How Sciensus supported the launch and distribution of a breakthrough therapy in Europe and beyond.

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Sciensus

Overview.

Sciensus has more than 30 years' experience supporting pharmaceutical companies with the launch and distribution of orphan drugs outside the US, providing a customisable, fully managed service.

The client, **US-based Eiger BioPharmaceuticals**, has developed a pioneering therapy for an ultra-rare paediatric disorder that causes rapid ageing and early death.

Using our expertise we designed and implemented a turn-key solution tailor-made to meet the company's needs, from early access to patients in Europe through market authorisation.

The objective.

Reaching patients globally with a first-to-market life-extending therapy.

Studies have shown the **client's innovative treatment** significantly extends the average life expectancy of individuals with this condition.

With no other drug available in Europe, this breakthrough therapy has the power to transform the lives of young people with this debilitating disease.

The company required our support to license and obtain approval for the distribution of its life-extending drug in Europe.

The challenge.

Navigating complex European regulations.

In order to access EU markets, the company not only required EMA approval but also compliance with regulatory and healthcare systems within individual countries in Europe, making it an extremely complex process.

Supporting with the application for an Early Access Program (EAP) - where the healthcare system supports and funds the treatment pre-EMA approval - was key to ensuring the quick and efficient delivery of this drug to patients. However, this was also a challenge as some countries follow EMA guidelines whilst others have their own national systems around early access, or Compassionate Use Programs (CUP).

The solution.

Partnering with Sciensus enabled the company to extend the reach of its pioneering treatment.

Sciensus supported the Client to:

- **Import the product into EU** using its Wholesale Distribution Authorisation (WDA) and Manufacturing and Import License (MIA).
- **Navigate through the complexity of setting up an Early Access Program in France**. This allowed people to benefit from the unlicensed medication.
- **Establish a new EU-based entity** and successfully obtaining EU marketing authorisation.
- **Facilitate the first ocial licenced launch of the drug in Germany** in as little as 4 months following EMA approval.

Delivering the best results for our client.

To enable both companies to continue to deliver the highest level of service to patients, Sciensus provided:

- **A complete tailor-made European infrastructure package** – effectively a 'one stop shop', adapting to any challenges and obstacles that were encountered.
- **A dedicated rare disease account director** who implemented tried and tested governance approach which consists of:
  - Quarterly Business Reviews, face to face with Senior Teams, Operations, Commercial, Finance, Quality and Legal when required.
  - Monthly Team KPI review sessions.
  - Bi-Weekly Quality, Operational, and Customer Service meetings with appropriate individuals.

> Sciensus is our trusted partner of choice: thanks to their international orphan disease market expertise and guidance, we were able to overcome expansion challenges into new markets. Their personalised solutions enabled us to find a viable way to grow our business in Europe and beyond. As a strategic partner, they have exceeded our expectations by finding global patients, who need our drugs, and enabling them to receive their life-extending medications.
>
> Chief Commercial Officer at Eiger BioPharmaceuticals, Inc

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Here are some examples of how our partnership achieved and exceeded Eiger's expectations:

Our multilingual customer service team is fluent in most European languages. This additional level of expertise was highly valued by our client, as it helped facilitate the Early Access Program in France and the licensed launch in Germany.

Sciensus designed a Patient Support Program comprising face-to-face and remote nurse interventions. This provides patients and their caregivers with the knowledge and skills to help them manage their condition and treatment autonomously and more effectively. Our european program is customised to comply with the Clinical and Information Governance regulation which may vary from one conuntry to another.

The client entrusted Sciensus with responsibility for key issues such as processing orders and returns management, as well as customer credit checks and contracts.

Thanks to our knowledge and expertise we were able to take care of tender management in different countries, as well as auditing, and managing all the legal and regulatory requirements.

We offer a range of shipping solutions via our well-established GDP-approved international delivery network. This provides validated routes for both European and international distribution. Orders are shipped using our special goods communication delivery service. This ensures that we overwhelmingly meet our targets for on-time delivery, which, in turn, helps to minimise stock loss.

In addition, we offer a full order to cash service. Once our dedicated team has received an order, we take control of the complete supply process across warehousing, customer communications, delivery and cash collection.

To learn more, visit:

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