we make as we scale.

Our values underpin that ambition and influence how we work day to day. Humility is fundamental. We listen to the ecosystem because the strongest science often sits in academic centres, and we know our progress relies on partnering with those teams. The detail that our name appears in lowercase captures that spirit. Co-creation is equally central. We do not innovate in isolation, we build by working with others and by seeking out the best ideas wherever they emerge. From that partnership mindset flow the other values that guide us, including innovation, excellence and empowerment. Together they define how we collaborate, how we make decisions and how we stay focused on delivering meaningful outcomes for patients.

**How do your academic partnerships contribute to this long-term vision, and what do they reveal about Europeâ??s ability to translate science into patient-facing innovation?**

Europeâ??s academic institutions produce science of outstanding quality, fully comparable to what comes from leading centres in the United States. The issue has never been the science itself but the difficulty of translating it into therapies that reach patients. That is where our model has been particularly effective. We devote significant effort to identifying high-quality academic work and bringing it into our platform so it can move through development in a more structured and efficient way.

When this approach succeeds, the benefits extend well beyond individual programmes. It helps retain talent and investment in Europe, creates opportunities for advanced manufacturing and ensures European patients can access therapies that originate within the continent. The societal value of this dynamic is considerable, and I would like to see it strengthened across Europe. France has recently seen a few encouraging venture successes, which shows that momentum is building, but we still need a more coordinated and ambitious approach to translation. In an ideal scenario, biotechnology would follow a trajectory similar to French Tech, which rose from a modest position fifteen years ago to a vibrant ecosystem through sustained collaboration and targeted investment. The scientific foundation is already here. The real task now is to convert that foundation into lasting impact for patients and for the broader European landscape.

**As we close, what do you see as the essential conditions for France to remain competitive and ensure long-term access to innovation?**

We are operating in a landscape that is shifting quickly, with countries competing more directly than before, and this should be at the centre of national priorities. France sometimes underestimates how deeply interconnected the global ecosystem has become. Decisions made in one market influence investment choices elsewhere, and they ultimately shape how quickly patients here can benefit from new therapies. What we need is a stable and predictable environment that gives companies the confidence to invest and reduces the administrative complexity that often slows progress. This is especially true for clinical research, where speed is critical. Biotechs move fast by necessity, and they will favour countries where trials can start without unnecessary delay, something several of our neighbours have already embraced.

Staying aligned with peer countries on trial timelines, pricing conditions and regulatory predictability is essential. At the same time, we need a framework that rewards innovation in a consistent and sustainable way with a multi-year vision, which is not possible under the annual social security financing bills. This is why the upcoming Social Security Financing Bill (PLFSS) is so important, as it sets the rules for the coming year that shape reimbursement, taxation and incentives for new medicines. The renewal of the agreement between Leem and the CEPS will be equally important, since it governs how innovation is valued over time. Together, these elements will determine whether France remains an attractive environment for biotech investment and can guarantee long-term access to emerging therapies for patients.

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