Vyuhpharma

Highlights from the week of
26th Oct - 02th Nov

Pfizer

(FDA, Approval)

Pfizer's TALZENNA gains extended approval from FDA in combination with XTANDI to treat men with mAPMN/S prostate cancer and mHSPC

Xbrane Biopharma

(FDA, Approval)

FDA approves Xbrane Biopharma's LUCAMZI, a biosimilar to LUCENTIS, for a cost-effective treatment option of wet AMD and other serious eye conditions

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Sun Pharma

(FDA, Approval)

FDA approves Sun Pharma's sBLA, ILUMYA, for the treatment of adults with active PsA

INOVIO

(FDA, Accelerated Approval)

Inovio obtains FDA accelerated approval for VOCERYQ, indicated to reduce the frequency of surgeries in adults with RRP



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AstraZeneca

(EU, Approval)

AstraZeneca and Daiichii Sankyo get EC approval for ENHERTU as monotherapy for the adjuvant treatment of adults with resected HER2-positive breast cancer

HUTCHMED

(FDA, Orphan Drug)

Hutchmed's sovleplenib gains Orphan Drug designation from FDA for the treatment of primary ITP

Sumitomo Pharma

(FDA, Breakthrough Therapy)

FDA grants Breakthrough Therapy designation to Sumitomo Pharma's DSP-5336 for the treatment of R/R KMT2A-rearranged acute leukemia

Octant

(FDA, Orphan Drug)

Octant's OCT-980 gets FDA Orphan Drug designation for the treatment of RP

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Sobi

(Phase 3, Results)

Sobi's Ph3 REDUCE-2 study evaluating AR882 in uncontrolled gout met its primary endpoint along with reductions in SU levels through 12 months with a safety profile comparable to placebo



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