

U.S. Food and Drug Administration

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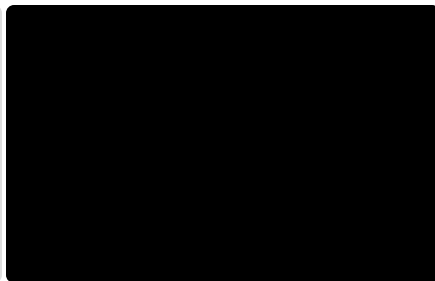
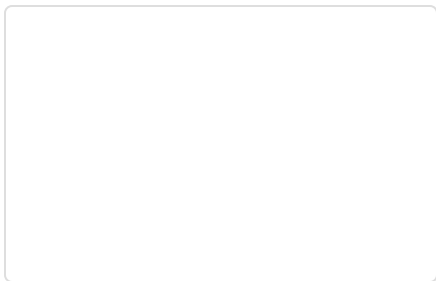
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New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products of 2014

Innovation drives progress. When it comes to innovation in the development of new drugs and therapeutic biological products, FDA's Center for Drug Evaluation and Research (CDER) supports the pharmaceutical industry at every step of the process. With its understanding of the science used to create new products, testing and manufacturing procedures, and the diseases and conditions that new products are designed to treat, FDA provides scientific and regulatory advice needed to bring new therapies to market.

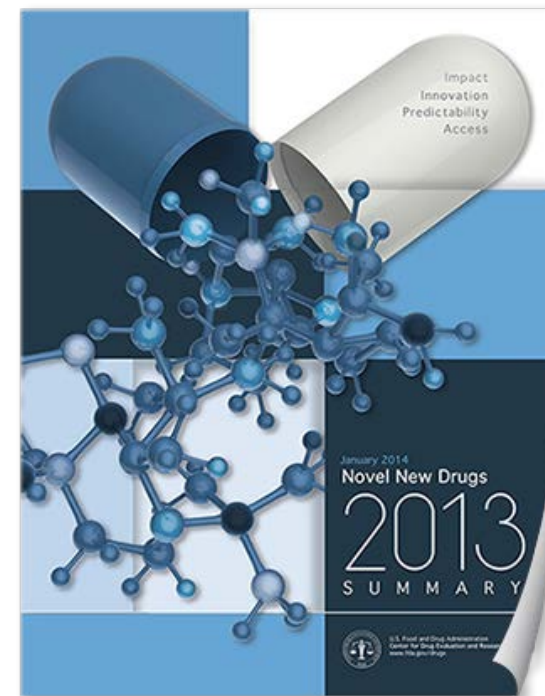
The availability of new drugs and biological products often means new treatment options for patients and advances in health care for the American public. For this reason, CDER supports innovation and plays a key role in helping to advance new drug development.

Each year, CDER approves a wide range of new drugs and biological products. Some of these products are innovative new products that never before have been used in clinical practice. Others




are the same as, or related to, previously approved products, and they will compete with those products in the marketplace.

Certain drugs are classified as new molecular entities (“NMEs”) for purposes of FDA review. Many of these products contain active moieties that have not been approved by FDA previously, either as a single ingredient drug or as part of a combination product; these products frequently provide important new therapies for patients. Some drugs are characterized as NMEs for administrative purposes, but nonetheless contain active moieties that are closely related to active moieties in products that have previously been approved by FDA. For example, CDER classifies biological products submitted in an application under section 351(a) of the Public Health Service Act as NMEs for purposes of FDA review, regardless of whether the Agency previously has approved a related active moiety in a different product. FDA’s classification of a drug as an “NME” for review purposes is distinct from FDA’s determination of whether a drug product is a “new chemical entity” or “NCE” within the meaning of the Federal Food, Drug, and Cosmetic Act.



[2013 Novel New Drugs Summary](#) (PDF - 3MB)

 [View animated charts](#) from the 2013 Novel New Drugs Summary publication on the right. (Not viewable in Internet Explorer version 7 and below.)

The list below includes the NMEs and BLAs approved by CDER in calendar year 2014.

(The Drug Name link provides full product details, i.e., prescribing information, approval history, and reviews.)

No.	Drug	Active Ingredient	Date	FDA-approved use on approval date
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	Name			
41.	Opdivo	nivolumab	12/22/2014	To treat patients with unresectable (cannot be removed by surgery) or metastatic (advanced) melanoma who no longer respond to other drugs Press Release
40.	Rapivab	peramivir	12/19/2014	To treat influenza infection in adults Press Release
39.	Zerbaxa	ceftolozane/tazobactam	12/19/2014	To treat adults with complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI) Press Release
38.	Viekira Pak	(ombitasvir, paritaprevir and ritonavir tablets co-packaged with dasabuvir tablets)	12/19/2014	To treat patients with chronic hepatitis C virus (HCV) genotype 1 infection, including those with a type of advanced liver disease called cirrhosis Press Release
37.	Lynparza	olaparib	12/19/2014	To treat advanced ovarian cancer Press Release
36.	Xtoro	finafloxacin otic suspension	12/17/2014	To treat acute otitis externa, commonly known as swimmer's ear Press Release
35.	Blinicyto	blinatumomab	12/3/2014	To treat patients with Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia (B-cell ALL) Press Release
34.	Esbriet	pirfenidone	10/15/2014	For the treatment of idiopathic pulmonary fibrosis (IPF) Press Release
33.	Ofev	nintedanib	10/15/2014	For the treatment of idiopathic pulmonary fibrosis (IPF) Press Release
32.	Lumason	sulfur hexafluoride lipid microsphere	10/10/2014	For patients whose ultrasound image of the heart (echocardiograms) are hard to see with ultrasound waves Press Release
31.	Akynzeo	netupitant and palonosetron	10/10/2014	To treat nausea and vomiting in patients undergoing cancer chemotherapy

