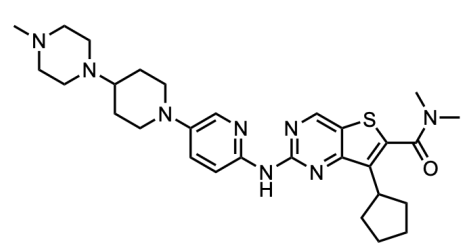
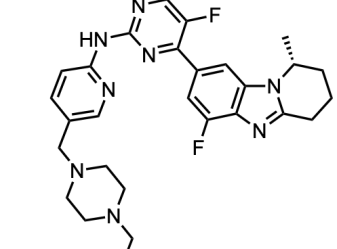


2025 Non-US Novel Small Molecule Drug Approvals

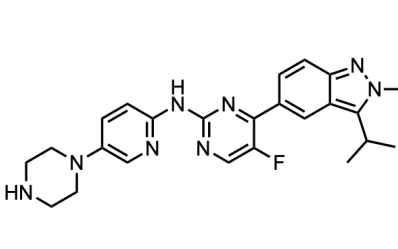
Oncology (18)



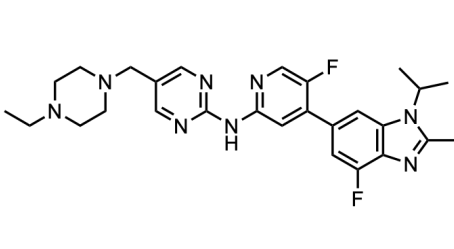
fovinaciclilib
(Futuoning®)
CDK4/6 inhibitor
to treat HR+/HER2- locally advanced, recurrent, or metastatic breast cancer
200 mg PO QD
approved by NMPA
FOCHONG PHARMA / AYANC PHARMA / SHANGHAI HENLIUS BIOTECH



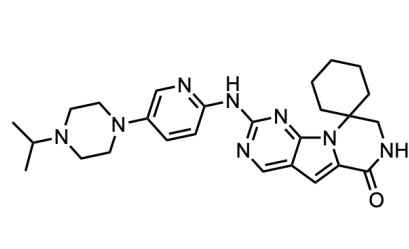
tibremciclib
(Kangmeina®)
CDK4/6 inhibitor
to treat HR+/HER2- locally advanced or metastatic breast cancer
400 mg PO QD
approved by NMPA
BETTA PHARMA



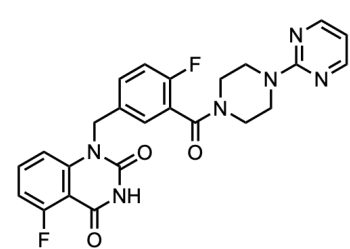
culmerciclib
(Saitanxin®)
CDK2/4/6 inhibitor
to treat HR+/HER2- locally advanced or metastatic breast cancer
180 mg PO QD
approved by NMPA
CHIA TAI TIANQING



bireociclib
(Xuanyuening®)
CDK4/6 inhibitor
to treat HR+/HER2- locally advanced or metastatic breast cancer in adults
360 mg PO BID
approved by NMPA
XUANZHU BIOPHARM

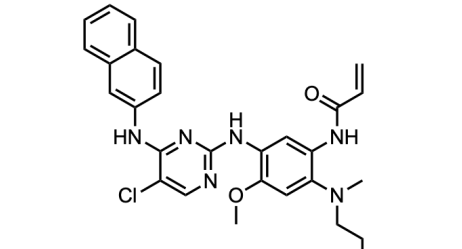


lerociclib
(Rujianing®)
CDK4/6 inhibitor
to treat HR+/HER2- locally advanced or metastatic breast cancer in adults
150 mg PO BID
approved by NMPA
G1 THERAPEUTICS / GENOR BIOPHARMA

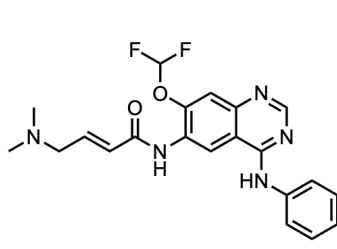


senaparib
(Paishuning®)
PARP1/2 inhibitor
to treat advanced epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer
100 mg PO QD
approved by NMPA
IMPACT THERAPEUTICS

