# First-in-Class Small Molecule Approvals of 2022

$$F_3C$$

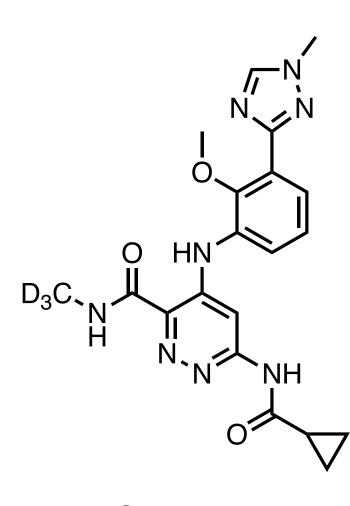
## **Sunlenca**

### HIV-1 capsid inhibitor

(lenacapavir)

for multidrug resistant HIV-1 infection INFECTIOUS DISEASES

927 mg SC Q6M after loading period **GILEAD** 



## Sotyktu

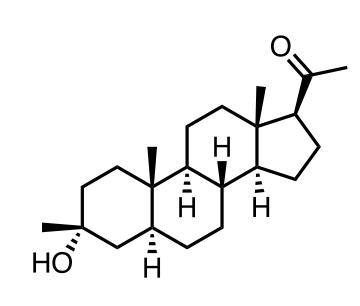
#### TYK2 allosteric inhibitor

(deucravacitinib)

for moderate-to-severe plaque psoriasis

DERMATOLOGY

6 mg orally QD BMS



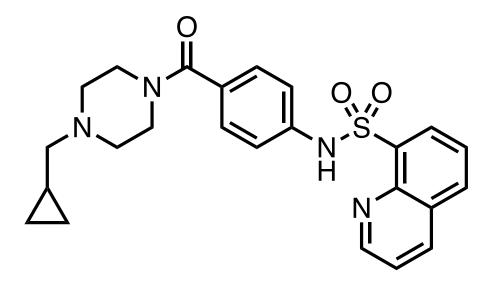
# Ztalmy GABAA PAM

(ganaxolone)

for seizures in CDKL5 deficiency disorder

NEUROLOGY 6 mg/kg orally TID

MARINUS PHARMACEUTICALS



# Pyrukynd

#### **PK** activator

(mitapivat)

for hemolytic anemia in PK deficiency
HEMATOLOGY

5 mg orally BID

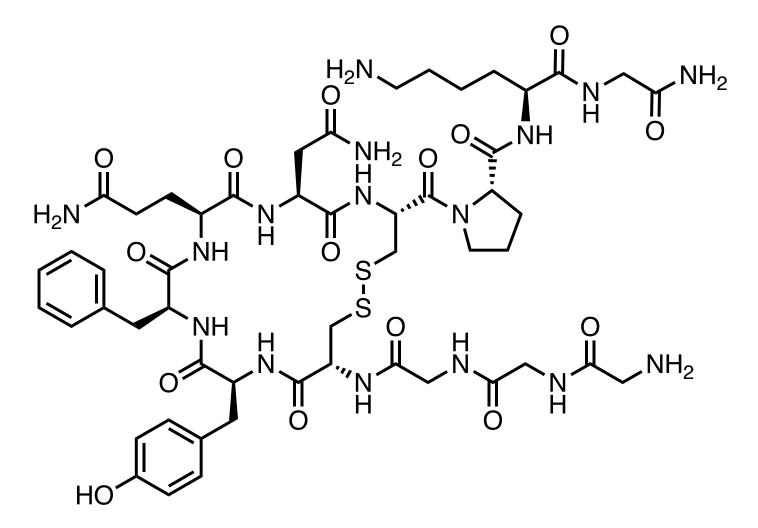
AGIOS

## **Pluvicto**

# **PSMA-targeted radiotherapy**

(lutetium <sup>177</sup>Lu vipivotide tetraxetan) for PSMA-positive prostate cancer ONCOLOGY

7.4 GBq (200 mCi) IV Q6W up to 6 doses **NOVARTIS** 



## **Terlivaz**

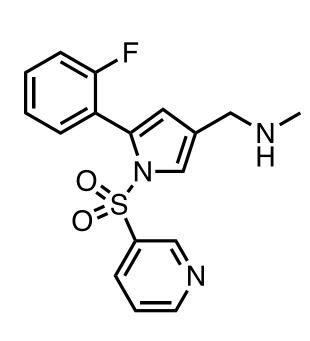
# vasopressin receptor agonist

(terlipressin)

for hepatorenal syndrome in patients with reduced kidney function **HEPATOLOGY** 

starting dose: 0.85 mg IV Q6h on day 1-3

MALLINCKRODT



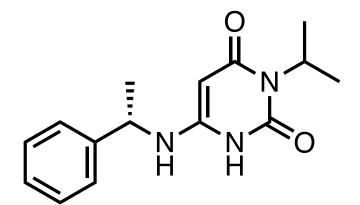
# Voquezna

## K+/H+-ATPase

#### potassium channel blocker

(vonoprazan\*, amoxicillin, and clarithromycin)
for H. pylori infection
INFECTIOUS DISEASES

20 mg BID for 14 days in combo **TAKEDA** 

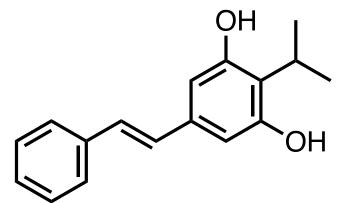


# Camzyos

#### myosin inhibitor

(mavacamten)
for obstructive HCM
CARDIOLOGY
5 mg orally QD

**BMS** 



# Vtama

#### AhR agonist

(tapinarof)
for plaque psoriasis

DERMATOLOGY

1% cream topically QD

DERMAVANT SCIENCES



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- how they work
- how they differentiate
  - ...and more

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\*novel component

CDER categorization of first-in-class based on mechanism of action

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