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Highlights from the Week of 25th August 2025 to 1st Septmeber 2025

Eisai, Biogen *(FDA, Approval)*

FDA approved LEQEMBI IQLIK for weekly at-home maintenance in early Alzheimer's ahead of October 2025 launch

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Amgen *(FDA, Approval)*

FDA expanded the approval for REPATHAl to include adults at risk of cardiovascular events from uncontrolled LDL-C without prior heart disease

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Sanofi *(FDA, Approval)*

Sanofi's WAYRILZ becomes the first FDA-approved BTK inhibitor for persistent or chronic ITP after LUNA 3 success

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Pfizer, BioNTech *(FDA, Approval)*

Pfizer and BioNTech's COMIRNATY LP.8.1 has been approved by the FDA for adults aged 65 and older, as well as high-risk individuals aged 5 to 64, to prevent severe COVID-19

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Novavax

(FDA , Approval)

Novavax's Nuvaxovid 2025-2026 formula approved in U.S. as only protein-based COVID-19 vaccine for seniors and high-risk individuals

Foresee Pharmaceuticals

(FDA , Approval)

Foresee Pharmaceuticals' Camcevi ETM approved by FDA as 3-month leuprolide LAI for advanced prostate cancer, following 97.9% testosterone suppression

Outlook Therapeutics

(FDA , CRL)

FDA issued complete response letter for Outlook Therapeutics' ONS-5010 wet AMD BLA over efficacy concerns

INOVIO

(BLA , Rolling Submission)

INOVIO is on track to file BLA for INO-3107 in adults with RRP in H2 2025, following FDA concurrence on rolling submission

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D3 Bio

(FDA, Breakthrough Therapy Designation)

D3 Bio's D3S-001 received FDA breakthrough therapy designation in KRAS G12C-mutant NSCLC and orphan drug status for KRAS G12C-mutant CRC

TOLREMO Therapeutics

(FDA , Fast Track Designation)

TOLREMO secured FDA Fast Track designations for TT125-802 in EGFR-mutated and KRAS-G12C NSCLC after prior therapy failure

BioArctic, Novartis

(Collaboration)

BioArctic's third BrainTransporter partnership with Novartis brought in $30 million upfront, with the potential for royalty income tied to a future neurodegeneration therapeutic

BioXcel Therapeutics

(Phase 3, Results)

BXCL501 met primary endpoint with no tolerability-related discontinuations in Phase 3 study, paving way for BioXcel's sNDA submission in Q1 2026

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Vor Bio

(Phase 3, Results)

Vor Bio and RemeGen report telitacicept met primary endpoint in IgAN Phase 3 trial, reinforcing its potential for multiple autoimmune conditions

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Eli lilly and company

(Phase 3, Results)

Lilly's oral GLP-1, orforglipron, met its primary and key secondary endpoints in the Phase 3 ATTAIN-2 obesity trial in patients with type 2 diabetes

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Regeneron

(Phase 3, Results)

Regeneron plans U.S. regulatory filing in early 2026 after cemdisiran achieves 2.3-point MG-ADL gain in gMG Phase 3 trial

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AstraZeneca

(Phase 3, Results)

AstraZeneca's baxdrostat cuts systolic blood pressure by 9.8 mmHg placebo-adjusted in Phase 3 BaxHTN trial in hard-to-control hypertension