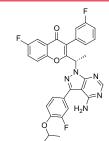
2021 FDA Novel Small Molecule Drug Approvals

Oncology (9)



umbralisib (Ukonia)

PI3Kδ and CK1ε kinase inhibitor marginal zone or follicular lymphoma oral: 800 mg QD

tivozanib (Fotivda)

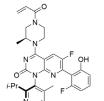
pan-VEGFR kinase inhibitor renal cell carcinoma oral: 1.34 mg QD for 21 days in 28 day cycle

melphalan flufenamide (Pepaxto*)

peptide-conjugated alkylating agent multiple myeloma continuous IV (30 mins): 40 mg Q4W

mobocertinib (Exkivity)

EGFR exon 20 insertion kinase inhibitor NSCLC oral: 160 mg QD



sotorasib (Lumakras)

KRASG12C GTPase inhibitor NSCLC oral: 960 mg QD

trilaciclib (Cosela)

CDK4 and 6 kinase inhibitor myelosuppression in SCLC continuous IV: 240 mg/m² prior to chemotherapy

pan-FGFR kinase inhibitor cholangio carcino maoral: 125 mg QD for 21 days of 28 day cycle

tepotinib (Tepmetko)

MET kinase inhibitor NSCLC oral: 450 mg QD

asciminib (Scemblix)

ABL/BCR-ABL1 kinase inhibitor myeloid leukemia oral: up to 200 mg BID

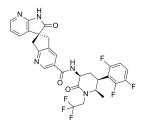
Neurology (5)

samidorphan + olanzapine (Lybalvi)

opioid antagonist schizophrenia, bipolar I disorder oral: up to 10 + 20 mg QD*

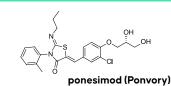
viloxazine (Qelbree)

selective norepinephrine reuptake inhibitor ADHD oral: up to 400 mg QD



atogepant (Qulipta)

calcitonin gene-related peptide (CGRP) receptor antagonist migraine oral: up to 60 mg QD

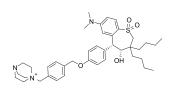


sphingosine 1-phosphate (S1P) receptor modulator multiple sclerosis oral: up to 20 mg QD

serdexmethylphenidate + dexmethylphenidate (Azstarys)

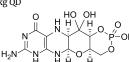
catecholamine reuptake inhibitor, CNS stimulant oral: up to 52.3 + 10.4 mg QD*

Genetic Conditions (5)



maralixibat (Livmarli)

ileal bile acid transporter (IBAT) inhibitor pruritus in Alagille syndrome oral: 380 μg/kg QD



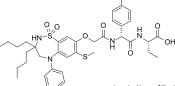
fosdenopterin (Nulibry)

cyclic pyranopterin monophosphate (cPMP) substrate replacement molybdenum cofactor deficiency type A continuous IV: up to 0.9 mg/kg QD



belzutifan (Welireg)

hypoxia-inducible factor 2a (HIF2a) inhibitor VHL disease oral: 120 mg QD

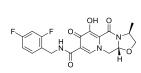


odevixibat (Bylvay)

ileal bile acid transporter (IBAT) inhibitor pruritus in familial intrahepatic P-G-O-E-H-P-N cholestasis (A-G-K-Y-K-R-A oral: 40 μg /kg QD N-K-K-G-L-S-K (D-(K-(L-(G-(F),C-(G

D-R-U-G-S-M-S но-С-С-С-С vosoritide (Voxzogo) C-type natriuretic peptide analog

Infectious Diseases (4)



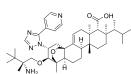
cabotegravir + rilpivirine (Cabenuva)

HIV1 integrase strand transfer inhibitor (INSTI) HIV1 infection IM: 400 + 600 mg Q1M*



maribavir (Livtencity)

CMV pUL97 kinase inhibitor post-transplant CMV infection oral: 400 mg BID

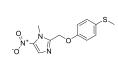


achondroplasia

SC: up to 0.8 mg QD

ibrexafungerp (Brexafemme)

 β -1,3-glucan synthesis inhibitor vulvovaginal candidiasis oral: 300 mg BID



fexinidazole (Fexinidazole)

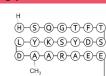
nitroimidazole antimicrobial African trypanosomiasis oral: up to 1200 mg QD

Endocrinology (2)



finerenone (Kerendia)

non-steroidal mineralocorticoid receptor antagonist (MRA) CKD in type 2 diabetes oral: up to 20 mg QD



S-E-L-W-K-V-F

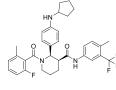
dasiglucagon (Zegalogue)

antihypoglycemic, glucagon receptor agonist hypoglycemia in diabetes mellitus SC: 0.6 mg STAT

Immunology (3)

voclosporin (Lupkynis)

calcineurin inhibitor immuno suppressantlupus nephritis oral: starting 23.7 mg BID



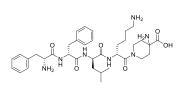
avacopan (Tavneos)

complement C5a receptor antagonist anti-neutrophil cytoplasmic autoantibody-associated vasculitis oral: 30 mg BID

belumosudil (Rezurock)

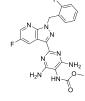
selective ROCK2 kinase inhibitor chronic graft-vs-host disease oral: 200 mg QD

Other (4)



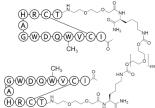
difelikefalin (Korsuva) kappa opioid receptor agonist

pruritus in CKD IV: 0.5 μg /kg



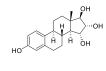
vericiguat (Verquvo)

guanylate cyclase stimulator reduce risk of heart failure oral: 2.5 mg QD



pegcetacoplan (Empaveli)

complement C3 inhibitor paroxysmal nocturnal hemoglobinuria SC: 1080 mg infusion BIW



estetrol + drospirenone (Nextstellis)

naturally-occurring estrogen E4 prevent pregnancy oral: 14.2 + 3 mg QD*



*Dosages for medicines with more than one active compound represent a total dosage

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