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Highlights from the week of
13th April - 20th April

Travere Therapeutics

(FDA, Approval)

Travere Therapeutics' FILSPARI gets FDA approval to reduce proteinuria in focal segmental glomerulosclerosis without nephrotic syndrome

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Alembic

(FDA, Approval)

Alembic gains FDA approval for methotrexate injection USP, 50 mg/2 mL (25 mg/mL) multi-dose vials & 1 g/40 mL (25 mg/mL) single-dose vials for the treatment of neoplastic diseases

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ARS Pharma

(Health Canada, Approval)

Health Canada approves ARS Pharma's NEFFY 2 mg for the emergency treatment of allergic reactions in those who weigh 30 kg or more, offering a new delivery method for epinephrine

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Merck

(FDA, Priority Review)

Merck receives Priority Review for ifinatamab deruxtecan, for the treatment of adult patients with extensive-stage small cell lung cancer

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Aicuris *(FDA, Priority Review)*

Aicuris secures Priority Review from FDA for pritelivir, a helicase primase inhibitor for the treatment of refractory herpes simplex virus infections, with or without resistance

Aligos Therapeutics *(FDA, Fast Track)*

Aligos Therapeutics' pevifoscorvir sodium, a capsid assembly modulator obtains FDA Fast Track designation for the treatment of chronic hepatitis B virus infection

Vir Biotechnology *(Collaboration)*

Vir Biotechnology and Astellas collaborate to co-develop and co-commercialize VIR-5500, a prostate-specific membrane antigen by sharing expenses and revenues

Eli Lilly *(Phase 3, Results)*

Eli Lilly's Phase 3 BRUIN CLL-322 trial met its primary endpoint, with JAYPIRCA plus venetoclax and rituximab significantly improving PFS in CLL or SLL when compared to placebo

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13th April - 20th April

SynOx Therapeutics

(Phase 3, Results)

SynOx Therapeutics' Phase 3 TANGENT study evaluating emactuzumab met its primary and secondary endpoints showing clinically meaningful improvements in tumor volume reduction when compared with placebo in TGCT