Marc de Garidel â?? CEO, Abivax

Drug development is an empirical craft; science sets the direction, but success depends on focus, discipline, and learning from experience.

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Born from a serendipitous scientific discovery in Montpellier, Abivax has evolved into one of Franceâ??s most promising global biotechs. Led by CEO Marc de Garidel, the company is harnessing its pioneering miR-124-based therapy, obefazimod, to redefine treatment possibilities in inflammatory bowel disease through an entirely new, immune-balancing mechanism of action. With positive Phase 3 induction results and a clear path toward US commercialisation, Abivax now stands at a transformative moment in its journey.

What is the story behind Abivax, and how did it evolve to where it stands today?

Abivaxâ??s origins trace back to Montpellier, where researchers from the CNRS (Franceâ??s National Centre for Scientific Research) and the Institut Curie in Paris were collaborating with Splicos, a private company, on a molecule designed to inhibit HIV replication. This compound would later come to be known as obefazimod. Building on this early scientific work, Abivax was formally established in 2013 through the consolidation of three French biotechs â?? Splicos, Wittycell, and Zophis â?? which consolidated their antiviral and vaccine platforms under a single structure. For several years, our focus remained on antiviral drug development, advancing obefazimod through preclinical models and early HIV studies.

When it became clear that the moleculeâ??s efficacy was not potent enough to cure HIV patients, an unexpected finding â?? that obefazimod appeared safe in these immunocompromised HIV patients â?? changed the course of the company. This observation prompted the company to test

obefazimod in a DSS-induced colitis model, a well-established preclinical model for ulcerative colitis. After very encouraging results, the company contacted Professor SÃ©verine Vermeire, a leading Belgian gastroenterologist at KU Leuven, who advised investigating obefazimodâ??s mechanism of action in a phase 2a clinical trial. Those two studies, launched in 2016, would ultimately redefine Abivaxâ??s trajectory.

What scientific insight led to the discovery of obefazimodâ??s novel immune-balancing mechanism?

By 2015, we had identified that obefazimod enhances the expression of microRNA-124 (miR-124), a naturally occurring molecule within immune cells that serves as a physiological brake on inflammation. Unlike conventional inflammatory bowel disease therapies such as anti-TNF or anti-IL-23 antibodies, which suppress a single immune pathway, obefazimod acts downstream across multiple cascades. It reduces the production of key cytokines (IL-6, IL-17, and IL-23) while stabilising macrophage activity to prevent further immune overactivation. In other words, it helps the immune system restore balance rather than shutting it down.

This differentiated mechanism defined Abivaxâ??s new direction. The DSS colitis model confirmed strong anti-inflammatory activity, and because obefazimod had already been tested in humans in previous HIV clinical development, we could move swiftly into clinical evaluation for ulcerative colitis. What began as an antiviral project thus became the foundation of a company dedicated to harnessing the bodyâ??s natural regulatory mechanisms to treat chronic inflammation.

What have been the main milestones on Abivaxâ??s journey since this pivot?

Our first Phase 2a trial, led by Professor Vermeire, enrolled around forty patients and demonstrated a clear clinical response after eight weeks of treatment, particularly at the 50 mg dose. Encouraged by these results, we advanced to a Phase 2b study involving 253 patients across Europe, which confirmed the drugâ??s potential despite challenges related to the COVID-19 pandemic and variability in trial-site quality. The data drew strong investor interest, and Abivaxâ??s stock price rose sharply on Euronext Paris.

However, we made the mistake of delaying a capital raise, anticipating a potential acquisition that ultimately did not occur. Investors got disappointed & our valuation decreased, and resources became tight. At that critical juncture, Sofinnova Partners stepped in, bringing both capital and deep expertise in global biotech development. Together with investors including TCG X, Venrock, Deep Track Capital and Invus, Sofinnova led a recapitalisation that provided roughly EUR 180 million in total to fund the Phase 3 ABTECT programme and strengthen our international ambitions.

It was during this period that I was approached to lead Abivax. Having recently guided CinCor Pharma through its successful acquisition by AstraZeneca, I was drawn to the clarity of the science and the conviction of the team. After attending the ECCO (European Crohnâ??s and Colitis Organisation) congress in Copenhagen and immersing myself in the IBD field, I became convinced that obefazimodâ??s profile was truly unique. I therefore accepted both the CEO and chairman roles to steer Abivax through its pivotal Phase 3 programme and the next stage of its global expansion.

Why are the Phase 3 results for obefazimod so significant, and what are the next steps toward approval and launch?

In ulcerative colitis, regulatory approval requires both induction and maintenance studies. The induction phase, typically eight to twelve weeks, measures remission and other clinical indicators such as symptom relief and endoscopic improvement. Ulcerative colitis, often diagnosed around age 35, is a debilitating chronic condition; patients often spend years cycling through 5-ASA and corticosteroids that manage flares but seldom deliver long-lasting remission. Our ambition with obefazimod has been to shift that paradigm toward durable, well-tolerated disease control.

