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Highlights from the Week of
July 14 - 21, 2025

Nanoscope Therapeutics

(Rare Disease, Eye Disease)

Nanoscope Therapeutics starts rolling BLA submission to the FDA for MCO-010, the first gene-agnostic therapy for retinitis pigmentosa

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Praxis

(Breakthroughs, Epilepsy)

Praxis's relutrigine has been granted FDA breakthrough status for the treatment of SCN2A- and SCN8A-associated developmental epileptic encephalopathies

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Illimis Therapeutics

(Financing, Drug Development)

Illimis Therapeutics has successfully completed a 58 billion KRW ($42 million) Series B financing round to accelerate its drug development efforts for CNS and immune diseases using its GAIA platform

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Endeavour BioMedicines

(Orphan Drugs, Pulmonary Fibrosis)

Endeavor BioMedicines receives orphan drug designation from the FDA and European Commission for taladegib (ENV-101) in the treatment of idiopathic pulmonary fibrosis

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Genascence

(Gene Therapy, Arthritis)

The FDA grants RMAT designation to Genascence's GNSC-001 for knee osteoarthritis, a first-in-class gene therapy designed to provide long-term IL-1 inhibition with a single intra-articular injection

Amphix Bio

(Orphan Drugs, Spine)

Amphix Bio receives FDA orphan drug designation for AMFX-200 to treat acute spinal cord injury

Cycle Pharmaceuticals

(Launches, Treatment)

First and only FDA-approved AKU therapy HARLIKU™ (nitisinone) goes live in the U.S., launched by Cycle Pharmaceuticals

Daiichi Sankyo

(Breakthroughs, Oncology)

The FDA awards Breakthrough Therapy designation to ENHERTU plus pertuzumab in first-line HER2-positive metastatic breast cancer

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GSK

(Vaccines, Prophylaxis)

The FDA approves GSK's Shingrix in a prefilled-syringe presentation, simplifying administration for shingles prevention

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Bio-Thera Solutions

(Biosimilar, Simponi)

The FDA has accepted the BLA for BAT2506, Bio-Thera's proposed biosimilar to SIMPONI, for multiple autoimmune indications

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Johnson & Johnson

(FDA Priority Review, Bladder Cancer)

The FDA grants priority review to TAR-200, Johnson & Johnson's new treatment for BCG-unresponsive high-risk NMIBC

Viatris

(Clinical Trial, Results)

Viatris fails to meet the debris-resolution endpoint in the Phase 3 MR-139 blepharitis trial and will reassess development strategy

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Roche *(FDA CRL, DLBCL)*

The FDA issues CRL for Columvi in earlier DLBCL, faulting low U.S. enrollment and regional efficacy gaps

Bayer *(FDA Approval, Finerenone)*

The FDA approves Bayer’s finerenone (KERENDIA) for heart failure with preserved or mildly reduced ejection fraction (LVEF ≥40%)

AstraZeneca *(Clinical Trial, Results)*

AstraZeneca’s baxdrostat met all endpoints in the Phase 3 BaxHTN trial for uncontrolled or treatment-resistant hypertension

Genentech *(Columbia, FDA CRL)*

Genentech’s supplemental BLA for Columvi plus GemOx in R/R DLBCL receives FDA CRL over insufficient U.S. STARGLO data