



●▶ **Sungen**

(FDA, FTD)

FDA grants Fast Track designation to Sungen Biomedical's SGC001 mAb for acute myocardial infarction

●▶ **Sermonix + Regor**

(Partnership)

Sermonix and Regor partner to enhance rCARD platform for advancing breast oncology therapeutics

●▶ **Palatin**

(FDA, ODD)

FDA grants Orphan Drug Status to Palatin's PL7737 for treating obesity from leptin receptor deficiency

●▶ **Vast**

(FDA, QIDP)

FDA grants QIDP designation to Vast's ALX1 for targeting pseudomonas and other critical pathogens





●► **GV20 + MTPC**

(Agreement)

GV20 Therapeutics enters collaboration with Mitsubishi Tanabe to advance next-gen ADCs for novel cancer targets

●► **Dermata**

(Clinical trial, Phase 3)

Dermata's XYNGARI™ achieves primary endpoints with statistically and clinically significant improvement in acne

●► **Novo Nordisk**

(Clinical trial, Phase 3)

Novo Nordisk's oral semaglutide 14 mg shows 14% reduction in cardiovascular risk in SOUL trial

●► **Novartis**

(FDA, Approval)

Novartis secures FDA nod for earlier use of Pluvicto® in PSMA-positive metastatic prostate cancer





●▶ **PTC Therapeutics**

(CHMP, EMA)

European Commission upholds CHMP Opinion, declines renewal of PTC Therapeutics' Translarna™ authorization

●▶ **IASO Bio**

(ISAF, NDA)

Macao's ISAF approves IASO Bio's equecabtagene autoleucel for the treatment of patients with relapsed or refractory multiple myeloma after ≥3 prior therapies

●▶ **IDEAYA Biosciences**

(FDA, BTB)

IDEAYA Biosciences receives FDA Breakthrough Therapy Designation for darovasertib as neoadjuvant monotherapy in uveal melanoma

●▶ **Halozyme**

(CHMP, EMA)

Halozyme announces positive CHMP opinion for SC Opdivo® with ENHANZE® in multiple solid tumor indications

