

No.	Drug Name	Active Ingredient	Dose	Formulation	Molecular Type	Indication	Target	Company	Absorption	Distribution	Metabolism	Excretion	Drug Interactions
1	Zelsuvmi	Berdazimer	Tube A (berdazimer gel) + Tube B (hydrogel) mixed equally (0.5 mL); applied once daily for up to 12 weeks	Topical gel	Small molecule	Molluscum contagiosum	Nitric oxide (NO) releasing agent	Ligand Pharmaceuticals	Plasma hydrolyzed MAP3 (hMAP3): Day 1: Undetectable; Day 15: Detectable in 2 subjects. Nitrate levels: Similar on Days 1 and 15; remained relatively flat during PK sampling (baseline through 1, 3, and 6 hours post-application).	Not provided	Not provided	Not provided	Not provided
2	Exblifep	Cefepime + Enmetazobactam	2 g cefepime/0.5 g enmetazobactam every 8 hours	IV injection	Small-molecule	Complicated urinary tract infections (cUTIs)	Beta-lactamase inhibitor	Allegra Therapeutics	Cefepime: C _{max} : 99.8 µg/mL (SD 26.4); AUC _{last} : 379.5 µg·h/mL (SD 123.3). Enmetazobactam: C _{max} : 19.8 µg/mL (SD 6.3); AUC _{last} : 75.3 µg·h/mL (SD 30.8).	Cefepime: Vd = 20.02 L (SD 6.44); plasma protein binding = 20%. Enmetazobactam: Vd = 25.26 L (SD 9.97); negligible plasma protein binding.	Cefepime: CL = 5.8 L/h (SD 1.9); t _{1/2} = 2.7 h (SD 1.1). Enmetazobactam: CL = 7.6 L/h (SD 2.9); t _{1/2} = 2.6 h (SD 1.1).	Cefepime: Urine = 85%. Enmetazobactam: Urine = 90%.	In vitro: Enmetazobactam inhibits CYP2E1.
3	Letybo	Letibotulinum toxinA-wlb	20 units, no more than once every 3 months	Intramuscular injection	Protein toxin	Temporary improvement of the appearance of moderate-to-severe glabellar lines	Acetylcholine release inhibitor + neuromuscular blocker	Hugel Inc.	Peripheral blood levels of Letybo are undetectable at recommended doses using current analytical techniques.	Not provided	Not provided	Not provided	Not provided
4	Tevimbra	Tislelizumab-jsg	200 mg every 3 weeks	IV injection	Monoclonal antibody	Unresectable/metastatic esophageal squamous cell carcinoma	PD-1	BeiGene	C _{max} : 110 µg/mL (22.2% CV); AUC _{tau} : 1283 µg/mL·day (28.7% CV). Steady state achieved by Week 12 (accumulation ratio: 2.14x).	Vd = 6.42 L (32.6% CV).	CL = 0.153 L/day (29.5% CV); t _{1/2} = 24 days (31% CV). Degraded via proteolysis (similar to endogenous IgG).	Not provided	Not provided

5	Rezdiffra	Resmetirom	80 mg/100 mg once daily	Oral tablet	Small molecule	Noncirrhotic non-alcoholic steatohepatitis with moderate to advanced liver scarring	Thyroid hormone receptor- β (THR- β)	Madrigal Pharmaceuticals	Steady state achieved in 3–6 days. 80 mg/day: $C_{\sim\max,ss\sim}$ = 778 ng/mL (41.5% CV); $AUC_{\sim\tau,ss\sim}$ = 5850 ng·h/mL (60.5% CV). 100 mg/day: $C_{\sim\max,ss\sim}$ = 971 ng/mL (40.9% CV); $AUC_{\sim\tau,ss\sim}$ = 7780 ng·h/mL (65.5% CV). $T_{\sim\max\sim}$ delayed by ~2 hours with food ($C_{\sim\max\sim}$ ↓33%, AUC ↓11%).	V_d = 68 L (227% CV); plasma protein binding >99%.	CL = 17.5 L/h (56.3% CV); $t_{\sim\frac{1}{2}\sim}$ = 4.5 hours. Metabolized by CYP2C8. Major metabolite MGL-3623 accounts for 33–51% of steady-state AUC.	Feces = 67% (MGL-3623: 3.3%); Urine = 24% (MGL-3623: 16%).	In vitro: Inhibits CYP2C8, UGT1A4/1A9, OATP1B1/1B3, BCRP, OAT3, and BSEP; a substrate of OATP1B1/1B3 and BCRP. Clinical: Clopidogrel (CYP2C8 inhibitor): ↑Resmetirom AUC by 1.7x. Pioglitazone (CYP2C8 substrate): ↑Pioglitazone AUC by 1.5x. Statins (e.g., simvastatin): ↑Simvastatin AUC by 1.7x..
6	Tryvio	Aprocitentan	12.5 mg once daily	Oral tablet	Small molecule	Hypertension	ETA/ETB receptors	Idorsia Pharmaceuticals	Single 25 mg dose (two folds the recommended dose): $C_{\sim\max\sim}$ = 1.3 μ g/mL (19% CV); $T_{\sim\max\sim}$ = 4–5 hours; $AUC_{0-\tau}$ =23 μ g·h/mL (17% CV). Steady state achieved by Day 8 (accumulation ratio: 3x).	V_d = 20 L; plasma protein binding >99%; blood-to-plasma ratio = 0.63.	CL = 0.3 L/h; $t_{\sim\frac{1}{2}\sim}$ = 41 hours. Metabolized via N-glycosylation (UGT1A1/2B7) and non-enzymatic hydrolysis.	Feces = 25% (6.8% unchanged); Urine = 52% (0.2% unchanged).	In vitro: Inhibits CYP3A4, CYP2C family, BCRP, BSEP and NTCP; inducer of CYP3A4; substrate and inhibitor of UGT1A1 and UGT2B7; substrate of P-gp and BCRP. Clinical: ↓Exposure with UGT inducers.
