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Highlights from the Week of
May 27 – June 02, 2025

## Fresenius Kabi

*( EMA, CHMP, Approval, Denosumab )*

Fresenius Kabi's denosumab biosimilars received a positive recommendation from the CHMP for osteoporosis and bone conditions, expanding their portfolios in autoimmune and oncology treatments. EC approval is anticipated in Q3 2025

## Bio-Thera & Hikma Pharmaceuticals

*( FDA, Biosimilar, Approval, Denosumab )*

Bio-Thera Solutions and Hikma Pharmaceuticals announced the FDA approval of STARJEMZA (ustekinumab-hmny)

## Sandoz

*( US, Launch, Biosimilar, Denosumab )*

Sandoz expands its US biosimilar portfolio with the launch of WYOST and JUBBONTI, the first interchangeable denosumab biosimilars approved by the FDA

## Samsung Bioepis

*( US, FDA, Adalimumab )*

The FDA has designated Samsung Bioepis and Organon's HADLIMA as fully interchangeable with HUMIRA, covering all high- and low-concentration formulations and device types

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## Formycon and Fresenius Kabi

*( Canada, Launch, Ustekinumab )*

Formycon AG and Fresenius Kabi launched OTULFI, an ustekinumab biosimilar, in Canada following Health Canada's approval in December 2024

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## TQ Therapeutics

*( Acquisition, Cellular therapy )*

TQ Therapeutics acquired Juno Therapeutics, thereby enhancing its capabilities in cellular therapies

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## Alvotech

*( Collaboration, EU )*

Alvotech and Advanz Pharma are broadening their European biosimilar partnership with three new candidates, including ILARIS, KESIMPTA and an undisclosed candidate

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## Sanofi

*( Acquisition, Immunology )*

Dren Bio's DR-0201 has joined Sanofi's leading immunology pipeline following the completion of the acquisition

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## Eli Lilly

*( Acquisition, Neurology )*

Lilly is strengthening its pain portfolio with the acquisition of SiteOne Therapeutics, targeting chronic pain with a novel Nav1.8 inhibitor

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## Astellas

*( DC, Collaboration )*

Astellas has secured exclusive global rights (excluding greater China) to Evopoint's promising CLDN18.2 ADC, XNW27011, for the treatment of solid tumors, including gastric and pancreatic cancers

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## BioNTech

*( Collaboration, ADC, Solid tumors )*

BioNTech's BNT327, a next-generation bispecific antibody targeting multiple solid tumor types, has entered into global co-development and co-commercialization with BMS

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## Moderna

*( Approval, FDA, COVID-19 )*

The FDA has approved mNEXSPIKE mRNA-1283, Moderna's latest COVID-19 vaccine, for individuals aged 65 and older, as well as for at-risk populations

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## Roche

*( Clinical trials, Breast cancer )*

Roche's Itovebi has demonstrated a significant survival advantage in patients with PIK3CA-mutated, HR-positive, HER2-negative advanced breast cancer, reducing the risk of death by over 30% according to a Phase 3 study

## Sanofi

*( Acquisition, Immunology )*

Sanofi to acquire Blueprint Medicines, accelerating its ambitions in immunology with an approved rare disease drug and promising early-stage assets

## Kura Oncology

*( FDA, NDA )*

Kura Oncology and Kyowa Kirin have announced the FDA's acceptance of the ziftomenib NDA for R/R NPM1-mutant AML, with a PDUFA target action date set for November 30, 2025

## Nxera Pharma

*( Collaboration )*

Nxera Pharma's collaboration with Eli Lilly has progressed, marking a significant development milestone in their metabolic disease program