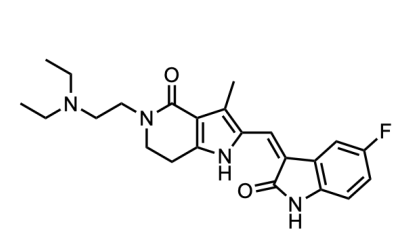
Oncology (18)



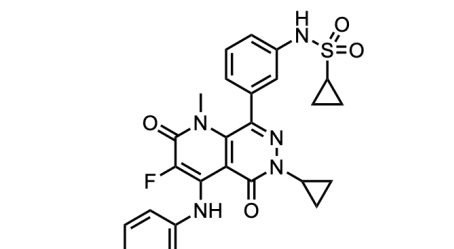
limertinib
(Aoyixin®)
covalent EGFR inhibitor
to treat locally advanced or metastatic nSCLC with confirmed EGFR T790M mutation
80 mg or 160 mg PO BID
approved by NMPA
JIANGSU AOSAIKANG PHARMA / SHANGHAI INSTITUTE OF MATERIA MEDICA / INNOVENT BIOLOGICS



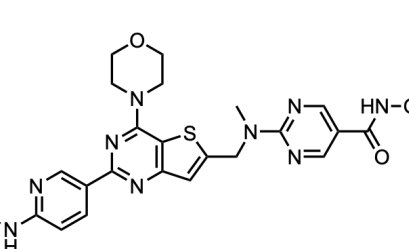
mifanertinib
(Mairuidong®)
covalent EGFR inhibitor
to treat locally advanced or metastatic nSCLC harboring EGFR exon 21 mutations
60 mg PO QD
approved by NMPA
HANGZHOU ZHONGMEI HUADONG PHARMA



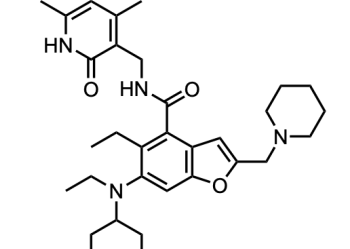
famitinib
multi-target receptor tyrosine kinase inhibitor
to treat recurrent or metastatic cervical cancer
20 mg PO QD
approved by NMPA
JIANGSU HENGRUI PHARMA



luvometinib
(Fumaining®)
MEK1/2 inhibitor
to treat Langerhans cell histiocytosis, histiocytic neoplasms, and inoperable plexiform neurofibroma of NF1
8 mg PO QD
approved by NMPA
SHANGHAI FOSUN PHARMA / CHONGQING FOCHON PHARMA

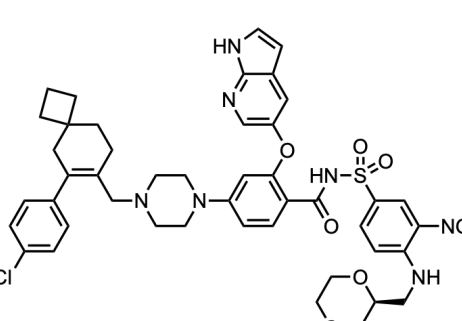


ifupinostat
(Beitelin®)
PI3Kα/HDAC inhibitor
to treat relapsed or refractory diffuse large B cell lymphoma
18.5 mg/m² IV 21-day cycle, 2 weeks on treatment (days 1, 3, 5, 8, 10, and 12), 1 week off
approved by NMPA
CURIS / HUANGZHOU BEBETTER MED

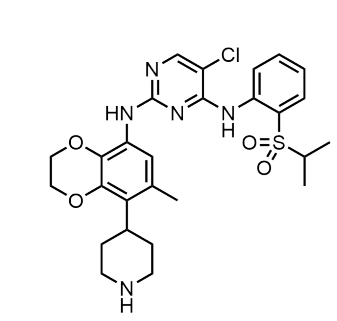


zeprumetostat
(Airuijing®)
EZH2 inhibitor
to treat relapsed or refractory peripheral T cell lymphoma
350 mg PO BID
approved by NMPA
JIANGSU HENGRUI PHARMA