				Press Release
30.	Harvoni	ledipasvir/sofosbuvir	10/10/2014	To treat chronic hepatitis C virus (HCV) genotype 1 infection Press Release
29.	Trulicity	dulaglutide	9/18/2014	To treat adults with type 2 diabetes. Press Release
28.	Movantik	naloxegol	9/16/2014	To treat opioid-induced constipation in adults with chronic non-cancer pain. Press Release
27.	Keytruda	pembrolizumab	9/4/2014	For treatment of patients with advanced or unresectable melanoma who are no longer responding to other drugs. Press Release
26.	Cerdelga	eliglustat	8/19/2014	For the long-term treatment of adult patients with the Type 1 form of Gaucher disease Press Release
25.	Plegridy	peginterferon beta-1a	8/15/2014	For the treatment of patients with relapsing forms of multiple sclerosis
24.	Belsomra	suvorexant	8/13/2014	To treat difficulty in falling and staying asleep (insomnia) Press Release
23.	Orbactiv	oritavancin	8/6/2014	To treat adults with skin infections Press Release
22.	Jardiance	empagliflozin	8/1/2104	To improve glycemic control in adults with type 2 diabetes Press Release
21.	Striverdi Respimat	olodaterol	7/31/2014	To treat chronic obstructive pulmonary disease Press Release
20.	Zydelig	idelalisib	7/23/2014	To treat patients with three types of blood cancers Press Release
19.	Kerydin	tavaborole	7/7/2014	For the topical treatment of onychomycosis of the toenails (No Press Release)

18.	Beleodaq	belinostat	7/3/2014	To treat patients with peripheral T-cell lymphoma (PTCL) Press Release
17.	Sivextro (tablet) Sivextro (injection)	tedizolid phosphate	6/20/2014	To treat adults with skin infections Press Release
16.	Jublia	efinaconazole	6/6/2014	Treat mild to moderate onychomycosis (fungal infection) No Press Release
15.	Dalvance	dalbavancin	5/23/2014	To treat adults with skin infections Press Release
14.	Entyvio	vedolizumab	5/20/2014	To treat adult patients with moderate to severe ulcerative colitis and adult patients with moderate to severe Crohn's disease Press Release
13.	Zontivity	vorapaxar	5/8/2014	To reduce the risk of heart attacks and stroke in high-risk patients Press Release
12.	Zykadia	ceritinib	4/29/2014	To treat patients with a certain type of late-stage (metastatic) non-small cell lung cancer (NSCLC) Press Release
11.	Sylvant	siltuximab	4/23/2014	To treat patients with multicentric Castleman's disease (MCD), a rare disorder similar to lymphoma (cancer of the lymph nodes) Press Release
10.	Cyramza	ramucirumab	4/21/2014	To treat patients with advanced stomach cancer or gastroesophageal junction adenocarcinoma Press Release
9.	Tanzeum	albiglutide	4/15/2014	To improve glycemic control, along with diet and exercise, in adults with type 2 diabetes Press Release
8.	Otezla	apremilast	3/21/2014	To treat adults with active psoriatic arthritis (PsA) Press Release

7.	Impavido	miltefosine	3/19/2014	To treat a tropical disease called leishmaniasis Press Release
6.	Neuraceq	florbetaben F 18 injection	3/19/2014	For Positron Emission Tomography (PET) imaging of the brain
5.	Myalept	metreleptin for injection	2/24/2014	To treat the complications of leptin deficiency Press Release
4.	Northera	droxidopa	2/18/2014	To treat neurogenic orthostatic hypotension (NOH) Press Release
3.	Vimizim	elosulfase alfa	2/14/2014	Treatment for Mucopolysaccharidosis Type IVA (Morquio A syndrome) Press Release
2.	Hetlioz	tasimelteon	1/31/2014	To treat non-24-hour sleep-wake disorder ("non-24") in totally blind individuals. Non-24 is a chronic circadian rhythm (body clock) disorder in the blind that causes problems with the timing of sleep. Press Release
1.	Farxiga	dapaglifozin	1/8/2014	To improve glycemic control, along with diet and exercise, in adults with type 2 diabetes Press Release

Drug Approval Information

- [New and Generic Drug Approvals](#)
- [Drug Approval Reports by Month](#)
- [Drug and Biologic Approval and IND Activity Reports](#)

Related Information from Other FDA Centers

- [Focus on Innovation](#)

- [Driving Biomedical Innovation: Initiatives for Improving Products for Patients](#)
- [Innovation and Regulatory Science \(CBER\)](#)
- [CDRH Innovation](#)

Page Last Updated: 12/29/2014

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