

Highlights from the Week of October 21-27, 2025



Bayer's LYNKUET
(elinzanetant) approved by
FDA for moderate-to-severe
menopausal hot flashes

(FDA, Approval)



FDA grants approval to
GAZYVA (obinutuzumab) for
the treatment of lupus
nephritis

(FDA, Approval)



Formycon's FYB201
(RANIVISIO) launched as
Europe's first ranibizumab
biosimilar in pre-filled
syringe

(EU, Launch)

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Xspray Pharma's XS003 (nilotinib) NDA accepted by FDA for CML, with PDUFA date set for June 18, 2026

(FDA, NDA)



FDA issues complete response letter to Sydnexis for SYD-101 in children with progressive myopia

(FDA, CRL)



Astellas' PADCEV (enfortumab vedotin-ejfv) plus KEYTRUDA (pembrolizumab) sBLA granted FDA priority review for muscle-invasive bladder cancer

(FDA, sBLA, Priority Review)

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Electra Therapeutics' lead candidate ELA026 secured FDA Breakthrough Therapy and EMA PRIME designations for the treatment of sHLH

(FDA, Breakthrough Therapy)



Partner Therapeutics' zenocutuzumab-zbco receives FDA Breakthrough Therapy designation for advanced NRG1+ cholangiocarcinoma

(FDA, Breakthrough Therapy)



Halia Therapeutics' ofirnoflast (HT-6184) receives FDA Orphan Drug designation for myelodysplastic syndromes

(FDA, Orphan Drug)

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AnnJi's AJ20I receives FDA
Fast Track designation for
Kennedy's disease

(FDA, Fast Track)



Heidelberg Pharma's lead
ADC candidate HDP-10I
awarded FDA Fast Track
designation for multiple
myeloma

(FDA, Fast Track)



Myosin Therapeutics secures
FDA Fast Track designation
for MT-125 in glioblastoma

(FDA, Fast Track)

Highlights from the Week of October 21-27, 2025

 &  **Avadel**

Alkermes to acquire Avadel
Pharmaceuticals in \$2.1
billion deal, adding
LUMRYZ™ to sleep medicine
portfolio

(Acquisition)

 **IPSEN** & 
Innovation for patient care

Ipsen to acquire ImCheck
Therapeutics for up to €1
billion, enhancing oncology
pipeline

(Acquisition)

 & 

Eli Lilly announces acquisition
of Adverum Biotechnologies,
expanding gene therapy
portfolio

(Acquisition)

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Biogen acquires global rights to Vanqua Bio's oral C5aRI antagonist to bolster immunology strategy

(Acquisition)



Novartis to acquire Avidity Biosciences for \$12 billion, expanding RNA therapeutics portfolio

(Acquisition)