

# GLOBAL REGULATORY PARTNERS SUPPORTS ANVISA APPROVAL OF ORPHAN THERAPY BEYONTTA® IN BRAZIL

Waltham, MA & São Paulo, Brazil | May 4, 2026

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Global Regulatory Partners ("GRP") announced the successful ANVISA approval of Beyontra® (acoramidis) in Brazil, achieved through its role as the local regulatory representative and Marketing Authorization Holder (MAH).

Developed by BridgeBio Pharma, Beyontra® is indicated for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM), a rare, progressive, and life-threatening cardiac condition. The product has been granted orphan drug designation in Brazil, highlighting its importance in addressing unmet medical needs for patients with rare diseases.

## Enabling Market Access Through Local Regulatory Expertise

In Brazil, regulatory approval requires a locally established legal entity to hold the marketing authorization and interface directly with ANVISA. Through its Brazilian entity, Global Regulatory Partners fulfilled this requirement, enabling a compliant and efficient pathway to approval.

- ✓ Acted as the local legal and regulatory representative in Brazil.
- ✓ Managed the regulatory submission and ongoing engagement with ANVISA.
- ✓ Ensured compliance with all Brazilian regulatory requirements.
- ✓ Supported ANVISA GMP inspections.

*"This approval underscores the importance of strong local regulatory expertise in enabling access to innovative therapies," said Suzan Davis, Chief Executive Officer of Global Regulatory Partners. "We are proud to support companies bringing critical treatments to patients with rare diseases through compliant and efficient regulatory pathways."*

## About Global Regulatory Partners

Global Regulatory Partners is a global regulatory affairs and market access organization enabling pharmaceutical, biotechnology, MedTech, and consumer product companies to navigate complex regulatory pathways throughout the product lifecycle. GRP provides integrated, end-to-end regulatory and compliance capabilities, including local representation and quality oversight, supporting efficient and compliant global market entry across key global markets.