

Kedrion Biopharma receives FDA approval for QIVIGY® and confirms its plan to increase investments in the US throughout its global operations

Kedrion Biopharma announced today that it has received **FDA approval for QIVIGY®**, a new 10% Immunoglobulin for intravenous use, indicated for treatment of adults with Primary humoral Immunodeficiency (PI), a serious and often underdiagnosed group of disorders that compromise the immune system's ability to function effectively. This 10% IVIG therapy, developed in Kedrion's research labs and produced exclusively by Kedrion through its globally integrated network of facilities in the United States and Italy, addresses the unmet needs of patients with PI.

Ugo Di Francesco, Kedrion's Chief Executive Officer commented: "Seeing QIVIGY® receive FDA approval is a deeply meaningful moment for all of us at Kedrion. This achievement is the result of years of vision, planning, and relentless dedication from countless employees, both current and previous." Di Francesco went on to add: "It reflects not only our scientific and operational capabilities, but also the heart and purpose that drive our mission to serve patients. Today, we celebrate two success stories: one in the delivery of a product that helps improve patient care and another that defines us as an organization, demonstrating our ability to deliver while also illuminating the path ahead."

The clinical study outcomes showed that patients on this treatment can expect fewer infections and less time away from school and work. Kedrion's commitment to addressing these critical lifestyle needs is what drives us at our core.

The product will be launched in the US first, with plans for global expansion in Europe and other markets upon approval. This growth will be possible thanks to the strength of Kedrion's supply chain infrastructure and the expansion of its distribution network, ensuring greater access for patients and providers across global markets. The new therapy is expected to be available in the US in early 2026.

Primary Immunodeficiency Disorders (PID) encompass more than 550 rare, chronic disorders in which components of the immune system are either missing or impaired, leaving individuals highly susceptible to recurrent infections, autoimmune complications, and other serious health challenges.

An estimated 500,000 people in the US are currently living with PID, though the true number may be significantly higher due to underdiagnosis and / or misdiagnosis. According to the Immune Deficiency Foundation (IDF), Primary Immunodeficiencies may affect as much as 1 to 2% of the population when all types and variations are considered, highlighting the urgent need for greater awareness, earlier detection, and expanded access to effective therapies.

"2025 has been a year of meaningful transformation for Kedrion, and this new therapy marks a pivotal accomplishment. As our first product approval since rebranding in April, it reflects the company that we are becoming, more focused, more connected, and more committed to patients. We're evolving with purpose, raising awareness, and bringing our values to life. This is just a step along a journey toward something great, and I'm excited to be a part of it, to

celebrate this occasion, and to begin working on our next endeavor.” said **Bob Rossilli, Global Chief Commercial Officer and US General Manager.**

With this new product, we are adding another IVIG treatment option for patients and healthcare providers to our broad suite of therapies designed to meet the diverse needs of patients. QIVIGY® holds a distinct position in our growing portfolio as a brand to be developed from concept to commercialization exclusively by us. It will join our existing global portfolio of 38 products across various therapeutic areas. This achievement demonstrates the depth and breadth of Kedrion’s growing capabilities from manufacturer to researcher, developer and branded innovator.

Kedrion’s commitment to its Global and US infrastructure as well as lifecycle management for this new product includes ongoing research and development activities aimed at identifying new opportunities to meet the unmet needs of broader patient populations with rare immunological and neurological conditions, as well as **long-term investments in manufacturing facilities and capacity expansion** to support growth. Kedrion’s financial commitment to this product encompasses every phase of its production, starting from increasing its US plasma collection network by investing over \$260 million in developing over 40 new US collection centers over the next several years. As plasma collection efforts accelerate, manufacturing capacity must keep pace. To support this growth, Kedrion is planning to invest over \$60 million in capacity expansion projects in the US at its Melville, New York manufacturing facility, while simultaneously expanding capacity globally. In addition, Kedrion is investing an additional \$80 million to be spent on IT infrastructure and clinical studies as well as over \$15 million to launch this new product in the US.

“Kedrion’s commitment to global growth with a specific focus on the US is impressive and doesn’t stop with this new therapy. Kedrion will continue to grow its new product development programs, with significant capex investments over the next few years. Our strategic direction is to continue expanding in the United States to meet the growing demand for rare disease therapies,” said **Bob Rossilli.**