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Pfizer Secures FDA Approval for Expanded Hympavzi Use in Hemophilia

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The expanded indication includes pediatric patients aged six and above and patients with inhibitors, broadening access to once-weekly subcutaneous prophylaxis.



Pfizer has received US FDA approval for an expanded indication of Hympavzi for hemophilia A or B, broadening its use to more patient groups with significant treatment needs.

The approval now includes patients aged 12 years and older with inhibitors, as well as pediatric patients aged six to 11 years with or without inhibitors. Hympavzi is now indicated for routine prophylaxis to prevent or reduce bleeding episodes in adults and pediatric patients aged six years and older with hemophilia A or B, with or without inhibitors.

This matters because hemophilia is typically diagnosed in childhood and affects more than 800,000 people worldwide. Repeated bleeding can damage joints, and children are particularly vulnerable because their cartilage and bones are still developing.

Hympavzi is a once-weekly subcutaneous non-factor therapy that targets tissue factor pathway inhibitor. This differentiates it from traditional factor replacement therapies, which can be burdensome and may become less effective in patients who develop inhibitors.

The expanded approval was supported by Phase 3 BASIS data, where Hympavzi significantly reduced mean treated annualised bleeding rate by 93 percent compared with on-demand intravenous bypassing agents. BASIS KIDS data also supported use in children aged six to 17 years.

However, adoption will depend on physician confidence, payer coverage, long-term safety monitoring and how families view once-weekly prophylaxis compared with existing treatment routines. The label also includes safety considerations such as thromboembolic events and hypersensitivity.

The approval strengthens the movement toward simpler prophylactic options in hemophilia care. For patients and caregivers, treatments that reduce bleeding risk while lowering administration burden may have a meaningful impact on long-term disease management.