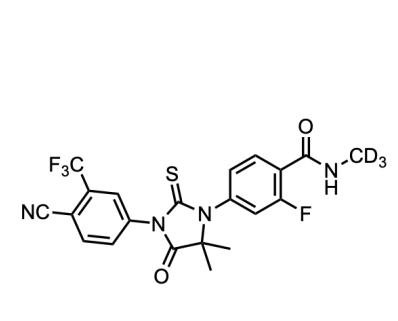
Oncology (18)



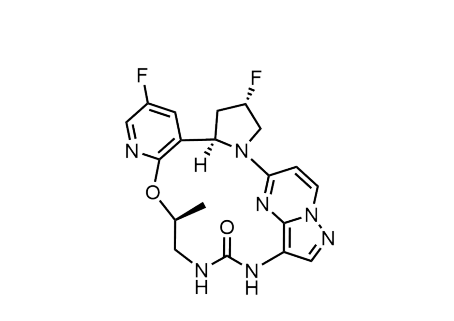
lisaftoclax
(Lishengtuo®)
BCL-2 inhibitor
to treat chronic lymphocytic leukemia/small lymphocytic lymphoma
600 mg (after dose escalation period from 20 to 600 mg) PO QD
approved by NMPA
SUZHOU ASCENTAGE PHARMA / UNIVERSITY OF MICHIGAN



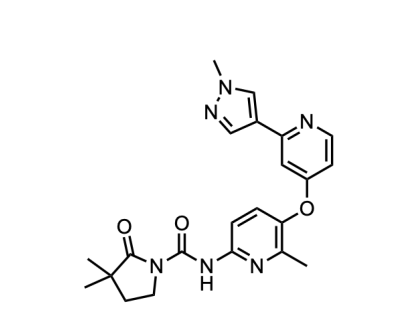
dirozalkib
(Xuanfeining®)
ALK tyrosine kinase inhibitor
to treat ALK-positive locally advanced or metastatic nSCLC
500 mg PO QD
approved by NMPA
XUANZHU BIOPHARMA



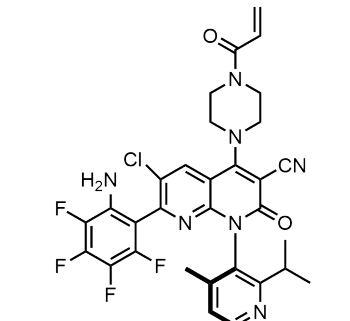
deutenzalutamide
AR antagonist
to treat metastatic castration-resistant prostate cancer
80 mg PO QD
approved by NMPA
HINOVA PHARMA



zurletrectinib
(Yinuoxin®)
TRK inhibitor
to treat solid tumors harboring NTRK gene fusions in adults and adolescents
8 mg PO QD
approved by NMPA
INNOVACARE PHARMA



pimicotinib
(Beijiemia®)
CSF-1R inhibitor
to treat symptomatic tenosynovial giant cell tumors
50 mg PO QD
approved by NMPA
ABBISKO THERAPEUTICS / MERCK EMD SERONO

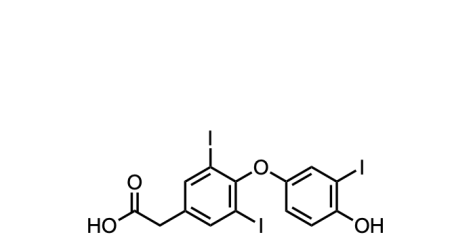


glecirasib
(Airuikai®)
covalent KRAS G12C inhibitor
to treat KRAS G12C-mutated advanced nSCLC in adults
800 mg PO QD
approved by NMPA
JACOBIO PHARMA / SHANGHAI ALLIST PHARMA

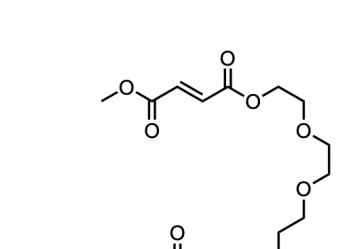
Genetic Disease (1)

Neurology & Pain (3)

