

CY 2015 CDER Breakthrough Therapy Calendar Year Approvals

Data as of September 30, 2015

Application Number	Submission Type and Number	Proprietary Name	Established Name	Applicant	Approval Date
NDA 205552	SUPPLEMENT-2	IMBRUVICA	IBRUTINIB	PHARMACYCLICS INC	29-Jan-2015
NDA 207103	ORIGINAL-1	IBRANCE	PALBOCICLIB	PFIZER INC	03-Feb-2015
BLA 125156	SUPPLEMENT-106	LUCENTIS	RANIBIZUMAB	GENENTECH, INC.	06-Feb-2015
NDA 207925	ORIGINAL-1	KALYDECO	IVACAFTOR	VERTEX PHARMACEUTICALS INC	17-Mar-2015
BLA 125387	SUPPLEMENT-48	EYLEA	AFLIBERCEPT	REGENERON PHARMACEUTICALS, INC.	25-Mar-2015
NDA 21110	SUPPLEMENT-73	RAPAMUNE	SIROLIMUS	PF PRISM CV	28-May-2015
NDA 21083	SUPPLEMENT-55	RAPAMUNE	SIROLIMUS	PF PRISM CV	28-May-2015
NDA 206038	ORIGINAL-1	ORKAMBI	LUMACFTOR/IVACAFTOR	VERTEX PHARMACEUTICALS INC	02-Jul-2015
NDA 207931	ORIGINAL-1	TECHNIVIE	OMBITASVIR, PARITAPREVIR, RITONAVIR	ABBVIE INC	24-Jul-2015
NDA 208169	ORIGINAL-1	XURIDEN	URIDINE TRIACETATE	WELLSTAT THERAPEUTICS CORP	04-Sep-2015