7	Duvyzat	Givinostat	22.2–53.2 mg twice daily (weight-based)	Oral suspension	Small molecule	Duchenne muscular dystrophy (patients \geq 6 years)	Histone deacetylase inhibitor	Italfarmaco	Steady state achieved in 5–7 days after twice daily dosing (accumulation ratio <2x). High-fat meal ↑AUC by ~40%, ↑ $C_{\sim\max\sim}$ by ~23%, delays $T_{\sim\max\sim}$ by 2–3 hours.	Plasma protein binding \approx 96%; blood-to-plasma ratio = 1.3.	$t_{\sim\frac{1}{2}\sim}$ = 6 hours; minimal metabolism via CYP450/UGT.	Elimination via metabolism → renal/biliary excretion of metabolites. Urine excretion <3% of dose.	In vitro: Induces CYP1A2/2B6/3A4; substrate of P-gp/BCRP. Clinical: Weak inhibition of OCT2; unlikely to inhibit P-gp.
8	Winrevair	Sotatercept-csrk	0.7 mg/kg every 3 weeks	Subcutaneous injection	Recombinant fusion protein	Pulmonary arterial hypertension (PAH)	ActRIIA	Accelaron Pharma, Merck	0.7 mg/kg every 3 weeks: AUC = 172 μ g·d/mL (34.2% CV); C_{\max} = 9.7 μ g/mL (30% CV). Steady state achieved at ~15 weeks (accumulation ratio: 2.2x). Absolute bioavailability = 66%. $T_{\sim\max\sim}$: ~7 days.	V_d = 5.3 L (27% CV); increases with body weight.	CL = 0.18 L/day; $t_{\sim\frac{1}{2}\sim}$ = 24 days. Metabolized via catabolism into small peptides.	Not provided	Not provided

9	Vafseo	Vadadustat	300 mg once daily	Oral tablet	Small molecule	Anemia due to chronic kidney disease (CKD)	HIF-PH inhibitor	Akebia Therapeutics	T~max~ = 2–3 hours. Dose-proportional exposure (80–1200 mg). Steady state achieved by Day 3 (no accumulation).	Plasma protein binding >99.5%; no distribution into RBCs.	t~½~ = 9.2 hours (CKD patients). Metabolized via UGT glucuronidation. CL ↓ with renal impairment.	Feces = 26.9% (9% unchanged); Urine = 58.9% (<1% unchanged).	Clinical: ↑AUC with OAT1/3 inhibitors; ↓C~max~/AUC with iron-based phosphate binders. ↑Exposure with HMG-CoA reductase inhibitors/CYP2C9 substrates/OTA3 substrates/BCRP substrates.
10	Voydeya	Danicopan	150 mg/200 mg three times daily	Oral tablet	Small molecule	Extravascular hemolysis with paroxysmal nocturnal hemoglobinuria (PNH)	Complement factor D	AstraZeneca	Steady state achieved by Day 2. 150 mg TID: C~max,ss~ = 535 ng/mL; AUC~24,ss~ = 8180 ng·h/mL. 200 mg TID: C~max,ss~ = 665 ng/mL; AUC~24,ss~ = 10200 ng·h/mL. High-fat meal ↑C~max~ by 93%, ↑AUC by 25%.	Vd = 395 L (75 kg); plasma protein binding = 91.5–94.3%; blood-to-plasma ratio = 0.545.	CL = 63 L/h; t~½~ = 7.9 hours. Metabolized via hydrolysis (96%), minimal CYP involvement.	Feces = 69% (3.57% unchanged); Urine = 25% (0.48% unchanged).	Clinical: ↑Rosuvastatin (BCRP substrate) C~max~ by 3.3x, AUC by 2.2x; ↑fexofenadine (P-gp substrate) C~max~ by 1.4x, AUC by 1.6x. ↑tacrolimus (P-gp substrate) C~max~ by 1.1x, AUC by 1.5x. In vitro: Inhibits BCRP/P-gp; A substrate of P-gp.
11	Zevtera	Ceftobiprole medocartil sodium	667 mg (equivalent to 500 mg ceftobiprole) every 8 hours	IV injection	Small molecule	Bloodstream infections, bacterial skin and associated tissue infections, and community-acquired bacterial pneumonia	Bacterial cell wall synthesis inhibitor	Basilea Pharmaceutica	Dose-proportional exposure (125–1000 mg). 667 mg dose: C~max~ = 33 µg/mL (SD 4.83); AUC~0-8h~ = 102 µg·h/mL (SD 11.9).	Vd = 18 L; plasma protein binding = 16%. ELF/unbound plasma ratio = 15–19%.	CL = 4.98 L/h (SD 0.582); t~½~ = 3.3 hours (SD 0.3).	Urine = 83% (unchanged).	In vitro: Inhibits OATP1B1/1B3, MRP2, BSEP.
