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Korea's Samsung Bioepis enters into landmark 10-Year agreement to supply Eculizumab to Brazil

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Samsung Bioepis to contribute to the growth of Brazilâ??s biopharmaceutical industry through technology transfer and local manufacturing



South Korea-based Samsung Bioepis has announced a landmark 10-year agreement with its local partners in Brazil—state-level public laboratory Bahiafarma and local pharmaceutical leader Bionovis, to supply its eculizumab biosimilar, SB12, to Brazil's universal public health system, the Sistema Único de Saúde (SUS).

Formed under Brazil's strategic Productive Development Partnership (PDP) framework, this milestone agreement expands Samsung Bioepis's footprint in Latin America's largest biopharmaceutical market.

The PDP model is one of the key drivers of Brazil's national health strategy, designed to enhance the sustainability of the SUS. Introduced by the Brazilian government in 2008, the PDP scheme supports the growth of the country's pharmaceutical industry by facilitating technology transfer from established companies in return for guaranteed purchases from the SUS.

Brazil's Ministry of Health (MoH) has been expanding the PDP initiative to include rare diseases to increase local production and expand access for rare disease patients who often face limited treatment options and costly care.

The incorporation of SB12 directly addresses a significant budgetary and public health challenge. Eculizumab represents the single highest-expenditure specialty medicine for the MoH, with annual public spending exceeding BRL 947 million (approximately $171 million) in 2025 alone. By delivering a clinically equivalent, cost-effective biosimilar, the 10-year PDP enables the MoH to alleviate severe budgetary strain and explore expanding access for patients who previously faced barriers to care. Currently, the reference eculizumab is covered by the SUS for only one of its approved indications: Paroxysmal Nocturnal Hemoglobinuria (PNH).

Under the PDP, Samsung Bioepis will supply the finished product to its local partners for sale to the SUS over a 10-year period from 2027. During this period, Samsung Bioepis will provide technology transfer so that manufacturing responsibilities can be gradually transferred to its local partners, enabling local manufacturing in Brazil.

SB12, Samsung Bioepis's eculizumab, was approved by Brazil's Health Regulatory Agency (Agência Nacional de Vigilância Sanitária, ANVISA) as a biosimilar to Soliris in December 2024. It is indicated for the treatment of adults and children with PNH and atypical hemolytic uremic syndrome (aHUS).