Highlights from the Week of 02nd November 2026 - 09th November 2026

VYUHPHARMA

(FDA, Accelerated Approval)

Johnson&Johnson

FDA grants accelerated approval to Johnson & Johnson's RYBREVANT FASPRO, 160 mg/2,000 units per mL, SC injection to treat adults with recurrent or metastatic HNSCC

(Health Canada, Approval)

moderna

Health Canada authorizes Moderna's mFLUSIVA to treat influenza and mCOFLU, a combined influenza and COVID-19 mRNA vaccine, both for adults aged 50 years and older

(NMPA, Approval)

BAYER

NMPA of China grants approval to Bayer's sevabertinib to treat adults with unresectable, locally advanced, or metastatic NSCLC with HER2-activating mutations

(FDA, Priority Review)

BeOne

FDA accepts BeOne's sNDA, BRUKINSA, for Priority Review in combination with rituximab for the treatment of adults with untreated MCL

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(FDA, Fast Track)

graviton

FDA provides Fast Track designation to Graviton's GV101 for the treatment of Friedreich's ataxia

(FDA, Breakthrough Therapy)

idorsia

FDA gives Breakthrough Therapy designation to Idorsia's daridorexant to treat insomnia disorder in those aged 10 to <18 years

(FDA, Orphan Drug)

HUTCHMED

Hutchmed gets FDA Orphan Drug designation for sovleplenib to treat autoimmune hemolytic anemia

(Phase 3, Results)

InventisBio 益方生物

InventisBio's Ph3 study evaluating D-2570 in moderate-to-severe plaque psoriasis met its primary and key secondary endpoints, achieving PASI 90 and PGA 0/1 responses at week 16 with a safety profile comparable to placebo

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(Collaboration)

CStone Pharmaceuticals and Kimia Therapeutics collaborate to advance the clinical development of an asset targeting DDR pathways critical for solid tumor cell survival

(Collaboration)

Boehringer Ingelheim collaborates with SBP to advance next-generation ADC-based cancer treatments and TcE technologies, for an upfront payment of USD 358M

(Collaboration)

Fresenius collaborates with WuXi Biologics to expand its biosimilar pipeline, including monoclonal and bispecific antibodies, antibody-drug conjugates and fusion proteins

(Collaboration)

Evommune and Hinova Pharmaceuticals collaborate to develop, manufacture and commercialize EVO570 to treat a wide range of chronic inflammatory diseases for an upfront payment of USD 20M

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