12	Lumisight	Pegulicianine	1 mg/kg	IV injection	Fluorescent probe (PEG peptide)	Optical imaging of cancerous tissues	Fluorescent probe	Lumecell, Inc.	Not provided	Not provided	Metabolized by cathepsins and MMPs into fragments 2 and 3. Low hepatic metabolism in vitro.	In humans is unknown. However, the observed blue/green discoloration of urine in subjects suggests renal excretion of pegulicianine and/or its metabolites.	Not provided

13	Anktiva	Nogapendekin alfa inbakicept-pmIn	Induction: 600 µg weekly ×6 weeks; Maintenance: 400 µg once a week for 3 weeks at months 4, 7, 10, 13 and 19	Intravesical solution	Cytokine fusion protein	BCG-unresponsive non-muscle invasive bladder cancer (NMIBC)	IL-15 receptor	ImmunityBio	Systemic exposure <100 pg/mL (below quantification limit).	Not provided	Not provided	Not provided	Not provided
14	Ojemda	Tovorafenib	380 mg/m ² weekly (max 600 mg)	Oral tablet/suspension	Small molecule	Relapsed/refractory pediatric low-grade glioma	RAF	Day One Biopharmaceuticals	C _{~max~} = 6.9 µg/mL (23% CV); AUC = 508 µg·h/mL (31% CV). Steady state achieved by Day 12 (no accumulation). T _{~max~} : 3 hours (1.5-4 hours) following a single dose. High-fat meal delays T _{~max~} to 6.5 hours.	Vd = 60 L/m ² (23% CV); plasma protein binding = 97.5%.	CL = 0.7 L/h/m ² (31% CV); t _{~1/2~} = 56 hours (33% CV). Metabolized by aldehyde oxidase and CYP2C8.	Feces = 65% (8.6% unchanged); Urine = 27% (0.2% unchanged).	Clinical: ↓Midazolam (CYP3A4 substrate) exposure by ≥20%. In vitro: Inhibits CYP2C8/2C9/2C19/3A; induces CYP3A/2C8/1A2/2B6/2C9/2C19; inhibits BCRP.
15	Xolremdi	Mavorixafor	300 mg (≤50 kg)/400 mg (>50 kg) once daily	Oral capsule	Small molecule	WHIM syndrome (warts, hypogammaglobulinemia, infections, myelokathexis)	CXCR4	X4 Pharmaceuticals	400 mg once daily: C _{~max~} = 3304 ng/mL (58.6% CV); AUC _{0-24h~} = 13970 ng·h/mL (58.4% CV). Greater than dose-proportional (50-400 mg). Steady state reached after ~9 to 12 days. Tmax: 2.8 hours (1.9-4 hours). High-fat meal ↓C _{~max~} by 66%, ↓AUC by 55%.	Vd = 768 L; plasma protein binding >93%.	CL = 62 L/h (40% CV); t _{~1/2~} = 82 hours (34% CV). Primarily metabolized by CYP3A4.	Feces = 61%; Urine = 13.2% (3% unchanged).	Clinical: ↑exposure 2x with itraconazole (strong CYP3A4 and P-gp inhibitor); ↑dextromethorphan (CYP2D6 substrate) C _{~max~} 6x, AUC 9x. ↑midazolam (CYP3A4 substrate) C _{~max~} 1.1x, AUC 1.7x; ↑digoxin (P-gp substrate) C _{~max~} 1.5x, AUC 1.6x; ↓metformin (P-gp substrate) C _{~max~} 35%, AUC 35%. In vitro: Substrate/inhibitor of multiple CYPs and transporters.
16	Imdelltra	Tarlatamab-dlle	Step-up dosing: 1 mg → 10 mg → 10 mg every 2 weeks	IV injection	Bispecific antibody	Extensive-stage small cell lung cancer	DLL3/CD3	Amgen	Dose-proportional exposure (1–100 mg every 2 weeks). Steady state (10 mg every 2 weeks): C _{~avg~} = 1040 ng/mL (44% CV); C _{~max~} = 3400 ng/mL (40% CV).	Vd = 8.6 L (18.3% CV).	CL = 0.65 L/day (44% CV); t _{~1/2~} = 11.2 days (4.3–26.5 days). Degraded into small peptides.	Not provided	May transiently inhibit CYP450 enzymes due to cytokine release.

17	Rytelo	Imetelstat	7.1 mg/kg every 4 weeks	IV injection	Oligonucleotide	Low- to intermediate-risk myelodysplastic syndromes (MDS)	Telomerase	Geron Corporation	7.1 mg/kg dose every 4 weeks: C _{max} = 18.3 µM (27.3% CV); AUC _{0-28d} = 114.2 h·µM (43.2% CV). No accumulation after 4-week cycles.	Vd = 14.1 L (27.2% CV); plasma protein binding >94%.	t _{1/2} = 4.9 hours (43.2% CV). Degraded by nucleases into nucleotide fragments.	Not provided	In vitro: Inhibits OATP1B1/1B3.
18	Iqirvo	Elafibranor	80 mg once daily	Oral tablet	Small molecule	Primary biliary cholangitis (with ursodeoxycholic acid)	PPARα/δ	Ipsen Biopharmaceuticals	Steady state (80 mg): C _{max,ss} = 802 ng/mL (SD 443); AUC _{0-24,ss} = 3758 ng·h/mL (SD 1749). Tmax: 1.25 hours (0.5-2 hours). High-fat meal ↓C _{max} /AUC and delays T _{max} by 0.5 hours.	Vd = 4731 L; plasma protein binding = 99.7%.	t _{1/2} = 70.2 hours (range 37.1–92.2). CL = 50.0 L/h. Metabolized via PTGR1 to active metabolite GFT1007, and also via CYP2J2 and UGT isoforms.	Urine = 19.3% (11.8% inactive metabolite GFT3351); Feces = 77.1% (56.7% unchanged, 6.08% GFT1007).	Clinical: No significant interactions with warfarin, simvastatin, atorvastatin, or sitagliptin. In vitro: GFT1007 inhibits UGT1A6; GFT3351 inhibits MRP2/3.
19	Sofdra	Sofpironium	0.67 mL gel (72 mg) per axilla once daily	Topical gel	Small molecule	Primary axillary hyperhidrosis	AChR	Botanix Pharmaceuticals	C _{max} = 2.71 ng/mL (SD 6.94); AUC _{0-t} = 45.1 ng·h/mL (SD 85.1); T _{max} = 5.34 hours (SD 5.45).	Plasma protein binding: 34.8–37.8% (sofpironium), 2.3–3.7% (metabolite BBI-4010).	Metabolized via non-enzymatic hydrolysis, CYP2D6/3A4 oxidation, and glycine conjugation.	Urine: <0.5% of dose (sofpironium/BBI-4010).	Clinical: No significant interactions with CYP3A4/OCT2/MATE inhibitors. In vivo: ↑Exposure by two folds with paroxetine HCl (strong CYP2D6 inhibitor). In vitro: Inhibits CYP2D6/3A4, OCT1/2, MATE1.
