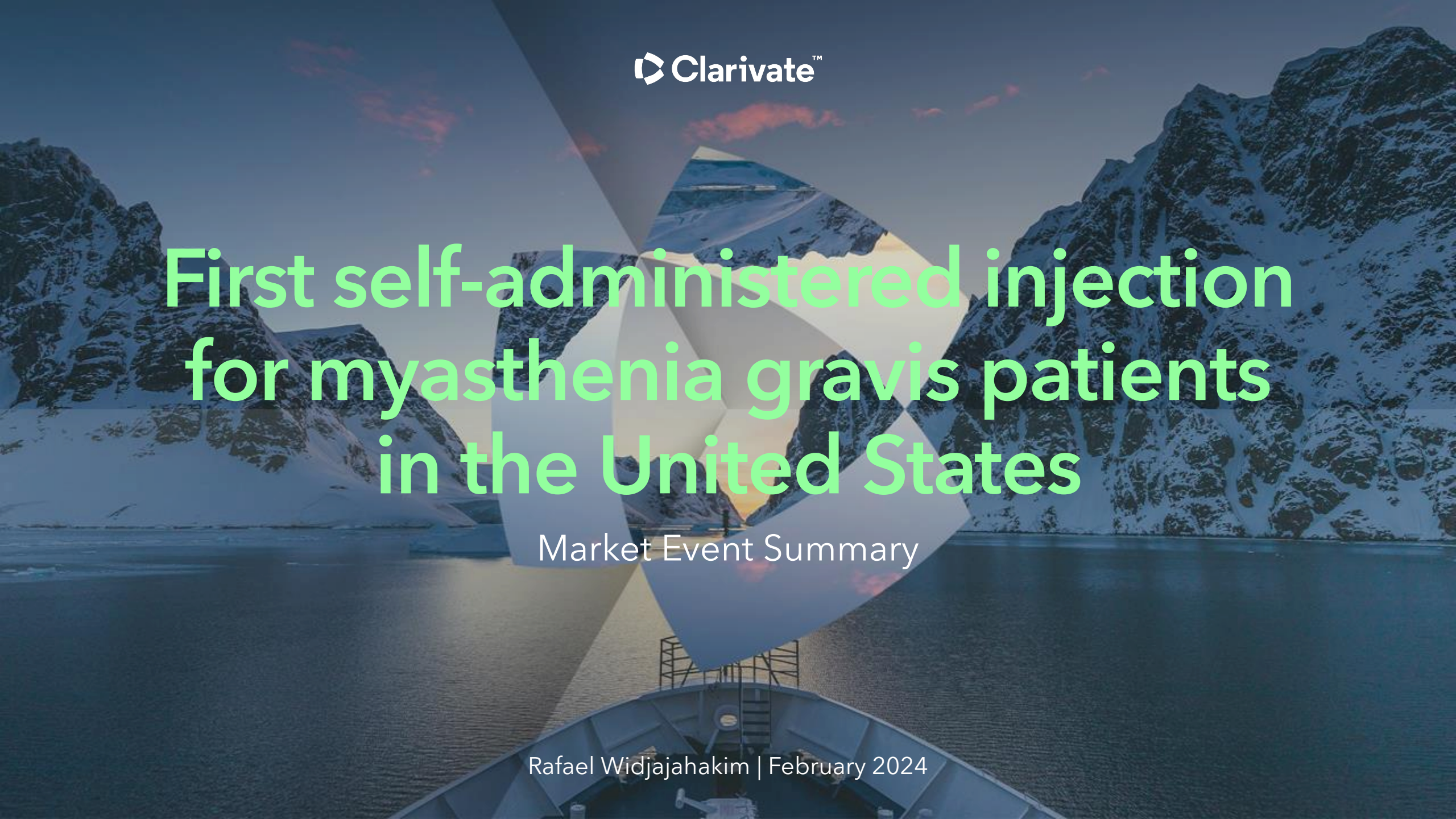


Clarivate™

First self-administered injection for myasthenia gravis patients in the United States

Market Event Summary

Rafael Widjajahakim | February 2024

Addressing myasthenia gravis patients' unmet need

Background and context

- **Zilbrysq**

  In early 2024, UCB's Zilbrysq launched in the United States for myasthenia gravis. It is a small molecule that inhibits the complement pathway, similar to the first biologic approved to treat MG, Alexion's Soliris. Zilbrysq is also approved in the EU and United Kingdom.

  - **Marketing advantage**

    It is marketed as the first and only self-injected drug for MG patients.

A contrast

- **Vyvgart Hytrulo**

  In June 2023, the FDA approved Argenx's Vyvgart Hytrulo, an SC version of the company's IV-administered Vyvgart. The pivotal trial was originally designed with self-administered injection of the drug. However, in the United States, the drug is limited to administration by an HCP. In the EU, it is available as Vyvgart SC with the option for self-administration.

Comparison of MG agents	**Soliris** (eculizumab)	**Vyvgart** (efgartigimod alfa)	**Ultomiris** (ravulizumab)	**Vyvgart Hytrulo** (efgartigimod – hyaluronidase)	**Rystiggo** (rozanolixizumab)	**Zilbrysq** (zilucoplan)
Administration	HCP – IV	HCP – IV	HCP – IV	HCP – SC	HCP – SC	Self - SC
Frequency	2 weeks*	1 week	8 weeks*	1 week	1 week	Daily

* If the agent has a loading dose and a maintenance dose, this table is showing the maintenance dose frequency.

Clarivate's takeaways

Are patients' unmet needs being addressed?

Zilbrysq offers this self-administration flexibility, but access may still be a challenge for some patients.

How does the new ROA impact patients' treatments?