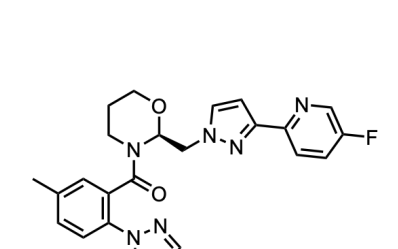
Infectious Disease (7)



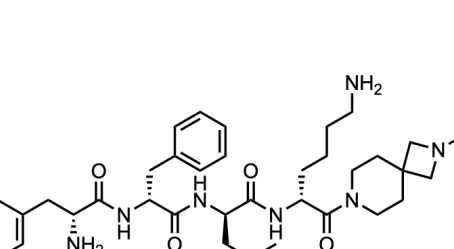
tiratrical
(Encitate®)
thyroid hormone (T3) analog
to treat peripheral thyrotoxicosis in patients with MCT8 deficiency
350 µg PO QD (increased by 350 µg every two weeks until a maintenance dose is reached)
approved by EMA
EGETIS THERAPEUTICS



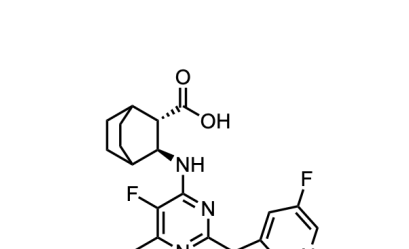
tegomil fumarate
(Riulvy®)
covalent KEAP1 modifier/ Nrf2 activator
to treat relapsing remitting multiple sclerosis
174 mg PO BID initial dose 34.8 mg PO BID maintenance dose after 2 weeks of treatment
approved by EMA
NRATIOPHARM / NEURAXPHARM PHARMA



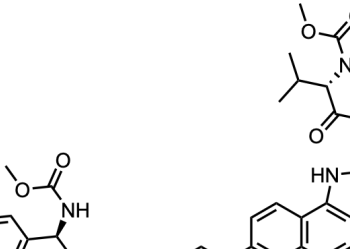
vornorexant
(Vorzzz®)
dual OX1R/OX2R antagonist
to treat insomnia
5 mg PO QD
approved by PMDA
TAISHO PHARMACEUTICAL / MEIJI SEIKA PHARMA



anrikefon
(Sishujing®)
peripherally restricted κ-opioid receptor agonist
to treat mild to moderate pain after abdominal surgery and pruritus
1.0 µg/kg IV 1-3 times a day after surgery as needed
approved by NMPA
SICHUAN HAISCO PHARMA



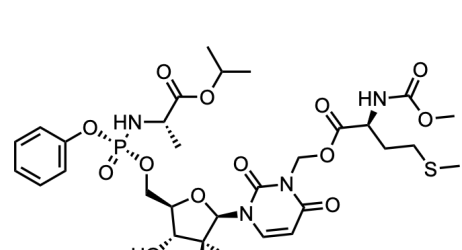
onradivir
(Anruwei®)
Influenza A RNA polymerase PB2 inhibitor
to treat uncomplicated Influenza A
600 mg PO QD
approved by NMPA
MEDSHINE DISCOVERY / GUANGDONG ZHONGSHENG PHARMA / GUANGDONG ZHONGSHENG RUICHUANG BIOTECHNOLOGY



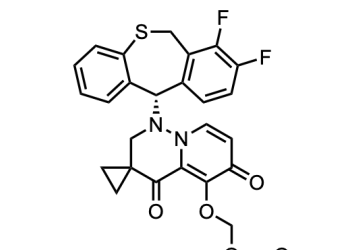
netanasvir
(Dongweizhuo®)
HCV NS5A inhibitor
to treat chronic HCV infection (genotypes 1/2/3/6) in combination with enfosobuvir
100 mg PO QD
approved by NMPA
SUNSHINE LAKE PHARMA

Infectious Disease (7)

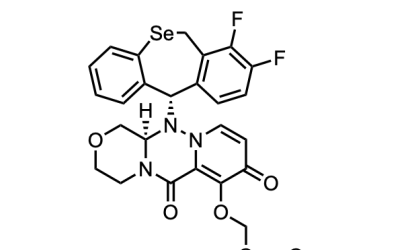
Ophthalmic (2)