20	Piasky	Crovalimab-akkz	Initial: 1000 mg IV; Maintenance: 340 mg SC weekly	IV/SC injection	Monoclonal antibody	Paroxysmal nocturnal hemoglobinuria (PNH)	C5	Roche	C _{max,ss} = 292 µg/mL (30.1% CV); C _{trough,ss} = 230 µg/mL (31.6% CV); AUC _{tau,ss} : 7478 µg·d/mL (30.5% CV). Bioavailability = 83% (SC).	Central Vd = 3.23 L; peripheral Vd = 2.32 L.	t _{1/2} = 53.1 days; CL = 0.0791 L/day. Degraded via lysosomal proteolysis.	Not excreted via renal/hepatic pathways.	Transient ↑CL during transition from other C5 inhibitors (no dose adjustment needed).
21	Ohtuvayre	Ensifentrine	3 mg twice daily	Oral inhalation suspension	Small molecule	Chronic obstructive pulmonary disease (COPD)	PDE3/PDE4	Verona Pharma	T _{max} = 0.6–1.5 hours post-inhalation. ~90% of dose delivered to lungs.	Central Vd = 2700 L (healthy), 8150 L (COPD); peripheral Vd = 1820 L (healthy), 5490 L (COPD); plasma protein binding ≈90%.	t _{1/2} = 10.6–12.6 hours. Metabolized via oxidation (CYP2C9 > CYP2D6) and conjugation.	Feces = majority; Urine = <0.3% (unchanged).	Clinical: ↑Exposure with CYP2C9 inhibitors (e.g., fluconazole). In vitro: Substrate of BCRP.

22	Kisunla	Donanemab-azbt	700 mg every 4 weeks	IV injection	Monoclonal antibody	Alzheimer's disease	Amyloid-beta	Eli Lilly	Dose: 700 mg → 1400 mg every 4 weeks. Steady state reached after first dose (accumulation <1.3x). Dose-proportional exposure (10–40 mg/kg).	Central Vd = 3.36 L.	$t_{1/2} \sim$ = 12.1 days; CL = 0.0255 L/h. Degraded via proteolysis (similar to endogenous IgG).	Negligible renal elimination.	Not provided
23	Leqselvi	Deuruxolitinib	8 mg twice daily	Oral tablet	Small molecule	Severe alopecia areata	JAK1/JAK2	Sun Pharma	$T_{\sim\max} \sim$ = 1.5 hours (post-dose). No food effect; bioavailability = 90%. Dose-proportional exposure (8–48 mg). Steady state achieved in 1–2 days (minimal accumulation).	Vd = 50 L; plasma protein binding = 91.5%; blood-to-plasma ratio = 1.3.	$t_{1/2} \sim$ = 4 hours. Metabolized via CYP2C9 (76%), CYP3A4 (21%), CYP1A2 (3%).	Urine/Feces: No unchanged drug detected.	Clinical: ↓AUC by 78% with rifampin (strong CYP3A4 inhibitor and moderate CYP2C9 inducer); based on modeling: predicted ↑AUC by 200% with strong CYP2C9 inhibitors; ↑AUC by 140% with fluconazole (moderate CYP2C9 inhibitor and moderate CYP3A inhibitor). In vitro: Substrate of BCRP/MDR1; inhibitor of BCRP/BSEP/OAT3/MATE2-K.
24	Voranigo	Vorasidenib	50 mg once daily	Oral tablet	Small molecule	IDH-mutant grade 2 astrocytoma/oligodendroglioma	IDH1/IDH2	Servier Pharmaceuticals	Dose-proportional exposure (10–200 mg). At the highest approved recommended dosage (50 mg/day): $C_{\sim\max} \sim$ = 133 ng/mL (73% CV); AUC = 1988 h·ng/mL (95% CV). T_{\max} : 2 hours (0.5–4 hours). Absolute bioavailability = 34%. High-fat meal ↑ $C_{\sim\max} \sim$ by 3.1x, AUC by 1.4x. Low-fat and low-calorie meal ↑ C_{\max} by 2.3x, AUC by 1.4x.	Vd = 3930 L (40% CV); plasma protein binding = 97%; brain tumor-to-plasma ratio = 1.6.	$t_{1/2} \sim$ = 10 days (57% CV); CL = 14 L/h (56% CV). Primarily metabolized by CYP1A2; 30% via non-CYP pathways.	Feces = 85% (56% unchanged); Urine = 4.5%.	In vitro: Induces CYP2B6/2C8/2C9/2C19/3A/UGT1A4; inhibits BCRP. Clinical: ↑AUC by 2.5x with moderate CYP1A2 inhibitors (e.g., ciprofloxacin); ↑AUC ≥5x with strong CYP1A2 inhibitors (e.g., fluvoxamine); ↓AUC by 40% with moderate CYP1A2 inducers (e.g., phenytoin or rifampicin).
