

US FDA approves Taiwan-based PharmaEssentia's BESREMi® to treat rare blood disorder

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BESREMi has been approved for adults with essential thrombocythemia, regardless of genotype or disease status



PharmaEssentia USA Corporation, a subsidiary of Taiwan-based PharmaEssentia Corporation, has announced that the US Food and Drug Administration (FDA) has approved BESREMi® (ropeginterferon alfa-2b-njft) for the treatment of adults with essential thrombocythemia (ET), making it the first new FDA-approved treatment for ET in nearly three decades.

BESREMi has been approved for adults with ET, regardless of their genotype or disease status, including newly diagnosed patients who are naive to cytoreductive therapy. The ET approval expands the BESREMi product label, which has been commercially available for the treatment of adults with polycythemia vera (PV).

This approval marks a major milestone for people living with ET, a rare chronic blood cancer characterised by an overproduction of platelets. The approval of BESREMi provides a new ET treatment option and offers the potential for durable disease control, addressing a longstanding unmet need in ET care.

BESREMi is a long-acting interferon-based therapy designed to provide sustained disease management for ET. It offers a differentiated treatment option compared with current therapies that primarily focus on controlling platelet counts and symptoms, with limited impact on the underlying disease biology. Using novel monopegylation technology and an extended half-life, BESREMi is designed to target disease-driving cells in the bone marrow while reducing elevated platelet counts and disease burden.