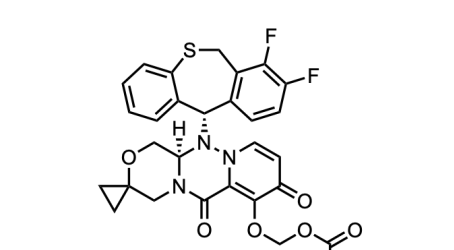
encofosbuvir
(Dongyinghe®)
HCV NS5B polymerase inhibitor
to treat chronic HCV infection (genotypes 1/2/3/6) in combination with netanasvir
600 mg PO QD
approved by NMPA
SUNSHINE LAKE PHARMA / YICHANG HEC CHANG JIANG PHARMA



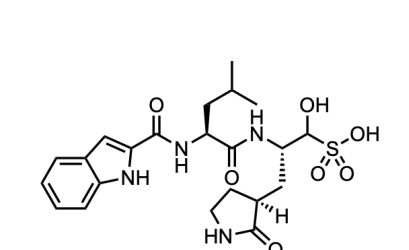
pixavir marboxil
(Yi Li Kang®)
Influenza cap-dependent endonuclease inhibitor
to treat uncomplicated influenza A and B
40 mg or 80 mg PO single dose
approved by NMPA
TAIGEN BIOTECHNOLOGY / JOINCARE PHARMA



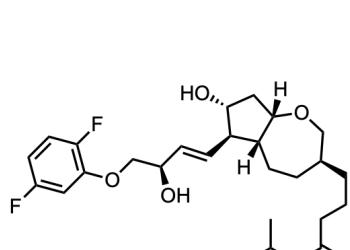
sebaloxavir marboxil
(Jike Shu®)
Influenza cap-dependent endonuclease inhibitor
to treat uncomplicated influenza A and B
80 mg PO single dose
approved by NMPA
NANJING ZENSHINE PHARMA



suraxavir marboxil
(Yisuda®)
Influenza cap-dependent endonuclease inhibitor
to treat uncomplicated influenza A and B
40 mg PO single dose
approved by NMPA
GINKGO PHARMA / JIANGXI CAISHI PHARMA / QINGFENG PHARMA



olgotrelvir
(Ovyds®)
SARS-CoV-2 M^{pro} and cathepsin L dual inhibitor
to treat mild to moderate COVID-19
600 mg PO BID
approved by NMPA
ACEA PHARMA



sepetaprost
(Setaneo®)
FP and EP3 prostaglandin receptors agonist
to treat glaucoma and ocular hypertension
one drop in each eye (sepetaprost 0.002%) topical QD
approved by PMDA
ONO PHARMA / SANTEN PHARMA

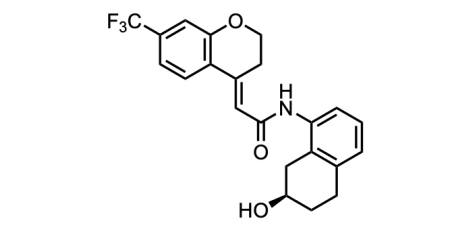
Ophthalmic (2)

Immunology (1)

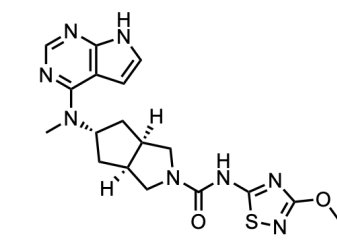
Cardiovascular (1)

Endocrinology (1)

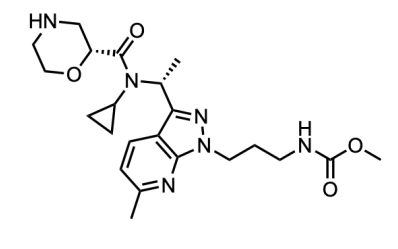
Reproductive (2)



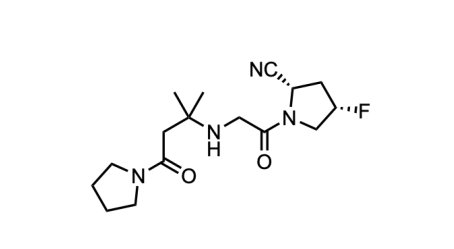
motugivatrep
(Avarep®)
TRPV1 antagonist
to treat dry eye disease
one drop in each eye (motugivatrep 0.3%) topical QID
approved by PMDA
MOCHIDA PHARMA / SENJU PHARMA



