

Highlights from the Week of July 21-28, 2025



FDA approved label expansion of SPRITAM to include its administration via NG and G-Tubes for patients unable to swallow pills

(Spritam, FDA ,approval)



Avidity's Del-Zota received FDA Breakthrough Therapy Designation for the treatment of Duchenne muscular dystrophy patients with exon 44 skipping mutations

(DelZota , Breakthrough Therapy)



LABORATOIRES
Pierre Fabre

FDA grants priority review to Pierre Fabre's application for tabellecleucel as a treatment for EBV+ PTLD

(FDA, Priority Review)

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Shanton's SAP-001 received FDA Fast Track Designation for the treatment of refractory gout

(Refractory Gout, Fast Track)



Janssen's DARZALEX received EC approval for the treatment of high-risk smoldering multiple myeloma

(DARZALEX, EC approval, Myeloma)



Biogen received positive CHMP opinion for the MA of ZURZUVAE (zuranolone) for the treatment of postpartum depression

(CHMP, Postpartum depression)

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Sobi's Doptelet approved by the FDA for pediatric patients with chronic immune thrombocytopenia (ITP)

(Doptelet, FDA approval)



Novo Nordisk received positive CHMP opinion for the EU label expansion of Alhemo to treat hemophilia A and B patients without inhibitors

(Alhemo, CHMP)



Pfizer and BioNTech received positive CHMP opinion for the MA of LP.8.1-adapted monovalent COVID-19 vaccine (COMIRNATY® LP.8.1) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals aged >6 months

(Pfizer, CHMP)

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Sanofi received EC approval of Sarclisa for the treatment of newly diagnosed, transplant-eligible multiple myeloma patients

(Myeloma, EC Approval)



Ipsen's Cabometyx received EC approval for the treatment of patients with advanced neuroendocrine tumors who have undergone prior therapy

(Neuroendocrine tumors, EC approval)



Candel Therapeutics received Orphan Drug Deisgnation for CAN-2409 for the treatment of pancreatic cancer from the EMA

(Pancreatic cancer, OrphanDrug)

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Revolution Medicines received FDA Breakthrough Therapy Designation for elironrasib for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer

(NSCLC, Breakthrough Therapy)



The European Commission approved IMBRUVICA (ibrutinib), claimed to be the first targeted treatment for newly diagnosed, transplant-eligible patients with mantle cell lymphoma

(Mantle Cell Lymphoma, EU approval)



The FDA issued a Complete Response Letter to Replimune's BLA of RPI in advanced melanoma

(Melanoma, CRL)

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ProMIS Neurosciences' PMN310 received FDA Fast Track Designation for the treatment of Alzheimer's disease

(Alzheimer, FastTrack)



Lilly acquired Verve Therapeutics to advance "one-time treatments" for high cardiovascular risk

(Pharma Acquisition, Cardiology)



Verastem Oncology received FDA Fast Track Designation for VS-7375 for the treatment of locally advanced or metastatic pancreatic cancer harboring a KRAS G12D mutation

(Metastatic pancreatic cancer, Fast Track)

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Lilly's donanemab received positive CHMP opinion for early symptomatic Alzheimer's disease

(Alzheimer)



GNT Pharma received IND approval to initiate multinational Phase 3 trials of nelonemdaz for stroke therapy

(Phase 3, Stroke)