CY2025 CBER Breakthrough Therapy Approvals

Data as of September 30, 2025

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date	Use
BLA 125832	ORIGINAL-1	PAPZIMEOS	zopapogene imadenovec-drba	Precigen, Inc.	14-AUG-2025	For the Treatment of Adults with Recurrent Respiratory Papillomatosis.
BLA 125807	ORIGINAL-1	ZEVASKYN	Prademagene zamikeracel	Abeona Therapeutics, Inc.	28-APR-2025	Treatment of wounds associated with recessive dystrophic epidermolysis bullosa (RDEB).
BLA 125820	ORIGINAL-1	VIMKUNYA	Chikungunya Vaccine, Recombinant	Bavarian Nordic A/S	14-FEB-2025	For the prevention of disease caused by Chikungunya virus in individuals 12 years of age and older.

* Breakthrough Therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012.