25	Yorvipath	Palopegteriparatide	6–30 µg once daily (individualized)	Subcutaneous injection	Peptide	Hypoparathyroidism	PTH1R	Ascendis Pharma	$T_{\sim\max} \sim$ = 4 hours (range 4–8 hours).	Vd = 4.8 L (50% CV).	$t_{1/2} \sim$ = 60 hours; CL = 0.58 L/day (52% CV). Releases active metabolites PTH1–34 and PTH1–33.	Not provided	Not provided
26	Nemluvio	Nemolizumab-iltio	Initial: 60 mg (two 30 mg injections); Maintenance: 30–60 mg every 4 weeks	Subcutaneous injection	Monoclonal antibody	Prurigo nodularis	IL-31	Galderma	$C_{\sim\max} \sim$ = 7.5 µg/mL (SD 2.31) at ~6 days post-dose. $T_{\sim\max} \sim$: ~6 days post-dose. Dose-proportional exposure (0.03–3 mg). Steady-state $C_{\sim\text{trough}} \sim$: 3.04 µg/mL (weight <90 kg), 3.66 µg/mL (weight ≥90 kg).	Vd = 7.67 L.	$t_{1/2} \sim$ = 18.9 days (SD 4.96); CL = 0.263 L/day. Degraded like endogenous IgG.	Not provided	Not provided

27	Livdelzi	Seladelpar	10 mg once daily	Oral capsule	Small molecule	Primary biliary cholangitis (PBC)	PPAR δ	Gilead Sciences	Steady state achieved by 4 days post-dose (10 mg): C~max,ss~ = 103 ng/mL (SD 29.3); AUC~0-24h,ss~ = 902 ng·h/mL (SD 238). T~max~ = 1.5 hours.	Vd = 133.2 L; plasma protein binding >99%.	t~½~ = 6 hours (healthy), 3.8–6.7 hours (PBC patients). Metabolized via CYP2C9 (primary), CYP2C8/3A4.	Urine = 73.4% (<0.01% unchanged); Feces = 19.5% (2.02% unchanged). Biliary excretion confirmed in animals.	Clinical: \uparrow AUC by 2.4x with fluconazole (moderate CYP2C9/3A4 inhibitors); \downarrow AUC by 44% with carbamazepine (CYP3A/2C9 inducers); \uparrow AUC by 2.1x with cyclosporine (BCRP inhibitor); \uparrow AUC by 2x with probenecid (OAT3 inhibitor); expect \uparrow AUC by 3.7x with sulphaphenazole (strong CYP2C9 inhibitor). In vitro: Substrate of CYP2C9/2C8/3A4, BCRP/P-gp/OAT3.
28	Niktimvo	Axatilimab-csfr	0.3 mg/kg (max 35 mg) every 2 weeks	IV injection	Monoclonal antibody	Chronic graft-versus-host disease (cGVHD)	CSF-1R	Incyte, Syndax Pharmaceuticals	AUC increases supra-proportionally at doses 0.15–3 mg/kg (0.5–10x approved dose).	Vd = 6.06 L (16.3% CV).	CL decreases from 2.32 mL/h/kg (0.15 mg/kg) to 0.21 mL/h/kg (3 mg/kg); t~½~ increases from 10.7 to 108 hours. Degraded into small peptides.	Not provided	Not provided
29	Lazcluze	Lazertinib	240 mg once daily	Oral tablet	Small molecule	Non-small cell lung cancer (NSCLC)	EGFR	Janssen	C~max~ = 133 ng/mL (73% CV); T~max~: 2–4 hours; AUC = 1988 h·ng/mL (95% CV). Dose-proportional increases in Cmax and AUC from 20 mg to 320 mg (0.08–1.3x the approved dose). Steady-state plasma exposure achieved by Day 15.	Vd = 2680 L (51% CV); plasma protein binding = 99.2%.	t~½~ = 3.7 days (56% CV); CL = 36.4 L/h (47% CV). Metabolized via glutathione conjugation and CYP3A4.	Urine = 4% (<0.2% unchanged); Feces = 86% (<5% unchanged).	In vitro: Inhibits CYP3A4/UGT1A1/BCRP/OCT1. Clinical: Strong CYP3A4 inducers (e.g., rifampin): \downarrow Cmax by 72%, \downarrow AUC by 83%. Strong CYP3A4 inhibitors (e.g., itraconazole): \uparrow Cmax by 1.2x, \uparrow AUC by 1.5x. CYP3A4 substrates (e.g., midazolam): \uparrow Midazolam Cmax by 1.4x, AUC by 1.5x. BCRP substrates (e.g., rosuvastatin): \uparrow Rosuvastatin Cmax by 2.2x, AUC by 2x.
30	Ebglyss	Lebrikizumab-ibkz	250 mg every 2/4 weeks	Subcutaneous injection	Monoclonal antibody	Moderate-to-severe atopic dermatitis	IL-13	Almirall, Eli Lilly	C~max~ = 108 μ g/mL (every 2 weeks), 63 μ g/mL (every 4 weeks); C~avg~ = 100 μ g/mL (every 2 weeks), 51 μ g/mL (every 4 weeks); C~trough~ = 87 μ g/mL (every 2 weeks), 36 μ g/mL (every 4 weeks). Following a single 250 mg dose, C~max~ achieved by ~7-8 days post-dose. Absolute bioavailability = 86%.	Vd = 5.14 L.	t~½~ = 24.5 days; CL = 0.154 L/day. Linear elimination. Degraded like endogenous IgG.	Not provided	Not provided

31	Miplyffa	Arimoclomol	47–124 mg three times daily (weight-based)	Oral capsule	Small molecule	Niemann-Pick disease type C (NPC)	Heat shock protein	Zevra Therapeutics	C~max,ss~ = 2090 ng/mL (23% CV); AUC~0-8h~ = 7207 h·ng/mL (19% CV). T~max~: 0.5 hours. No significant food effect.	Vd = 211 L; plasma protein binding = 10%.	t~½~ = 4 hours; CL = 34 L/h. Metabolized via glutathione conjugation, O-glucuronidation, and NO-oxime cleavage.	Urine = 77.5% (42% unchanged); Feces = 12%.	In vitro: Substrate of OCT2/MATE1/2-K. MATE inhibitors unlikely to affect exposure.