Our Phase 3 induction study exceeded expectations, delivering stronger results than Phase 2, an uncommon outcome when expanding to larger, more heterogeneous patient populations. Equally encouraging, the safety profile remained excellent, with only transient, mild headaches early in treatment. These findings confirm both the strength of obefazimodâ??s mechanism and the precision of our clinical execution. The one-year maintenance study, which will readout in Q2 2026, will now have to validate sustained efficacy and safety. Following the maintenance readout, we plan to file with the FDA and EMA and target a US launch in 2027, with commercialisation focused on the US and partnerships elsewhere.

In the near term, we recently presented detailed data at UEG (United European Gastroenterology) Week 2025 in Berlin, including results from 124 patients who had previously failed JAK inhibitor therapy, among the most refractory cases in ulcerative colitis. The abstractâ??s selections, with two full-room late-breaking presentations, underscored the significance of these outcomes. We are also analysing quality-of-life endpoints, covering fatigue, bowel urgency, work participation, and overall well-being. We will provide top-level information in that regard in November and next year, multiple abstracts at ECCO & DDW on more phase 3 sub-analyses.

While ulcerative colitis remains our lead indication, a Phase 2b trial in Crohnâ??s disease is underway. Given obefazimodâ??s broad, multi-pathway mechanism, we believe its potential extends well beyond a single condition, offering a potential new therapeutic option for patients across the inflammatory bowel disease spectrum.

How are you expanding Abivaxâ??s pipeline while maintaining focus on long-term growth and sustainability?

The global inflammatory bowel disease market is projected to reach around USD 30 billion by 2030, with ulcerative colitis representing roughly 40 to 45% and Crohnâ??s disease accounting for the remainder. Our strategy has been to build value progressively, beginning with ulcerative colitis, where we already have compelling Phase 3 data, and then expanding into Crohnâ??s disease. We are currently running a Phase 2b trial in Crohnâ??s, with results expected by the end of next year. If positive, we plan to advance directly into Phase 3 trials in H2 2027, alongside the US launch of obefazimod for ulcerative colitis, with potential regulatory approval for Crohnâ??s in late 2031.

In parallel, we are exploring combination therapies, drawing inspiration from oncology, where combining complementary mechanisms of action can accelerate early clinical response. Preclinical experiments pairing obefazimod with other anti-inflammatory agents are already underway, with initial data expected in 2026. Given the scale and cost of such programmes â?? potentially up to USD 300 million â?? we will advance them selectively and most likely in partnership with other industry players.

Our fourth area of focus is the development of a next-generation miR-124 enhancer, building on our proprietary expertise in this field. Our R&D team in Montpellier is leading the programme, and we expect preclinical results in 2026. Designing a molecule that surpasses obefazimod is proving complex; greater potency tends to come with more side effects, while improving tolerability may reduce efficacy. Rather than simply optimising the same compound, we are therefore investigating new inflammatory indications where this unique mechanism could bring additional value.

Looking ahead, our near-term value drivers include the forthcoming ulcerative colitis maintenance data, regulatory filings, and the planned US commercial launch, in addition to the Crohnâ??s Phase 2b readout in 2026. Even after our rapid rise, we see considerable room for continued growth. In 2023, we completed the largest-ever US IPO for a French biotech, raising USD 240 million, followed in 2025 by a USD 750 million follow-on offering, one of the biggest financings in European biotech history. On that day, our share price surged by almost 600% on NASDAQ, a milestone that underscored the extraordinary confidence investors have placed in our science, strategy, execution, and leadership team.

How are you deploying your financing runway and preparing for commercialisation and market entry?

With a cash runway extending through late 2027, our efforts are now focused on preparing for the US launch of obefazimod. We plan to begin establishing our commercial infrastructure in the second half of 2026, starting with key hires such as a Chief Commercial Officer. In the meantime, we are expanding our medical affairs and scientific engagement teams, aiming to position Abivax as a leading voice in inflammatory bowel disease. Over the next two years, we intend to be the most active IBD company in scientific communication, presenting around ten abstracts at each major congress, leveraging the depth of data generated by our Phase 3 program.

This scientific visibility is central to our ambition to redefine the IBD treatment landscape, a goal we first outlined at our IPO and which is now being realised. Following our Phase 3 success, independent surveys involving more than 70 US physicians, as well as one conducted by a major investor, confirmed strong enthusiasm for obefazimod; based on current data, clinicians anticipate that obefazimod could become a new standard of care, capturing potentially one-third of the refractory segment and approximately 15 percent of the first-line market. Our post-Phase 3 interactions with US payers also indicate we can likely benefit from a good net selling price without compromising our competitive ambition across treatment lines.

