

Seda's Integrated Expertise Supports FDA Approval of Emcitate

Clinical pharmacology, biopharmaceutics, pharmaceutical development and advanced analytical science combined to support the development of a treatment for an ultra-rare, predominantly pediatric patient population

Stockport, 05 October 2026: Seda is pleased to have made an important scientific and regulatory contribution to the New Drug Application supporting the US Food and Drug Administration approval of **Emcitate**.

U.S. Food and Drug Administration (FDA) has approved EMCITATE® (tiratricol), a thyroid hormone receptor agonist, for the treatment of peripheral thyrotoxicosis in adults and pediatric patients with monocarboxylate transporter 8 (MCT8) deficiency (Allan–Herndon–Dudley syndrome). EMCITATE is not recommended for the treatment of primary hypothyroidism. EMCITATE is the first FDA-approved treatment option for patients with MCT8 deficiency in the United States. ([Egetis Therapeutics Announces U.S. FDA Approval of EMCITATE® \(tiratricol\) for Patients with MCT8 Deficiency ; FDA Approves First Treatment for MCT8 Deficiency | FDA](#))

Developing medicines for ultra-rare diseases presents distinctive scientific and practical challenges. These become even more complex when the patient population is predominantly pediatric, clinical data are necessarily limited, and the medicine must be suitable for administration to children with a wide range of ages and capabilities.

Seda was uniquely placed to support this program through its integrated model, which brings together world class clinical pharmacology, biopharmaceutics, pharmaceutical development, regulatory strategy and high-end analytical science capabilities. This combination enabled Seda's multidisciplinary team to connect product performance, clinical exposure and real-world administration considerations within a single, coherent development strategy.

Connecting product science with clinical pharmacology

A central element of Seda's contribution was the integration of biopharmaceutics and pharmaceutical development with population pharmacokinetic modelling.

Seda completed a comprehensive **biopharmaceutics risk assessment** and provided scientific input into the design and interpretation of clinical bioavailability and bioequivalence studies and associated pharmacokinetic data. This work helped establish a clear understanding of product performance and its potential relationship with drug exposure.

The clinical pharmacology team developed a **population pharmacokinetic model** using data from single-dose studies in healthy volunteers together with sparse pharmacokinetic samples collected from pediatric patients. This modelling approach generated important insights into pharmacokinetics within the target patient population and provided exposure metrics to support exposure-response analyses and dose justification.

For an ultra-rare disease program, where the collection of extensive clinical data may be neither practical nor ethically appropriate, making the best possible use of every available data point is essential. The combination of modelling, biopharmaceutic understanding and robust analytical science helped translate limited but valuable clinical evidence into meaningful information for regulatory decision-making.

Developing analytical methods for a patient-focused drug product

Many patients with MCT8 deficiency have difficulties with swallowing and therefore receive medicines through enteral feeding tubes. In addition, individual dosing requirements may vary, particularly in growing children. Tablet formulations that are suitable for administration via feeding tubes and can be split into smaller doses provide the flexibility needed to support individualized treatment and dose adjustments.

Seda's laboratory-based pharmaceutical development specialists developed the quality control dissolution method and provided broader dissolution support across the program. This included dissolution assessments to support stability studies.

Seda also participated in the design of and conducted an extensive enteral feeding tube assessment. The work included:

- Identification of suitable administration apparatus and media
- Assessment of dose recovery
- Sedimentation and redispersibility testing
- In Use stability testing under relevant administration conditions

By considering administration requirements alongside product quality, pharmacokinetics and dose selection, Seda helped ensure that the development strategy remained focused not only on regulatory requirements, but also on how the medicine could be used in clinical practice.

Translating complex science into a robust regulatory submission

Seda provided regulatory authoring across key elements of the NDA, including the biopharmaceutics and clinical pharmacology summary modules **2.7.1 and 2.7.2**.

The team also contributed to the instructions for use and provided ongoing regulatory support, including scientific defense of the submission. This required the clear communication of complex and interconnected evidence spanning product performance, pharmacokinetic modelling, dose justification, analytical development and administration through enteral feeding tubes.

Christian Sonesson, PhD, Vice President, Product Strategy & Development at Egetis Therapeutics, commented:

“Seda has been an important scientific partner throughout the development of Emcitate. Their ability to integrate population pharmacokinetic modelling with biopharmaceutics, pharmaceutical development, advanced analytical testing and regulatory authoring was particularly valuable for a program involving an ultra-rare and predominantly pediatric population. The Seda team combined scientific rigor with understanding of the challenges involved in developing a medicine for patients with complex needs.”

Paul Stott, CEO at Seda commented:

“We are proud to have contributed to the successful development of Emcitate. Programs in ultra-rare and predominantly pediatric populations require scientific depth, and close collaboration across disciplines.

Seda's integrated model allowed our clinical pharmacology, biopharmaceutics, pharmaceutical development, analytical and regulatory specialists to work as a single team. By connecting how the product performs with how patients are exposed to the medicine and how it may need to be administered in practice, we were able to generate a more complete and decision-relevant evidence package in partnership with Egetis.

"The approval of a new medicine for an ultra-rare condition is an important achievement for everyone involved, most importantly for patients and their families."

About Seda

Seda supports biotechnology and pharmaceutical companies in the development of new medicines. Its integrated team combines expertise in clinical pharmacology, biopharmaceutics, pharmaceutical development, advanced analytical science, regulatory strategy and drug product supply (GMP manufacture).

By bringing these disciplines together, Seda helps clients understand the relationships between formulation, product performance, drug exposure, dose selection and patient use. This integrated approach is particularly valuable for complex programs, including pediatric medicines, rare and ultra-rare diseases, and products with challenging administration requirements.

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