

DRUG SUBSTANCE DEVELOPMENT LIST

ADVANCED STAGE

Kilolab process or pilot scale up is ready, including PAR measurements at least for the last two chemical steps and the DS purification step. Where we have EGIS own DS form, we have originator's form too. Documentation is available in Hungarian.

INN	Sample	Quality	Egis own DS form (besides originator's form)	Technical package
Abemaciclib	✓	ICH	x	✓
Avapritinib*	✓	ICH	✓	✓
Baricitinib*x	✓	ICH	✓	✓
Dapagliflozin-2-propanediol***	✓	ICH	x	✓
Empagliflozin**	✓	ICH	x	✓
Ibrutinib**x	✓	ICH	x	✓
LCZ 696***	✓	ICH	x	✓
Osimertinib	✓	ICH	x	✓
Palbociclib***x	✓	ICH	✓	✓
Pimavanserin*	✓	ICH	✓	✓
Pomalidomide*	✓	ICH	x	✓
Siponimod*	✓	ICH	x	✓
Tofacitinib*	✓	ICH	x	✓

*: kilolab process development is completed

** : kilolab process development is completed, pilot scale-up in progress

***: kilolab process development is completed, pilot scale-up is completed

x: Products developed under Strategic Cooperation with Polpharma

EARLY STAGE

INN	Sample	Egis own form
Acalabrutinib#	x	x
Alectinib##	✓	✓
Blarcomesine##	✓	✓
Brexpiprazole##	✓	✓
Deucravacitinib#	✓	✓
Elafibranor##	x	x
Epacadostat##	x	x
Evenamide##	✓	✓
Evobrutinib##	✓	✓
Filgotinib##	✓	✓
Fruquintinib##	✓	✓
Lasmiditan##	✓	✓
Lumateperone##	✓	✓
Mavacamten##	✓	✓
Mirabegron##	✓	✓
Ozanimod##	✓	✓
Ribociclib##	✓	✓
Solriamfetol##	✓	✓
Upadacitinib#	✓	x
Venetoclax##	✓	✓

#: lab synthesis development is in progress

##: lab synthesis development is completed

WISH LIST

INN
Abrocitinib
Brigatinib
Darolutamide
Entrectinib
Ponesimod
Resmetirom
Troriluzole
VK-2809

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