Rezdiffra – the first drug approved for NASH. What to expect?

Market Event Summary

Manasa Kadagathur, Sayani Datta | March 2024

Rezdiffra, a breakthrough treatment for NASH patients

Key takeaways

- **Status quo**

  Nonalcoholic steatohepatitis (NASH) treatment has been limited to lifestyle changes and the management of comorbidities with anti-obesity, anti-diabetic, and anti-lipidemic medications. The FDA accelerated approval of Madrigal Pharmaceuticals' Rezdiffra (resmetirom) marks the first drug approval for NASH, specifically non-cirrhotic NASH (F2-F3).

- **A new era of NASH treatment**

  The development of therapies aimed at addressing NASH-specific endpoints has been challenging, resulting in the discontinuation of several late-phase agents. Rezdiffra succeeded where others have failed. The lack of other approved drug treatments provides Rezdiffra with a significant commercial opportunity. Its convenient oral route of administration will also support its uptake.

- **Madrigal Pharmaceuticals lays the path in NASH**
  - Rezdiffra's approval showcases a successful regulatory roadmap for emerging NASH therapies.
  - Madrigal Pharmaceuticals announced an annual WAC price of $47,400 for Rezdiffra.

Rezdiffra's performance outlook

If payers require liver biopsy to confirm NASH diagnosis ahead of prescribing Rezdiffra, uptake of the drug will be tempered.

Rezdiffra's outcomes trial, MAESTRO-NASH-OUTCOMES, is due to complete in 2025. Positive results from this trial should support a label expansion to treat compensated cirrhotic patients, thereby expanding Rezdiffra's target population.

Despite having first-mover advantage, the launches of its competitors, starting in 2026, will constrain Rezdiffra's overall market opportunity.

How will the NASH market evolve?

- What impact will the launch of Rezdiffra have on the diagnosis and treatment rates of NASH?
- What challenges will Rezdiffra's clinical profile and its market adoption pose to future NASH drug launches?
- What restrictions will payers implement on the prescribing of high-cost NASH treatments?

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Manasa Kadagathur, M.S. (Pharm.), Ph.D., is an associate healthcare research & data analyst on the *Cardiovascular, Metabolic, Renal, and Hematology* team at Clarivate. Dr. Kadagathur has authored reports on osteoporosis and nonalcoholic steatohepatitis (NASH). She holds an M.S. (Pharm.) degree in medicinal chemistry from the National Institute of Pharmaceutical Education and Research (NIPER) in S.A.S. Nagar, India, and a bachelor's degree in pharmacy from Jawaharlal Nehru Technological University in Hyderabad, India. She earned her Ph.D. in medicinal chemistry from NIPER in Hyderabad, India.

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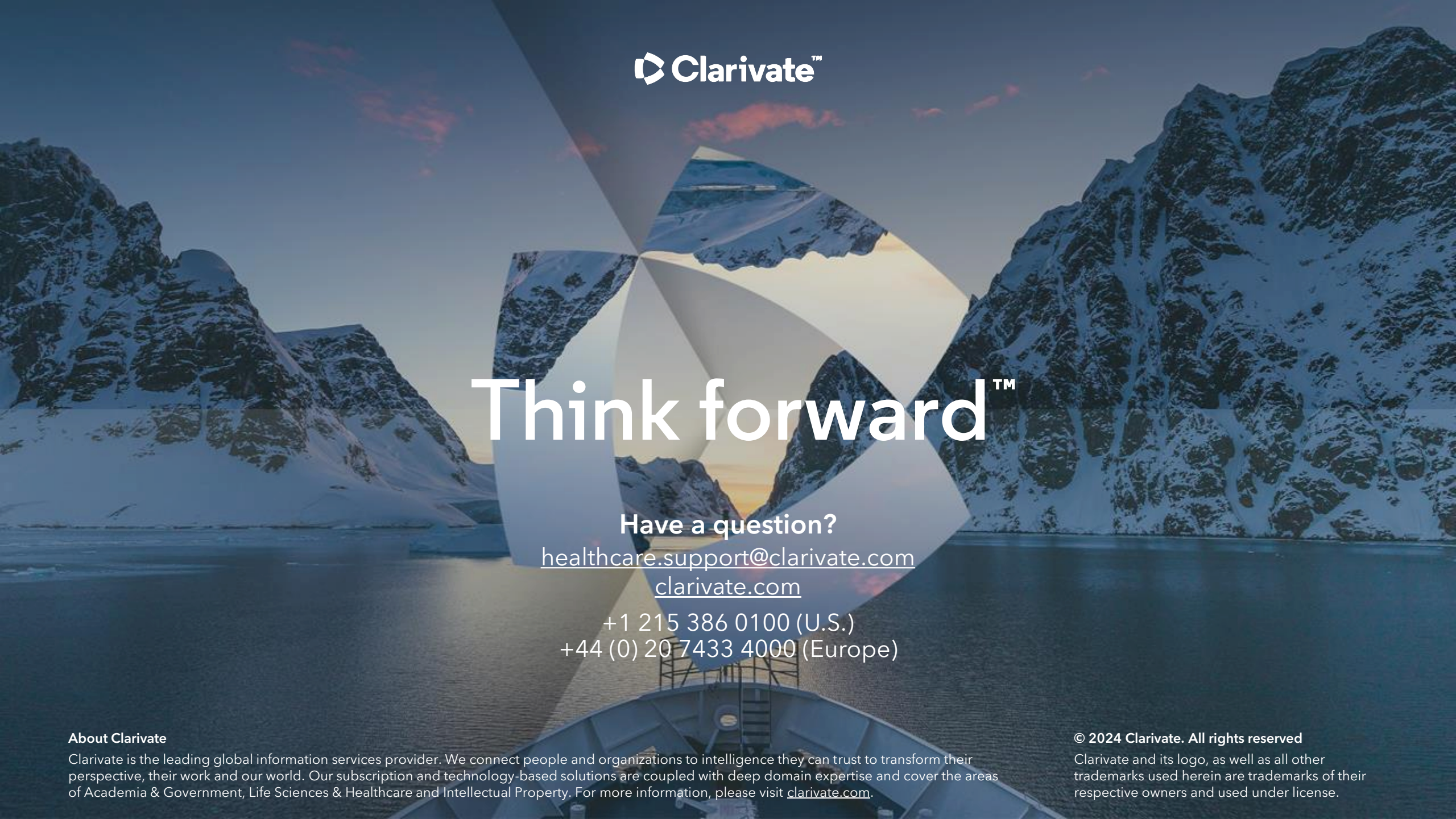
Clarivate coverage of nonalcoholic steatohepatitis (NASH)

- Disease Landscape & Forecast: NASH - G7
- Epidemiology: Diagnosed incidence and prevalence data for various population segments of NASH across the G7 markets and China
- Current Treatment: Physician Insights: US - Explores the current prescribing trends of hepatologists and gastroenterologists treating NASH
- Current Treatment: Treatment Algorithms: US – Explores the current prescribing trends of hepatologists and gastroenterologists treating NASH
- Unmet Need: NASH: US and EU5
- Access and Reimbursement: NASH: US and EU5
- Geographic Focus – China: NASH - China



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