Highlights from the Week of 02 February 2026 - 09 February 2026

VYUHPHARMA

(FDA, Approval)

FDA approves Exelixis' zanzalintinib in combination with atezolizumab for the treatment of adult patients with previously treated metastatic colorectal cancer, with a PDUFA date of December 3, 2026

(EU, Approval)

The European Commission approves GSK's NUCALA as an add-on maintenance treatment for adults with uncontrolled chronic obstructive pulmonary disease based on the data from Phase III MATINEE trial

(NMPA, Approval)

NMPA approves Bayer's NUBEQA in combination with androgen deprivation therapy for metastatic hormone-sensitive prostate cancer based on the Phase III ARANOTE trial

(NMPA, Approval)

NMPA approves a new indication of Kelun-Biotech's sacituzumab tirumotecan to treat unresectable or metastatic HR+/HER2- breast cancer who previously received endocrine therapy and at least one line of chemotherapy

(Breakthrough Therapy, Orphan Drug)

Sanofi announces that the FDA grants Breakthrough Therapy designation for rilzabrutinib and Orphan Drug designation in Japan for the first and only investigational BTKi for warm autoimmune hemolytic anemia

(FDA, Priority Review)

AstraZeneca and Daiichi Sankyo's DATROWAY earned FDA Priority Review for unresectable or metastatic triple-negative breast cancer ineligible for immunotherapy based on Phase III TROPION-Breast02 trial results

(FDA, Priority Review)

FDA grants Priority Review to Pfizer's sBLA HYMPAVZI for inclusion of pediatric patients aged 6-11 with hemophilia A or B without inhibitors

(FDA, Orphan Drug)

FDA grants Orphan Drug designation to Partner Therapeutics' zenocutuzumab-zbco for the treatment of advanced unresectable or metastatic cholangiocarcinoma with a neuregulin 1 gene fusion

(EU, CHMP)

AstraZeneca's durvalumab perioperative regimen receives posivtive CHMP opinion to treat resectable, early-stage, and locally advanced gastric and gastroesophageal junction cancers

(Collaboration)

Gedeon Richter and Fuji Pharma announce joint collaboration to identify and pursue the acquisition or in-licensing of external drug candidates in gynecology worldwide

(Collaboration)

Coherus Oncology enters into a clinical supply agreement with Johnson & Johnson to evaluate tagmokitug in combination with pasritamig in metastatic castration-resistant prostate cancer

(Commercialization)

Henlius and Eisai make an agreement for the commercialization of serplulimab in Japan, focusing on addressing unmet needs in extensive-stage small cell lung cancer and other solid tumors