32	Aqneursa	Levacetylleucine	1 g three times daily (weight-based)	Oral suspension	Small molecule	Niemann-Pick disease type C (NPC)	Amino acid metabolism	IntraBio Inc.	C~max~ = 8.3 µg/mL (SD 3.3); AUC~0-24h~ = 33.2 h·µg/mL (SD 12.5); T~max~ = 1 hour (0.5–2.5 hours).	Vd = 253 L (SD 125).	t~½~ ≈ 1 hour; CL = 139 L/h (SD 59). Metabolized by ubiquitous enzymes (no CYP450 involvement).	Not provided	In vitro: Substrate of OAT1/3; inhibits P-gp/BCRP/BSEP/OAT1/3.
33	Cobenfy	Xanomeline + Trospium chloride	50 mg/20 mg twice daily (starting dose)	Oral capsule	Small molecule	Schizophrenia	Xanomeline: Central M1/M4 muscarinic receptors. Trospium chloride: Peripheral muscarinic receptors	BMS	Xanomeline: T~max~ = 2 hours; high-fat meal ↑AUC by 30%. Trospium: T~max~ = 1 hour; high/low-fat meals ↓AUC by 85–90%, ↓Cmax by 70–75%.	Xanomeline: Vd = 10,800 L; plasma protein binding ≈95%. Trospium: Vd = 531 L; plasma protein binding ≈80%.	Xanomeline: t~½~ = 5 hours; CL = 1950 L/h. Metabolized by CYP2D6/2B6/1A2/2C9/2C19, FM01/3. Trospium: t~½~ = 6 hours; CL = 796 L/h. Metabolized via ester hydrolysis/glucuronidation.	Xanomeline: Urine = 78% (<0.01% unchanged); Feces = 12%. Trospium: Urine = 85–90% (unchanged).	Risk of increased adverse effects with CYP2D6 inhibitors, sensitive substrates of CYP3A4 or P-gp, or drugs eliminated via active renal tubular secretion.
34	Flyrcado	Flurpiridaz F 18	93–352 MBq (rest/stress imaging)	IV injection	Small molecule	Myocardial ischemia/infarction imaging	PET tracer	GE Healthcare	T~max~ = 2.3 minutes post-injection. Blood radioactivity declines to 3% by 7 hours.	Distributed to liver (19%), kidneys (9%), brain (8%), heart (3%) at 10 minutes.	Metabolized into polar metabolites. Cleared from blood within 48 hours.	Urine = 63% (0% unchanged); Feces = 30% (0% unchanged).	Not provided
35	Itovebi	Inavolisib	9 mg once daily	Oral tablet	Small molecule	Locally advanced/metastatic breast cancer	PI3Kα	Roche	C~max~ = 69 ng/mL (27% CV); AUC~ss~ = 1010 h·ng/mL (25% CV). Tmax: 3 hours (0.5-4 hours). Absolute bioavailability = 76%. Steady state is expected to be achieved by 5 days post-dose. No food effect.	Vd = 155 L (26% CV); plasma protein binding = 37%; blood-to-plasma ratio = 0.8.	t~½~ = 15 hours (24% CV); CL = 8.8 L/h (29% CV). Metabolized via hydrolysis (minimal CYP3A involvement).	Urine = 49% (40% unchanged); Feces = 48% (11% unchanged).	In vitro: Induces CYP3A/2B6; substrate of P-gp/BCRP; TDI of CYP3A.

36	Hypavzi	Marstacimab-hncq	Loading: 300 mg; Maintenance: 150 mg weekly	Subcutaneous injection	Monoclonal antibody	Prevent or reduce bleeding episodes related to hemophilia A or B	TFPI	Pfizer	Adults: C _{~max,ss~} = 17.9 µg/mL (77.5% CV); C _{~trough,ss~} = 13.7 µg/mL (90.4% CV); C _{~avg,ss~} = 16.5 µg/mL (81.2% CV). Adolescents: C _{~max,ss~} = 34.7 µg/mL (48.5% CV); C _{~trough,ss~} = 27.3 µg/mL (53.2% CV); C _{~avg,ss~} = 32.1 µg/mL (49.5% CV). Bioavailability = 71%. T _{max} : 23-59 hours (hemophilia patients)	Vd = 8.6 L (hemophilia patients).	Elimination half-life: 7–10 days. Degraded like endogenous IgG.	Not provided	Not provided
37	Vyloy	Zolbetuximab-clzb	Initial: 800 mg/m ² ; Maintenance: 600 mg/m ² every 3 weeks or 400 mg/m ² every 2 weeks	IV injection	Monoclonal antibody	Gastric/gastroesophageal junction adenocarcinoma	Claudin 18.2	Astellas Pharma	Dose-proportional exposure (33–1000 mg/m ²). Steady state achieved at 18 weeks (C _{~max~} = 415 µg/mL (22% CV), AUC _{~tau~} = 149 day·µg/mL (37% CV)).	Vd = 14.0 L (59% CV).	CL = 0.013 L/h (44% CV); t _{~1/2~} = 41 days (62% CV). Degraded into small peptides.	Not provided	Not provided
38	Orlynvah	Sulopenem etzadroxil + Probenecid	500 mg/500 mg twice daily	Oral tablet	Small molecule	Uncomplicated urinary tract infection (uUTI)	Bacterial cell wall synthesis inhibitor	Iterum Therapeutics	Sulopenem: T _{~max~} : 1.0 h (fasted) / 2.0 h (high-fat); C _{~max~} : 1.84 µg/mL (fasted) / 2.66 µg/mL (high-fat); AUC: 4.85 h·µg/mL (fasted) / 7.41 h·µg/mL (high-fat); Bioavailability: 40% (fasted) / 64% (high-fat). Probenecid: T _{~max~} : 3.0 h (fasted) / 2.0 h (high-fat); C _{~max~} : 41.2 µg/mL (fasted) / 30.4 µg/mL (high-fat); AUC: 255 h·µg/mL (fasted) / 237 h·µg/mL (high-fat). A high-fat meal ↑sulopenem AUC by 48% and ↓probenecid AUC by 8%.	Sulopenem: Vd = 134 L (fasted), 92.09 L (high-fat); plasma protein binding = 11%. Probenecid: Vd = 8.81 L (fasted), 11.94 L (high-fat).	Sulopenem: t _{~1/2~} = 1.18 (fasted), 1.28 hours (high-fat); CL = 77.6 (fasted), 50.55 L/h (high-fat). Probenecid: t _{~1/2~} = 2.93 (fasted), 3.83 hours (high-fat); CL = 2.06 (fasted), 2.22 L/h (high-fat).	Sulopenem: Feces = 44.3% (26.9% unchanged); Urine = 40.8% (3.1% unchanged).	In vitro: Sulopenem is OAT3 substrate; probenecid inhibits BCRP/OAT1/3. Clinical: No interactions with itraconazole/pantoprazole.

