18 dated FDA decisions are left in Q4 2026, 11 of them in November

PDUFA goal dates from November 14 to December 30, 2026. Data as of November 10, 2026.

18
dated PDUFA decisions left in the quarter

9
of them fall on a Saturday or Sunday

3
reviews extended by three months into Q4

Three more companies give a decision only as a month or a quarter (page 3). Probability of approval, the options-implied move, hedge fund and insider moves are open here for three names; the rest are on BiopharmaWatch.

- **November 11, December 7.** November is the busier month for FDA decisions.
- **November 14** has three decisions on one Saturday: Cytokinetics, Summit and Teva.
- **Open in this report:** Cytokinetics, Summit and Capricor, every figure.

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

Key takeaways

What the Q4 2026 PDUFA calendar says, in six lines

1. **18 dated FDA decisions** remain from November 14 to December 30: 11 in November and 7 in December.
2. **9 of the 18 dates fall on a weekend.** When a goal date is a Saturday or Sunday, the FDA can act on the business day before.
3. **Three reviews were extended by three months** into Q4: Savara, Capricor and Praxis. Capricor's is also a resubmission after a July 2025 complete response letter, and Corcept is back with a resubmitted NDA.
4. **Seven of the 17 companies have no approved drug** (Summit, Savara, Capricor, PolyPid, Cogent, Mineralys and Praxis). In our Biotech Anatomy 2026 report, since 2021 first-time sponsors got a complete response letter on 44% of first decisions, against 24% for experienced sponsors.
5. **Options price a move of about ±88.5%** for Capricor by its November 27 expiry (as of November 9), against ±25.8% for Summit and ±8.8% for Cytokinetics by November 20.
6. **On BiopharmaWatch for the other 15:** probability of approval, the options-implied move, hedge fund moves at June 30, 2026 and insider trades.

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

All 18 dated Q4 2026 PDUFA decisions

Weekend dates in amber. Data as of November 10, 2026.

DATE	COMPANY	DRUG	FOR	FILING
Nov 14 Sat	**Teva** $TEVA	IGALMI	agitation in bipolar disorder or schizophrenia, at home	sNDA
Nov 14 Sat	**Cytokinetics** $CYTK	MYQORZO (aficamten)	obstructive HCM, MAPLE-HCM label update	sNDA
Nov 14 Sat	**Summit Therapeutics** $SMMT	ivonescimab	EGFR-mutated non-small cell lung cancer	BLA
Nov 22 Sun	**Savara** $SVRA	molgramostim	autoimmune pulmonary alveolar proteinosis	BLA
Nov 22 Sun	**Capricor** $CAPR	deramiocel	Duchenne muscular dystrophy	BLA
Nov 25 Wed	**Sanofi** $SNY	venglustat	type 3 Gaucher disease	NDA
Nov 27 Fri	**BridgeBio** $BBIO	BBP-418	limb-girdle muscular dystrophy 2I/R9	NDA
Nov 27 Fri	**GSK** $GSK	neladalkib	ALK-positive non-small cell lung cancer	NDA
Nov 28 Sat	**PolyPid** $PYPD	D-PLEX 100	surgical site infection prevention	NDA
Nov 30 Mon	**Cogent Biosciences** $COGT	bezuclastinib + sunitinib	GIST after imatinib	NDA
Nov 30 Mon	**Vertex** $VRTX	povetacicept	IgA nephropathy	BLA
Dec 12 Sat	**Vanda** $VNDA	Quimilza	generalized pustular psoriasis	BLA
Dec 17 Thu	**Corcept** $CORT	relacorilant	Cushing's syndrome	NDA
Dec 22 Tue	**Mineralys** $MLYS	lorundrostat	hypertension, added to other drugs	NDA
Dec 23 Wed	**Gilead** $GILD	anito-cel	relapsed or refractory multiple myeloma	BLA
Dec 27 Sun	**Viatris** $VTRS	fast-acting meloxicam	moderate to severe acute pain	NDA
Dec 27 Sun	**Praxis Precision Medicines** $PRAX	relutrigine	SCN2A and SCN8A epileptic encephalopathies	NDA
Dec 30 Wed	**Cogent Biosciences** $COGT	bezuclastinib	nonadvanced systemic mastocytosis	NDA

Given only as a month or quarter: Regeneron (cemdisiran, November 2026); Novo Nordisk (CagriSema, Q4 2026); Alvotech (AVT03, AVT05, AVT06, Q4 2026).

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

9 of the 18 Q4 FDA decision dates fall on a weekend

The FDA can act on the business day before a weekend goal date, so watch the Friday ahead of each shaded day



- **November 14** has three decisions on a Saturday: Cytokinetics, Summit and Teva.
- **November 27** is the day after Thanksgiving, with BridgeBio and GSK.
- **December 23 to 30** holds four decisions in holiday week: Gilead, Viatris, Praxis and Cogent's second filing.