What is Abivaxâ??s strategy for commercialisation and partnerships across different global markets?

Outside the United States, we plan to commercialise obefazimod through partnerships, but in the US, our objective is to launch independently. As a CEO, I cannot rely on the prospect of an acquisition; that assumption during Phase 2 proved costly when no deal materialised. This time, our focus is firmly on building a sustainable business capable of standing on its own, while remaining open to collaboration if the opportunity arises.

Our US strategy will be driven by science and data. What was once perceived as a limitation has become a key differentiator. Unlike anti-TNFs, anti-IL-23s, or the newer anti-TL1A antibodies, all of which target single inflammatory pathways, obefazimod enhances miR-124, a natural regulator of immune balance that modulates several cytokines simultaneously, including IL-6, IL-17, and TNF-Î±.

This broad regulatory effect promotes more durable efficacy and reduces the risk of loss of response over time.

US real-world data highlights the need for such innovation; only about five percent of patients remain on existing treatments after three years due to declining efficacy or adverse events (ECCO 2025 - ABVX abstract). In contrast, obefazimod long-term data from roughly 100 patients, followed between four and up to six years, show markedly lower discontinuation rates and around 90% remission among those continuing therapy. These results underscore the enduring benefit of obefazimod and its potential to redefine standards of care in inflammatory bowel disease.

How do you plan to demonstrate the cost-effectiveness and broader healthcare value of obefazimod?

Cost efficiency is an increasingly important part of any therapeutic discussion, and with obefazimod, we aim to demonstrate both medical and economic value. For patients who are difficult to treat, avoiding surgery alone represents a major saving, but the broader impact comes from reducing the cycle of treatment switching that characterises current care. Each interruption leads to flares, hospital visits, and time away from work, adding pressure on patients and healthcare systems alike.

Our goal is to show that after one year of treatment, obefazimod can deliver measurable cost savings through fewer interventions, lower hospitalisation rates, and improved productivity. Alongside strong clinical outcomes, we are developing a robust pharmacoeconomic rationale to support pricing and reimbursement, a necessary step given the roughly USD 3 billion investment required to bring the therapy to market.

At a time of heightened debate over drug pricing and the perception that the United States shoulders much of the cost of medical innovation, Abivax strives to be a model of sustainable value creation. The key challenge for Europe and other markets will be recognising the innovation, risk, and investment underpinning this breakthrough. Failing to do so could result in a therapy that wins approval yet remains unreimbursed, limiting patient access despite its proven benefits.

What structural changes are needed to strengthen Franceâ??s biotech ecosystem and global competitiveness?

France has world-class science, a strong clinical network, and an innovation-friendly environment supported by public initiatives such as Bpifrance, R&D tax incentives, and reduced social charges for innovative enterprises and startups *(entreprises innovantes)*. These mechanisms make the country highly effective in nurturing early-stage research and company creation.

However, the real bottleneck appears beyond Phase I, when biotechs require substantial capital to scale. Late-stage financing remains limited compared to the United States, forcing many companies to look abroad. While leading investors like Sofinnova Partners, Jeito Capital, and Andera Partners, for example, play a vital role, the ecosystem still lacks the depth of capital and liquidity needed to sustain global ambitions.

A second challenge lies in management experience. Moving from discovery to global development demands a different skill set, one that blends scientific insight with clinical execution, regulatory strategy, and commercial foresight. The US benefits from a deep talent pool built over decades, with hundreds of listed biotechs and a mature operational culture that France is still developing.

At Abivax, we continue to expand our French footprint â?? around 35 employees split between Paris and Montpellier â?? while strengthening our US presence to access this complementary expertise. Our model reflects what Franceâ??s biotech sector must increasingly embrace: pairing scientific excellence at home with the scale, capital, and experience found in global markets.

What leadership lessons from your experience in big pharma have guided your approach at Abivax?

Developing breakthrough medicines requires both deep passion and a high tolerance for risk. Before joining Abivax, I led CinCor Pharma, where we advanced *baxdrostat*, a first-in-class aldosterone synthase inhibitor for treatment-resistant hypertension. Following promising Phase 2 results, the company was acquired by AstraZeneca in 2023, and the programme has since confirmed its potential with positive Phase 3 data.

These experiences reinforced my belief that leadership in biotech is ultimately about de-risking execution, ensuring that rigorous science is translated into real therapeutic value through disciplined implementation. Drug development remains an empirical craft: science sets the direction, but success depends on focus, precision, and the ability to adapt and learn from experience. Too often, teams stumble by trying to do too much or by not understanding their drug deeply enough. In the end, it is clarity of purpose and scientific integrity that drive progress at the frontier of innovation.

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