39	Revuforj	Revumenib	270 mg twice daily (≥40 kg, no strong CYP3A4 inhibitors)	Oral tablet	Small molecule	Relapsed/refractory acute leukemia	Menin	Syndax Pharmaceuticals	163 mg BID, with strong CYP3A4 inhibitor: C~max~ = 3220 ng/mL (34% CV); AUC~0-12h~ = 22610 ng·h/mL (50% CV). Steady state achieved in 2–3 days (accumulation ratio: 2x). No food effect.	Vd = 78 L (50% CV); plasma protein binding = 90%; blood-to-plasma ratio = 0.8.	t~½~ = 7.5 hours (57% CV); CL = 7 L/h (51% CV). Metabolized by CYP3A4 (active metabolite M1).	Urine = 27% (7% unchanged); Feces = 49% (7% unchanged).	In vitro: Inhibits CYP3A4; substrate of OCT1/2/OAT1/3/MATE1; inhibits MATE1 Clinical: ↑Exposure 2x with strong CYP3A4 inhibitors.
40	Ziihera	Zanidatamab-hrii	20 mg/kg every 2 weeks	IV injection	Bispecific antibody	Unresectable/metastatic HER2-positive (IHC 3+) biliary tract cancer	HER2	Jazz Pharmaceuticals	C~max~ = 600 µg/mL (22.2% CV); C~trough~ = 178 µg/mL (29.6% CV); AUC~0-336h~ = 3976 day·µg/mL (22.5% CV).	Vd = 7.5 L (33% CV).	t~½~ ≈ 21 days; CL = 0.012 L/h (27.9% CV). Degraded into small peptides.	Not provided	Not provided
41	Attruby	Acoramidis	712 mg twice daily	Oral tablet	Small molecule	Transthyretin-mediated amyloidosis cardiomyopathy (ATTR-CM)	TTR	BridgeBio Pharma	C~max~ = 13700 ng/mL (SD 6090); AUC~0-12h~ = 47200 ng·h/mL (SD 10300). T~max~ ≈ 1 hour.	Vd = 654 L; plasma protein binding = 96% (primarily to TTR).	t~½~ ≈ 6 hours; CL = 16 L/h. Metabolized via UGT1A9/1A1/2B7.	Urine = 68% (<10% unchanged); Feces = 32% (15% unchanged).	In vitro: Inhibits CYP2C9, OAT1/3; substrate of UGTs/OAT1/BCRP. Clinical: No significant interaction with OAT1/3 substrates.
42	Rapiblyk	Landiolol	1–36 µg/kg/min (titrated based on ventricular rate)	IV injection	Small molecule	Supraventricular tachycardia	β1 receptor	AOP Orphan Pharmaceuticals	Dose-proportional exposure up to 2x MRHD. Steady state achieved at ~15 minutes. C~max~: 0.2–1.0 µg/mL (9.3–37.3 µg/kg/min, healthy volunteers), 0.52–1.77 µg/mL (37.3 µg/kg/min, patients with atrial fibrillation or atrial flutter)	Vd = 0.4 L/kg; plasma protein binding <10%.	t~½~ = 4.5 minutes; CL = 57 mL/kg/min. Metabolized by pseudocholinesterase/carboxylesterase to inactive M1.	Urine (4h): 50–75% (~half as M1 + 8% as unchanged); Urine (24h): 89–99%.	In vitro: TDI of CYP2D6 (no inhibition of CYP1A2/2C9/2C19/3A4).
43	Iomervu	Iomeprol	Individualized volume/concentration	Intra-arterial/IV injection	Small molecule	CT imaging contrast agent	Imaging agent	Bracco Diagnostics	Dose-proportional exposure (250–1250 mg iodine/kg).	Vd = 0.28 L/kg (SD 0.05); no plasma protein binding.	t~½~ = 1.8 hours (SD 0.33); CL = 0.10 L/h/kg (SD 0.01). No significant metabolism.	Urine = 90% (unchanged).	Not provided

44	Bizengri	Zenocutuzu mab-zbco	750 mg every 2 weeks	IV injection	Bispecific antibody	NSCLC and pancreatic adenocarcinoma	HER2/HER3	Merus	Dose-proportional exposure (480–900 mg). Steady state achieved at 8 weeks (accumulation ratio: 1.6x).	Vd = 6.0 L (18% CV).	$t_{1/2} \sim 8$ days (SD ± 1.3 days); CL = 22 mL/h (37% CV). Degraded into small peptides.	Not provided	Not provided
45	Unloxcyt	Cosibelimab-ipdl	1200 mg every 3 weeks	IV injection	Monoclonal antibody	Cutaneous squamous cell carcinoma	PD-L1	Checkpoint Therapeutics	$C_{\sim \max, ss} \sim 492$ $\mu\text{g/mL}$ (24.3% CV); $AUC_{\sim ss} \sim 112000$ $\mu\text{g}\cdot\text{h/mL}$ (39.6% CV). Dose-proportional exposure (800–1200 mg). Steady state achieved by Week 12.	Vd = 5.67 L (19.7% CV).	$t_{1/2} \sim 17.8$ days (43.8% CV); CL = 0.256 L/day (41% CV).	Not provided	Not provided
46	Crenessity	Crinecerfont	100 mg twice daily	Oral capsule	Small molecule	Classic congenital adrenal hyperplasia (CAH)	CRF1 receptor	Neurocrine Biosciences	$C_{\sim \max, ss} \sim 4231$ ng/mL (46% CV); $AUC_{\sim 24h, ss} \sim 72846$ ng·h/mL (51% CV). $T_{\sim \max} \sim 4$ hours. Steady state achieved by Day 7 (accumulation ratio: 1.4x). High-fat meal $\uparrow C_{\sim \max} \sim /AUC$ by 4.9x (capsule) or 8.6x (solution).	Vd = 852 L (31% CV); plasma protein binding $\geq 99.9\%$.	$t_{1/2} \sim 14$ hours; CL = 3.5 L/h (37% CV). Metabolized via CYP3A4 > CYP2B6 > CYP2C8/2C19.	Feces = 47.3% (2.7% unchanged); Urine = 2% (unchanged not detected).	Clinical: \downarrow AUC by 62% with strong CYP3A4 inducers; \uparrow AUC by 45% with strong CYP3A4 inhibitors. No interaction with midazolam/oral contraceptives.
