Highlights from the Week of June 10–16, 2025

VYUHPHARMA

(SCLC, FDA,Priorityreview)

Jazz Pharmaceuticals

FDA grants priority review to Zepzelca and Atezolizumab combo as a first-line maintenance for extensive-stage SCLC

(FDA, NSAID)

azurity pharmaceuticals

FDA approved Azurity's XIFYRM injection for the treatment of moderate-to-severe adult pain

(FDA, Expanded indication)

abbvie

MAVYRET by AbbVie has become the first and only FDA-approved treatment for acute HCV following an expanded indication

(FDA , ODD)

Vascarta

Vascarta's Vasceptor has secured FDA Orphan Drug Designation for treating sickle cell disease

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VYUHPHARMA

(FDA , Fast Track Designation)

Sumitomo Pharma America's NUVISERTIB has been granted FDA Fast Track Designation for Myelofibrosis

(FDA, RSV Vaccine)

Moderna's mRESVIA receives FDA approval to prevent RSV in adults aged 18–59 at higher risk

(FDA , HNSCC)

KEYTRUDA receives FDA approval for PD-LI+ resectable locally advanced HNSCC: Neoadjuvant, followed by adjuvant with radiotherapy and then as monotherapy

(FDA, Oncology)

ZUSDURI by UroGen becomes the first FDA-approved intravesical therapy specifically indicated for recurrent low-grade intermediate-risk NMIBC

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(FDA)

FDA accepts Innoviva Specialty Therapeutics' NDA for zoliflodacin, a first-in-class oral antibiotic for uncomplicated gonorrhea

(NICE guidance)

Galderma's NEMLUVIO (nemolizumab) has been recommended by NICE for moderate-to-severe atopic dermatitis in England and Wales

(FDA, Oncology)

FDA approves tablet formulation of BeOne's BRUKINSA for all previously approved indications, expanding dosing flexibility for patients

(FDA , Targeted therapy)

Nuvation Bio's IBTROZI secures FDA approval as an oral precision therapy for ROS1-positive advanced non-small cell lung cancer

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(Phase 3, Results)

Sotyktu has mets its primary endpoints in the POETYK PsA-1 Phase 3 trial, with Bristol Myers Squibb highlighting its superiority over placebo in adults with psoriatic arthritis

(Parkinsons disease, Phase 3)

Roche announces its plans to initiate Phase 3 trials of prasinezumab for patients with early-stage Parkinson's disease

(FDA, PediatricCare)

Celltrion announces FDA approval of an additional presentation of STEQEYMA, which expands dosing flexibility for pediatric patients

(Phase3)

Novo Nordisk initiates Phase 3 clinical development of amycretin for weight management, available in both oral and injectable forms

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(FDA , IND)

FDA approves the IND application for Myrio's lead candidate, PHOX2B PC-CAR T therapy, intended for the treatment of neuroblastoma

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