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

Three Q4 decisions were pushed back three months, and two are second attempts

A longer review often follows new data the FDA asked for or the company sent

COMPANY	DRUG	WHAT CHANGED
Savara $SVRA	molgramostim	Extended three months to November 22, under priority review
Capricor $CAPR	deramiocel	Class 2 resubmission after a July 2025 complete response letter, then extended three months from August 22 to November 22 after new HOPE-3 data
Praxis $PRAX	relutrigine	Extended three months from September 27 to December 27 after added analyses
Corcept $CORT	relacorilant	Resubmitted NDA in Cushing's syndrome, decision by December 17
PolyPid $PYPD	D-PLEX 100	Priority review; November 28 is about one quarter earlier than the company had guided

- **Capricor** is both: a resubmission, then a three-month extension. Its decision is now November 22.
- **Savara** shares the same Sunday, November 22.
- **PolyPid** went the other way: an earlier date than guided.

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

Probability of approval for every Q4 decision is on BiopharmaWatch

Open here for three names; the live PDUFA calendar shows all 18 with the reasons behind each figure

DATE	COMPANY	DRUG	PROBABILITY OF APPROVAL
Nov 14	**Cytokinetics** $CYTK	MYQORZO	**99.99%**
Nov 14	**Summit Therapeutics** $SMMT	ivonescimab	**62%**
Nov 22	**Capricor** $CAPR	deramiocel	**62%**
Nov 14	**Teva** $TEVA	IGALMI	On BiopharmaWatch
Nov 22	**Savara** $SVRA	molgramostim	On BiopharmaWatch
Nov 25	**Sanofi** $SNY	venglustat	On BiopharmaWatch
Nov 27	**BridgeBio** $BBIO	BBP-418	On BiopharmaWatch
Nov 27	**GSK** $GSK	neladalkib	On BiopharmaWatch
Nov 28	**PolyPid** $PYPD	D-PLEX 100	On BiopharmaWatch
Nov 30	**Cogent Biosciences** $COGT	bezuclastinib + sunitinib	On BiopharmaWatch
Nov 30	**Vertex** $VRTX	povetacicept	On BiopharmaWatch
Dec 12	**Vanda** $VNDA	Quimilza	On BiopharmaWatch
Dec 17	**Corcept** $CORT	relacorilant	On BiopharmaWatch
Dec 22	**Mineralys** $MLYS	lorundrostat	On BiopharmaWatch
Dec 23	**Gilead** $GILD	anito-cel	On BiopharmaWatch
Dec 27	**Viatris** $VTRS	fast-acting meloxicam	On BiopharmaWatch
Dec 27	**Praxis Precision Medicines** $PRAX	relutrigine	On BiopharmaWatch
Dec 30	**Cogent Biosciences** $COGT	bezuclastinib	On BiopharmaWatch

- **Cytokinetics 99.99%:** MYQORZO is already approved; this decision adds MAPLE-HCM data to its label.
- **Summit 62%** for ivonescimab in EGFR-mutated lung cancer, filed on HARMONi.
- **Capricor 62%** for deramiocel, on its second attempt.

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

What options expect around each FDA decision

The move the options market prices into each date, as of November 10, 2026 (Capricor as of November 9)

DATE	COMPANY	DRUG	OPTIONS-IMPLIED MOVE
Nov 14	**Cytokinetics** $CYTK	MYQORZO	**±8.8%** by Nov 20
Nov 14	**Summit Therapeutics** $SMMT	ivonescimab	**±25.8%** by Nov 20
Nov 22	**Capricor** $CAPR	deramiocel	**±88.5%** by Nov 27
Nov 14	**Teva** $TEVA	IGALMI	On BiopharmaWatch
Nov 22	**Savara** $SVRA	molgramostim	On BiopharmaWatch
Nov 25	**Sanofi** $SNY	venglustat	On BiopharmaWatch
Nov 27	**BridgeBio** $BBIO	BBP-418	On BiopharmaWatch
Nov 27	**GSK** $GSK	neladalkib	On BiopharmaWatch
Nov 28	**PolyPid** $PYPD	D-PLEX 100	On BiopharmaWatch
Nov 30	**Cogent Biosciences** $COGT	bezuclastinib + sunitinib	On BiopharmaWatch
Nov 30	**Vertex** $VRTX	povetacicept	On BiopharmaWatch
Dec 12	**Vanda** $VNDA	Quimilza	On BiopharmaWatch
Dec 17	**Corcept** $CORT	relacorilant	On BiopharmaWatch
Dec 22	**Mineralys** $MLYS	lorundrostat	On BiopharmaWatch
Dec 23	**Gilead** $GILD	anito-cel	On BiopharmaWatch
Dec 27	**Viatris** $VTRS	fast-acting meloxicam	On BiopharmaWatch
Dec 27	**Praxis Precision Medicines** $PRAX	relutrigine	On BiopharmaWatch
Dec 30	**Cogent Biosciences** $COGT	bezuclastinib	On BiopharmaWatch

- **Capricor ±88.5%** by November 27: the market prices a very large move either way.
- **Summit ±25.8%** by November 20.
- **Cytokinetics ±8.8%** by November 20, for a label update to an approved drug.

