

# Highlights from the Week of June 03-09, 2025



The EMA has granted Orphan Drug Designation to Spinogenix's SPG302, the first therapy aimed at regenerating synapses in patients with ALS

*( ALS, OrphanDrug, EMA, Rare Disease )*



ascletis

Denifanstat (ASC40), Ascletis's oral FASN inhibitor for acne, meets all primary and secondary Phase 3 trial endpoints, demonstrating up to 178% higher efficacy than standard treatments like sarecycline and doxycycline

*( Dermatology, Phase3 )*



FDA grants a third approval to Bayer's NUBEQA for advanced prostate cancer, supported by Phase 3 ARANOTE trial results, enabling its use in mHSPC with ADT, with or without docetaxel

*( FDA, Approval )*

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*Johnson & Johnson*

Johnson & Johnson leads with the first PARP inhibitor combination to enhance outcomes in HRR-mutated mCSPC, as Phase 3 AMPLITUDE study results show AKEEGA® significantly delays disease progression and symptom worsening

*( PARP inhibitor )*

Innovent

Innovent's IBI363, a first-in-class PD-1/IL-2 $\alpha$ -bias bispecific antibody, has received its second BTB from the NMPA for sqNSCLC, further building on its global regulatory recognition and expanding its reach in hard-to-treat tumors

*( Breakthrough Therapy, NMPA )*

**YolTech**  
THERAPEUTICS

YolTech Therapeutics has announced that the FDA has approved its Investigational New Drug (IND) application for YOLT-101, as in vivo base editing therapy intended for the treatment of heterozygous familial hypercholesterolemia (HeFH)

*( FDA )*