



FDA approves PTC Therapeutics' SEPHIENCE (sepiapterin) for the treatment of phenylketonuria (PKU) in children and adults

*( FDA, Approval )*



FDA approves Novartis' twice-yearly LEQVIO (inclisiran) for new first-line monotherapy use in adults with high cholesterol

*( FDA, Approval )*



Novo Nordisk's ALHEMO receives expanded FDA approval as a once-daily subcutaneous prophylactic for hemophilia A or B without inhibitors

*( FDA, Approval )*



FDA approves Apellis' EMPAVELI (pegcetacoplan) as the first C3G and primary IC-MPGN treatment for patients 12 and older, demonstrating significant efficacy

*( FDA, Approval )*





*( sBLA submission, FDA )*  
Johnson & Johnson files with FDA to highlight TREMFYA (guselkumab) as the sole IL-23 inhibitor demonstrating significant inhibition of joint structural damage in psoriatic arthritis



*( FastTrack, FDA )*  
FDA grants Fast Track designation to rezpegaldesleukin for severe alopecia areata, aiming to accelerate development for adults and children 12 and older



*( Orphan Drug, Clinical Trials )*  
Kedrion Biopharma's Coagadex secures FDA Orphan Drug Designation and "Study may proceed" letter to evaluate efficacy and safety in acquired Factor X deficiency



*( FDA, FastTrack )*  
Revalesio's RNS60, an oxygen-supersaturated saline, receives FDA Fast Track designation for the treatment of acute ischemic stroke, aiming to protect brain tissue





*( Collaboration )*  
Boehringer Ingelheim and Re-Vana Therapeutics form strategic collaboration to develop first-in-class extended-release therapies for eye diseases, with potential for over \$1 billion



*( Collaboration, Agreements )*  
GSK secures a license for potential best-in-class PDE3/4 inhibitor (HRS-9821) and options for 11 additional programs through a new strategic agreement with Hengrui Pharma in key therapeutic areas