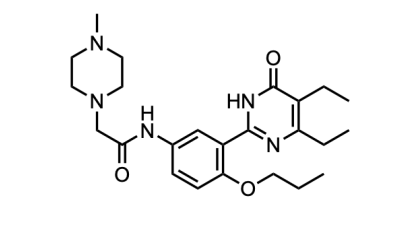
ivarmacitinib
(Aisuda®)
JAK1 inhibitor
to treat active ankylosing spondylitis, rheumatoid arthritis, or atopic dermatitis
4 mg or 8 mg PO QD
approved by NMPA
JIANGSU HENGRUI PHARMA



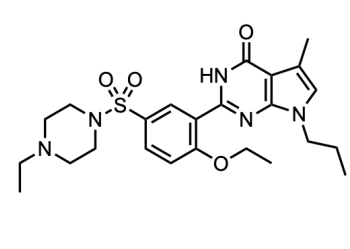
sitokiren
(Xintuoan®)
renin inhibitor
to treat essential hypertension
100 mg PO QD
approved by NMPA
SHANGHAI PHARMA / MITSUBISHI TANABE / SHANGHAI SHANGYAO XINYI PHARMA



prusogliptin
(Shanzeping®)
DPPIV inhibitor
to improve blood glucose control in type 2 diabetes
100 mg PO QD
approved by NMPA
NATIONAL HEALTH RESEARCH INSTITUTES / CSPSC OUYI PHARMA



simenafil
(Angweida®)
PDE5 inhibitor
to treat erectile dysfunction
2.5 mg, 5 mg or 10 mg PO PRN
approved by NMPA
SHANGHAI INSTITUTE OF MATERIA MEDICA OF CAS / TOPHARMAN SHANGHAI / TOPHARMAN SHANDONG / SUZHOU WANGSHAN WANSUI BIOPHARMA

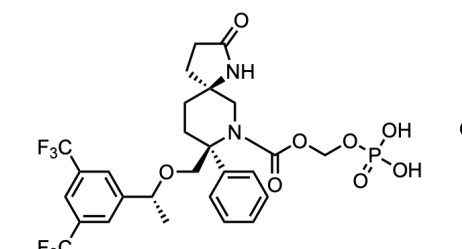


tunodafil
PDE5 inhibitor
to treat erectile dysfunction
50 mg or 100 mg PO QD
approved by NMPA
YANGZIJANG PHARMA (TIANJIN NORTH PHARM SCI TECH, YANGTZE RIVER PHARMA GROUP)

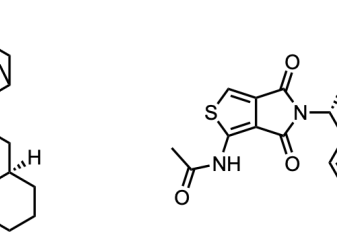
Gastrointestinal (1)

Dermatology (1)

Footnotes



fosrolapitant and palonosetron
(Ritanine®)
fosrolapitant: NK-1R antagonist
palonosetron: 5-HT₃ antagonist
to prevent chemotherapy-induced nausea and vomiting
218 mg (fosrolapitant) and 0.25 mg (palonosetron) IV single dose
approved by NMPA
JIANGSU HENGRUI MEDICINE / SHANGHAI SHENGDI PHARMA / SHANGHAI SENHUI MEDICINE / FUJIAN SHENGDI PHARMA



mufemilast
PDE4 inhibitor
to treat moderate to severe plaque psoriasis in adults
60 mg PO BID
approved by NMPA
TIANJIN MICHELE SCI TECH DEVELOPMENT / TIANJIN HEMAY BIOTECHNOLOGY / GANZHOU HEMEI PHARMA

Abbreviations:

NMPA: National Medical Products Administration (China); EMA: European Medicines Agency; PMDA: Pharmaceuticals and Medical Devices Agency (Japan)

The reported doses are general guidelines and may not apply to special populations.

This poster is for informational purposes only and is not intended for medical use.