Press Release
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Terumo Blood and Cell Technologies Supports Expanded Access to Rare Disease Therapies in Latin America

- *Regulatory approvals in 14 countries expand treatment options for sickle cell disease, Guillain-Barré syndrome and myasthenia gravis*
- *Approvals align with the historic World Health Assembly resolution on rare diseases*

LAKEWOOD, Colo., USA - September 16, 2025 – In a significant step toward expanding treatment access for people with rare and chronic diseases in Latin America (LATAM), Terumo Blood and Cell Technologies (Terumo BCT), a global medical technology company, today announced that its Spectra Optia™ Apheresis System has received regulatory approvals for new therapeutic indications in 14 countries across the region.

The newly approved treatment indications include sickle cell disease (SCD), Guillain-Barré syndrome (GBS) and myasthenia gravis (MG) — offering clinicians a vital tool in managing these debilitating conditions through automated red blood cell exchange (aRBCX) and therapeutic plasma exchange (TPE).

Global vision, local impact

"Proven therapies are now within reach for thousands of people living with rare and often life-threatening conditions," said Antoinette Gawin, President and CEO, Terumo Blood and Cell Technologies. "These approvals matter — they are a step toward clinical inclusion, establishing a new standard of care in the region and broader health equity."

She added, "And our work isn't done; our goal is to ensure these therapies are not limited to a few, but integrated into clinical guidelines and hospital protocols and covered by insurance systems."

A call to action from the WHA resolution

This announcement follows the historic adoption of the first-ever World Health Assembly (WHA) resolution on rare diseases, passed on May 25, 2025. The WHA is the main decision-making body of the World Health Organization (WHO) and comprises 194 member states. The resolution calls to strengthen efforts around early diagnosis, equitable access and treatment innovation for people living with rare diseases.

Terumo BCT's newly approved therapy indications across Latin America align with this vision — opening new clinical possibilities for underdiagnosed and underserved patient populations in Argentina, Bolivia, Brazil, Chile*, Colombia, Costa Rica, Dominican Republic, Ecuador, El Salvador, Guatemala, Mexico, Panama, Paraguay, Peru and Uruguay.

The approvals, granted by health authorities across LATAM, are based on clinical evidence demonstrating how aRBCX and TPE are safe and effective in helping manage the diseases [1, 2, 3].

About the diseases — the human impact of SCD, GBS and MG

- **Sickle cell disease (SCD):** A genetic blood disorder that causes red blood cells to become sickle-shaped, leading to vaso-occlusion, causing severe pain episodes and other serious complications. Automated red blood cell exchange is a procedure where sickled cells are replaced with healthy ones using an apheresis system, which helps reduce episodes of pain and complications related to the disease [3]. It is estimated that in Brazil alone, there are 60,000 to 100,000 patients with SCD [4].
- **Guillain-Barré syndrome (GBS):** A rare autoimmune neurological disorder in which a person's immune system attacks part of their peripheral nervous system — the network of nerves that carries signals from the brain and spinal cord to the rest of the body. Symptoms include weakness in the body, numbness, or paralysis, which in the worst form could be life-threatening. Guillain-Barré syndrome is not contagious or inherited, and the exact cause is unknown. There is no known cure for GBS, though immunotherapy can ease symptoms and help speed recovery. TPE removes the plasma containing antibodies from the patient's blood and replaces it with healthy plasma. Considering the reported incident rates, it can be estimated that there are between 7,234 and 11,837 cases of GBS in Latin America per year [5,6].

- **Myasthenia gravis (MG):** A chronic neurological disorder that causes muscle weakness. Approximately 15 to 20% of people with MG experience at least one myasthenic crisis in their life — a state where the muscles that control breathing weaken to the point where a ventilator is needed [7]. Myasthenia gravis is managed with medications and lifestyle changes; however, in more severe cases where rapid response is needed, intravenous immunoglobulin or TPE is used. Worldwide incidence of MG is estimated at over 700,000 people (three to 28 cases per million people) [2].

*Chile is not regulated for these types of medical devices, visit the Instituto de Salud Publica for more information https://www.ispch.cl/andim/listado-de-dispositivos-medicos-establecimientos-y-empresas/dispositivos-medicos-con-registro-sanitario/

About Terumo Blood and Cell Technologies

Terumo Blood and Cell Technologies is a medical technology company. Our products, software and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees worldwide believe in the potential of blood and cells to do even more for patients than they do today. This belief inspires our innovation and strengthens our collaboration with customers.

Terumo Blood and Cell Technologies' customers include blood centers, hospitals, therapeutic apheresis clinics, cell collection and processing organizations, researchers and private medical practices. Our customers are based in over 150 countries across the globe. We have 750+ granted patents, with more than 150 additionally pending.

We have global headquarters in Lakewood, Colorado, U.S.A., along with five regional headquarters, eight manufacturing sites and six innovation and development centers across the globe. Terumo Blood and Cell Technologies is a subsidiary of Terumo Corporation (TSE: 4543), a global leader in medical technology.

Spectra Optia™ Apheresis System

The Spectra Optia system is a user-friendly, versatile, industry-leading therapeutic apheresis, cell processing and cell collection platform that allows operators to spend more time focusing on patient care. Therapeutic apheresis is used widely for a variety of applications. For example, practitioners use red blood cell exchange (RBCX) for sickle cell disease treatment; cell collections for stem cell transplantations and to collect starting material for cell therapies; and therapeutic plasma exchange (TPE) to treat a variety of blood and neurological disorders.

Product and protocol availability varies by country based on regulatory approvals.

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