47	Ensacove	Ensartinib	225 mg once daily	Oral capsule	Small molecule	Non-small cell lung cancer (NSCLC)	ALK	Betta Pharmaceuticals' Xcovery Holdings, Inc.	$C_{\sim \max} \sim 292$ ng/mL (60% CV); $AUC_{\sim 0-24h} \sim 4920$ ng·h/mL (62% CV). $T_{\sim \max} \sim 3$ hours (2-8 hours). Steady state achieved by Day 15 (accumulation ratio: 2.7x). No food effect.	Vd = 1720 L (42% CV); plasma protein binding = 91.6%.	$t_{1/2} \sim 30$ hours (SD 20 hours). Metabolized via CYP3A.	Feces = 91% (38% unchanged); Urine = 10% (4.4% unchanged).	In vitro: Substrate of P-gp.
48	Tryngolza	Olezarsen	80 mg once monthly	Subcutaneous injection	Oligonucleotide (GalNAc3-conjugated)	Familial chylomicronemia syndrome	APOC3	Ionis Pharmaceuticals	80 mg/month: $C_{\sim \max} \sim 883$ ng/mL (SD 662); $AUC_{\sim \tau} \sim 7440$ ng·h/mL (SD 3880). $T_{\sim \max} \sim 2$ hours (post-SC). No accumulation.	Central Vd = 91.9 L; peripheral Vd = 2960 L; plasma protein binding >99%. Primarily distributes to liver/kidneys.	$t_{1/2} \sim 4$ weeks. Metabolized by hepatic endo-/exonucleases into oligonucleotide fragments.	Urine = <1% (unchanged within 24h).	In vitro: No interaction with CYP450, transporters, or plasma proteins.

49	Alyftrek	Vanzacaftor + Tezacaftor + Deutivacaftor	20 mg/100 mg/250 mg once daily	Oral tablet	Small molecule	Cystic fibrosis	CFTR	Vertex Pharmaceuticals	Vanzacaftor: C _{max,ss} : 0.812 µg/mL; AUC _{0-24h,ss} : 18.6 µg·h/mL. T _{~max~} : 7.8 hours (3.7–11.9 hours). Food effect: ↑AUC by 4x (low-fat meals), 6x (high-fat meals). Tezacaftor: C _{~max,ss~} : 6.77 µg/mL; AUC _{0-24h,ss} : 89.5 µg·h/mL. T _{max} : 1.6 hours (1.4–1.7 hours). Deutivacaftor: C _{max,ss} : 2.33 µg/mL; AUC _{0-24h,ss} : 39.0 µg·h/mL. T _{~max~} : 3.7 hours (2.7–11.4 hours). Food effect: ↑AUC by 3x (low-fat meals), 4x (high-fat meals)	Vanzacaftor: V _d = 121 L; plasma protein binding >99%. Tezacaftor: V _d = 73.1 L; plasma protein binding ≈99%. Deutivacaftor: V _d = 159 L; plasma protein binding >99%.	Vanzacaftor: t _{~½~} = 92.8 hours; CL = 1.34 L/h. Tezacaftor: t _{~½~} = 22.5 hours; CL = 1.22 L/h. Deutivacaftor: t _{~½~} = 19.2 hours; CL = 7.29 L/h. All metabolized by CYP3A4/5.	Vanzacaftor: Feces = 91.6% (metabolites); Urine = 0.5%. Tezacaftor: Feces = 72% (unchanged/M 2-TEZ); Urine = 13.7%. Deutivacaftor: Not provided.	In vitro, vanzacaftor is a substrate of CYP3A, and inhibits BCRP and P-gp; Tezacaftor is a substrate of CYP3A, P-gp, BCRP and OATP1B1, and inhibits P-gp; Deutivacaftor is a substrate of CYP3A and P-gp, and inhibits CYP2C8/2C9/3A4, P-gp and BCRP. Avoid strong/moderate CYP3A4 inducers (↓efficacy) or inhibitors (↑toxicity).
50	Alhemo	Concizumab-mtci	Loading: 1 mg/kg; Maintenance: 0.2 mg/kg daily (individualized)	Subcutaneous injection	Monoclonal antibody	For routine prophylaxis to prevent bleeding episodes in hemophilia A and B	TFPI	Novo Nordisk	Steady state achieved by Day 4. C _{~max,ss~} = 1167.1 ng/mL (128% CV); C _{~trough,ss~} = 665.4 ng/mL (221% CV). T _{~max~} ranges from 8 hours to 4.1 days.	V _d = 3 L (70 kg patient).	CL dominated by linear pathway (catabolism) at target saturation. 90% eliminated by ~4 days post-last dose. Degraded into small peptides.	Not provided	Not provided