Interviewed U.S. expert sees the new ROA as a benefit for patients; however, a meta-analysis in other indications showed mixed opinion between IV vs. SC,[1] and Zilbrysq is only accessible through UCB's program,[2] thus the impact is still unclear.

Could Zilbrysq's approval lead to more diverse MG drugs?

Multiple companies have agents in the mid- / late-phase pipeline with diverse ROAs that could increase treatment options, but passing through regulatory agencies is still a huge milestone.

1. Overton PM, et al. Patient preferences for subcutaneous versus intravenous administration of treatment for chronic immune system disorders: a systematic review. *Patient Prefer Adherence.* 2021.
2. https://zilbrysqrems.com/, accessed February 15, 2024.

About the Author

Rafael Widjajahakim

Healthcare Research & Data Analyst

LinkedIn:
linkedin.com/in/rafaelwidjajahakim/

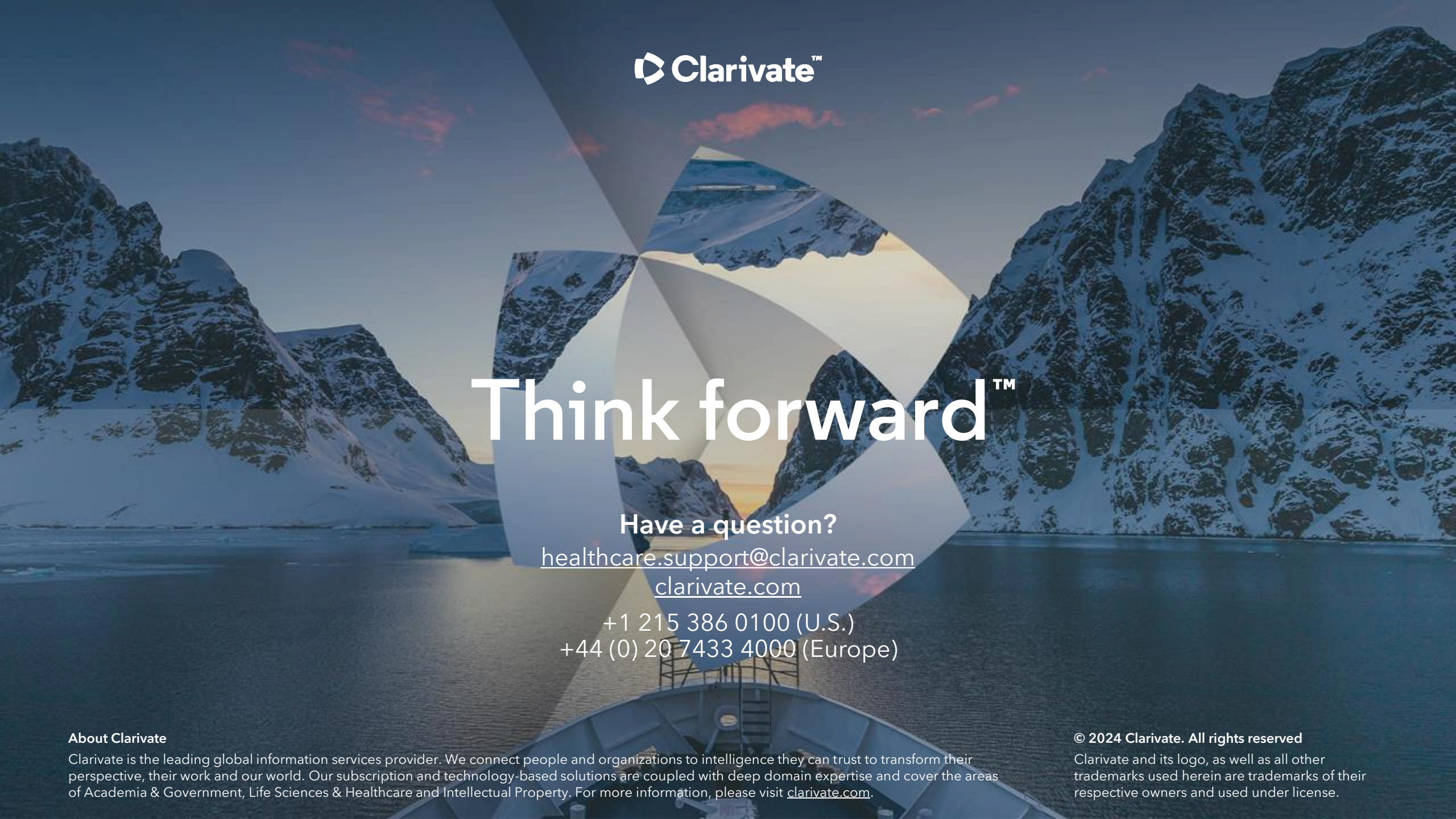
Rafael.Widjajahakim@clarivate.com

Clarivate coverage of myasthenia gravis

- Current Treatment: Physician Insights (US), providing insights on medical practice from surveyed physicians
- Treatment Algorithms: Claims Data Analysis (US), providing details on the treatment journey and brand usage practices based on patient-level claims data
- Epidemiology, with global coverage of diagnosed prevalence data for MG, as well as subpopulation data in select regions
- Executive Insights (US), providing a summary of MG market insights

Author Bio

Prior to joining Clarivate, Mr. Widjajahakim was a clinical research coordinator at the Department of Ophthalmology at University of Massachusetts Medical School. He received his master of science degree in clinical investigation from Boston University and his bachelor of science degree in biology from Suffolk University. As an analyst, he has worked in numerous therapy areas, including rheumatology, neurology, and rare diseases.



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healthcare.support@clarivate.com
clarivate.com

+1 215 386 0100 (U.S.)
+44 (0) 20 7433 4000 (Europe)

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