VYUHPHARMA

Highlights from the Week of September 01-08, 2025

NANOSCOPE THERAPEUTICS

Nanoscope's MCO-010 therapy received FDA RMAT designation and five EMA Orphan designations, accelerating its development for a variety of retinal diseases

(FDA, RMAT Designation, EMA, Orphan Drug Designation)

MENARINI group

Menarini Group's obicetrapib and a combination therapy with ezetimibe have been accepted for review by the EMA for treating primary hypercholesterolaemia and mixed dyslipidaemia, supported by positive data from Ph3 trials

(EMA, MAA)

IDEAYA BIOSCIENCES

Servier and IDEAYA Biosciences have partnered to commercialize the eye cancer treatment darovasertib outside the US, with IDEAYA receiving a $210 million upfront payment and up to $320 million more in potential milestones

(Partnership)

VYUHPHARMA

Highlights from the Week of September 01-08, 2025

agios

FDA has extended the PDUFA goal date for PYRUKYND®, Agios's drug for thalassemia. The new decision date for the sNDA is December 7, 2025

(FDA, PDUFA)

Andelyn BIOSCIENCES
Reliably Expert. Purposefully Driven.

Andelyn Biosciences and Tern Therapeutics have partnered for the late-stage manufacturing of TTX-381, a gene therapy being developed to treat vision loss in children with CLN2 Batten disease

(Partnership)

HENGRUI

Braveheart Bio has secured exclusive global rights to Hengrui Pharma's cardiac myosin inhibitor, HRS-1893, which is currently in a Ph3 trial for obstructive hypertrophic cardiomyopathy

(Collaboration)

Highlights from the Week of September 01-08, 2025

Servier has acquired KER-0193, a potential oral treatment for Fragile X syndrome from Kaerus Bioscience, which has already received both Orphan Drug and Rare Pediatric Drug designations from the FDA

(Acquisition, Orphan Drug Designation, Rare Pediatric Drug Designation)

Takeda has paid Novavax a milestone fee following regulatory approval in Japan for Nuvaxovid®, a COVID-19 vaccine for initial and booster immunization for various age groups

(Approval)