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

Hedge fund moves before each decision

Tracked hedge funds, holdings at June 30, 2026 (the Q3 13F filings are due November 16)

DATE	COMPANY	DRUG	FUNDS HOLDING	NEW / RAISED / CUT
Nov 14	**Cytokinetics** $CYTK	MYQORZO	**13**	4 / 2 / 3
Nov 14	**Summit Therapeutics** $SMMT	ivonescimab	**4**	3 / 0 / 1
Nov 22	**Capricor** $CAPR	deramiocel	**8**	1 / 3 / 1
Nov 14	**Teva** $TEVA	IGALMI	On BiopharmaWatch	
Nov 22	**Savara** $SVRA	molgramostim	On BiopharmaWatch	
Nov 25	**Sanofi** $SNY	venglustat	On BiopharmaWatch	
Nov 27	**BridgeBio** $BBIO	BBP-418	On BiopharmaWatch	
Nov 27	**GSK** $GSK	neladalkib	On BiopharmaWatch	
Nov 28	**PolyPid** $PYPD	D-PLEX 100	On BiopharmaWatch	
Nov 30	**Cogent Biosciences** $COGT	bezuclastinib + sunitinib	On BiopharmaWatch	
Nov 30	**Vertex** $VRTX	povetacicept	On BiopharmaWatch	
Dec 12	**Vanda** $VNDA	Quimilza	On BiopharmaWatch	
Dec 17	**Corcept** $CORT	relacorilant	On BiopharmaWatch	
Dec 22	**Mineralys** $MLYS	lorundrostat	On BiopharmaWatch	
Dec 23	**Gilead** $GILD	anito-cel	On BiopharmaWatch	
Dec 27	**Viatris** $VTRS	fast-acting meloxicam	On BiopharmaWatch	
Dec 27	**Praxis Precision Medicines** $PRAX	relutrigine	On BiopharmaWatch	
Dec 30	**Cogent Biosciences** $COGT	bezuclastinib	On BiopharmaWatch	

- **Cytokinetics:** 13 funds held it; 4 were new and 3 cut.
- **Summit:** 4 funds, 3 of them new in the quarter.
- **Capricor:** 8 funds; 3 raised, 1 cut.

Source: SEC 13F filings and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

Insider buying and selling before each decision

Open-market Form 4 trades, August 12 to November 10, 2026

DATE	COMPANY	DRUG	BUYERS	SELLERS	SOLD
Nov 14	**Cytokinetics** $CYTK	MYQORZO	0	5	$11.9M
Nov 14	**Summit Therapeutics** $SMMT	ivonescimab	0	0	none
Nov 22	**Capricor** $CAPR	deramiocel	0	0	none
Nov 14	**Teva** $TEVA	IGALMI	On BiopharmaWatch		
Nov 22	**Savara** $SVRA	molgramostim	On BiopharmaWatch		
Nov 25	**Sanofi** $SNY	venglustat	On BiopharmaWatch		
Nov 27	**BridgeBio** $BBIO	BBP-418	On BiopharmaWatch		
Nov 27	**GSK** $GSK	neladalkib	On BiopharmaWatch		
Nov 28	**PolyPid** $PYPD	D-PLEX 100	On BiopharmaWatch		
Nov 30	**Cogent Biosciences** $COGT	bezuclastinib + sunitinib	On BiopharmaWatch		
Nov 30	**Vertex** $VRTX	povetacicept	On BiopharmaWatch		
Dec 12	**Vanda** $VNDA	Quimilza	On BiopharmaWatch		
Dec 17	**Corcept** $CORT	relacorilant	On BiopharmaWatch		
Dec 22	**Mineralys** $MLYS	lorundrostat	On BiopharmaWatch		
Dec 23	**Gilead** $GILD	anito-cel	On BiopharmaWatch		
Dec 27	**Viatris** $VTRS	fast-acting meloxicam	On BiopharmaWatch		
Dec 27	**Praxis Precision Medicines** $PRAX	relutrigine	On BiopharmaWatch		
Dec 30	**Cogent Biosciences** $COGT	bezuclastinib	On BiopharmaWatch		

- **Cytokinetics:** 5 insiders sold $11.9M; none bought.
- **Summit and Capricor:** no open-market insider trades in the 90 days.
- Every Form 4 for all 18 companies is on each company page.

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.

See all 18 on BiopharmaWatch

The live PDUFA calendar updates as companies change their dates

1. **Probability of approval** for every FDA decision, with the reasons behind it.
2. **The options-implied move** into each date, on the FDA calendar.
3. **Hedge fund and insider moves** for every company on the list.
4. **Catalyst alerts** for the companies you follow.

biopharmawatch.com/PDUFA-calendar

biopharmawatch.com/subscription

Source: SEC filings, company releases and BiopharmaWatch data. Data as of November 10, 2026. Dates move; the live PDUFA calendar has the current version. Data, not investment advice.