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Highlights from the Week of
October 13 - 20, 2025

**AbbVie** *( FDA, Drug Approval )*

FDA approves revised indication for Abbvie's RINVOQ® (upadacitinib) to treat inflammatory bowel disease

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**Roche** *( FDA, Approval )*

FDA approves Roche's Elecsys® pTau181 as the exclusive blood test for primary care to rule out Alzheimer's-related amyloid pathology

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**Roche** *( FDA, Approval )*

Roche's Gazyva/Gazyvaro receives FDA approval for lupus nephritis treatment

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**Novo Nordisk** *( FDA, Approval )*

FDA has approved Novo Nordisk's oral semaglutide to lower heart disease risk in high-risk adults with type 2 diabetes, even if they have not had a heart attack or stroke before

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## Amgen

*( FDA, Approval )*

AstraZeneca and Amgen announce FDA approval of Tezspire for chronic rhinosinusitis with nasal polyps

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## Celltrion

*( FDA, Approval )*

Expanded pediatric indications for YUFLYMA® (adalimumab-aaty) and unbranded adalimumab-aaty receive FDA approval in the U.S.

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## Sanofi

*( CHMP Opinion, EU Approval )*

CHMP recommends Sanofi's Wayrilz for EU approval in immune thrombocytopenia treatment

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## Insmed

*( CHMP, EU Approval )*

Viatris' BRINSUPR recommended by CHMP for EU approval in the treatment of non-cystic fibrosis bronchiectasis

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## Avidity Biosciences *( FDA, BLA submission )*

Avidity Biosciences achieves positive pre-BLA meeting with U.S. FDA for del-zota in DMD44, plans to submit in Q1 2026

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## Denali Therapeutics *( FDA, Review )*

Denali Therapeutics receives FDA review extension for tividenofusp alfa in MPS II (Hunter Syndrome)

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## atai Life Sciences and Beckley Psytech *( FDA, Breakthrough Therapy )*

BPL-003 from atai Life Sciences and Beckley Psytech receives FDA Breakthrough Therapy designation for treatment-resistant depression

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## BeOne Medicines *( FDA, Breakthrough Therapy )*

FDA designates Sonrotoclax as Breakthrough Therapy for relapsed/refractory mantle cell lymphoma

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## Blacksmith Medicines

*( FDA, QDIP )*

Blacksmith Medicines obtains FDA QIDP and Fast Track designation for FG-2101, a novel antibiotic aimed at LpxC

## ReviR

*( FDA, Orphan Drug )*

FDA has granted Orphan Drug designation to ReviR Therapeutics' RTX-117 for the treatment of Charcot-Marie-Tooth disease (CMT)

## Minovia Therapeutics

*( FDA, Orphan Drug )*

FDA grants Orphan Drug designation to Minovia Therapeutics' MNV-201 for myelodysplastic syndrome

## Krystal Biotech

*( FDA, Platform Designation )*

Krystal Biotech’s HSV-1 viral vector in KB801 receives FDA Platform Technology designation for treating neurotrophic keratitis

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## Viatris

*( Acquisition )*

Viatris acquires Aculys Pharma, including exclusive rights to pitolisant and Spydia in Japan and several Asia-Pacific markets

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## EVOQ and Sanofi

*( Collaboration )*

EVOQ Therapeutics partners with Sanofi under new collaboration and license agreement

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## Genentech

*( Phase 3, Results )*

Genentech's Phase 3 evERA data show giredestrant significantly improved progression-free survival in people with ER-positive advanced breast cancer