U.S. Food and Drug Administration
Center for Drug Evaluation and Research
www.fda.gov/drugs

# Novel New Drugs

# 2014

# SUMMARY

January 2015

IMPACT · INNOVATION · PREDICTABILITY · ACCESS

## Novel New Drugs 2014 Summary

# Contents




U.S. Food and Drug Administration
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# Introduction

## Welcome to the FDA Center for Drug Evaluation and Research's (CDER) fourth annual Novel New Drugs Summary.

Each year, CDER approves hundreds of new medications, most of which are variations of previously existing products, such as important new dosage forms of already approved products, or cost-saving generic formulations. These new products contribute to quality of care, greater access to medication, more consumer choice, and a competitive marketplace that enhances affordability and public health. However, products in a small subset of these new approvals, which we refer to as **novel new drugs**, are among the more truly innovative products that often help advance clinical care to another level. At the end of each calendar year, CDER summarizes these new products.

Although our annual summary reports the *quantity* of novel new drugs that we approved, our main focus is on the unique *qualities* of many of these new drugs, their contributions to enhanced patient care, and the various regulatory tools CDER used to help ensure their safe and efficient development and approval.

As you will see, 2014's field of novel new drugs will offer much to patients in need. For instance, we approved more "orphan" drugs for rare diseases than any previous year in our history; more than half of this year's approvals are "Priority Review" drugs that provide improvements over existing therapies (the highest number since we started keeping track); more than three times as many drugs compared to last year were approved under FDA's Breakthrough designation for promising new therapies; and we approved several novel new antibiotics.

We hope this summary provides an appreciation of the expected impact that many of the novel new drugs of 2014 will have on patient care, as well as the valuable role CDER played in helping to bring these drugs to market.

**Janet Woodcock, M.D.**
Director, Center for Drug Evaluation and Research

# CDER's 2014 Novel New Drugs

## 41 Novel New Drugs

In calendar year 2014, FDA's Center for Drug Evaluation and Research (CDER) approved 41 novel new drugs, approved as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs).[1] Below lists CDER's novel new drugs of 2014.

In
**2014**
CDER Approved
**41**
Novel New Drugs

Novel new drugs are often innovative products that serve previously unmet medical needs or otherwise significantly help to advance patient care and public health. In some cases, while categorized as novel for technical and/or administrative purposes, a particular novel new drug may not necessarily offer unique clinical advantages over existing therapies. This report summarizes all of the 2014 novel new drug approvals, emphasizing those that offer new and innovative treatments to patients in need.

The vertical bars in the chart on the next page indicate the number of novel new drugs approved by CDER in each year of the past decade. CDER approved 41 novel new drugs in 2014, more than in any other year during this time. From 2005 through 2013, CDER has averaged about 25 novel new drug approvals per year.

## Applications For New Approvals Remain Steady

CDER approved a higher than average number of novel new drugs in 2014; however, the number of applications for these drugs that sponsors have submitted over time has remained relatively stable.

The purple portion of the graph on the next page indicates the number of new NDA and BLA applications for new molecular entities and new therapeutic biologics CDER has received and filed for approval during the last 10 years. From 2005 through 2013, CDER filed an average of about 34 applications for novel new drugs per year. CDER projects 41 filings for 2014, which is consistent with previous years in this decade.

Novel New Drugs Approved by CDER in Calendar Year 2014 (see pages 14–16 for their non-proprietary names, approval dates, and what these drugs are used for.)

| | | | | | | |
|---|---|---|---|---|---|---|
| Akynzeo | Dalvance | Impavido | Lynparza | Opdivo | Striverdi Respimat | Xtoro |
| Beleodaq | Entyvio | Jardiance | Movantik | Orbactiv | Sylvant | Zerbaxa |
| Belsomra | Esbriet | Jublia | Myalept | Otezla | Tanzeum | Zontivity |
| Blincyto | Farxiga | Kerydin | Neuraceq | Plegridy | Trulicity | Zydelig |
| Cerdelga | Harvoni | Keytruda | Northera | Rapivab | Viekira Pak[2] | Zykadia |
| Cyramza | Hetlioz | Lumason | Ofev | Sivextro | Vimizim | |

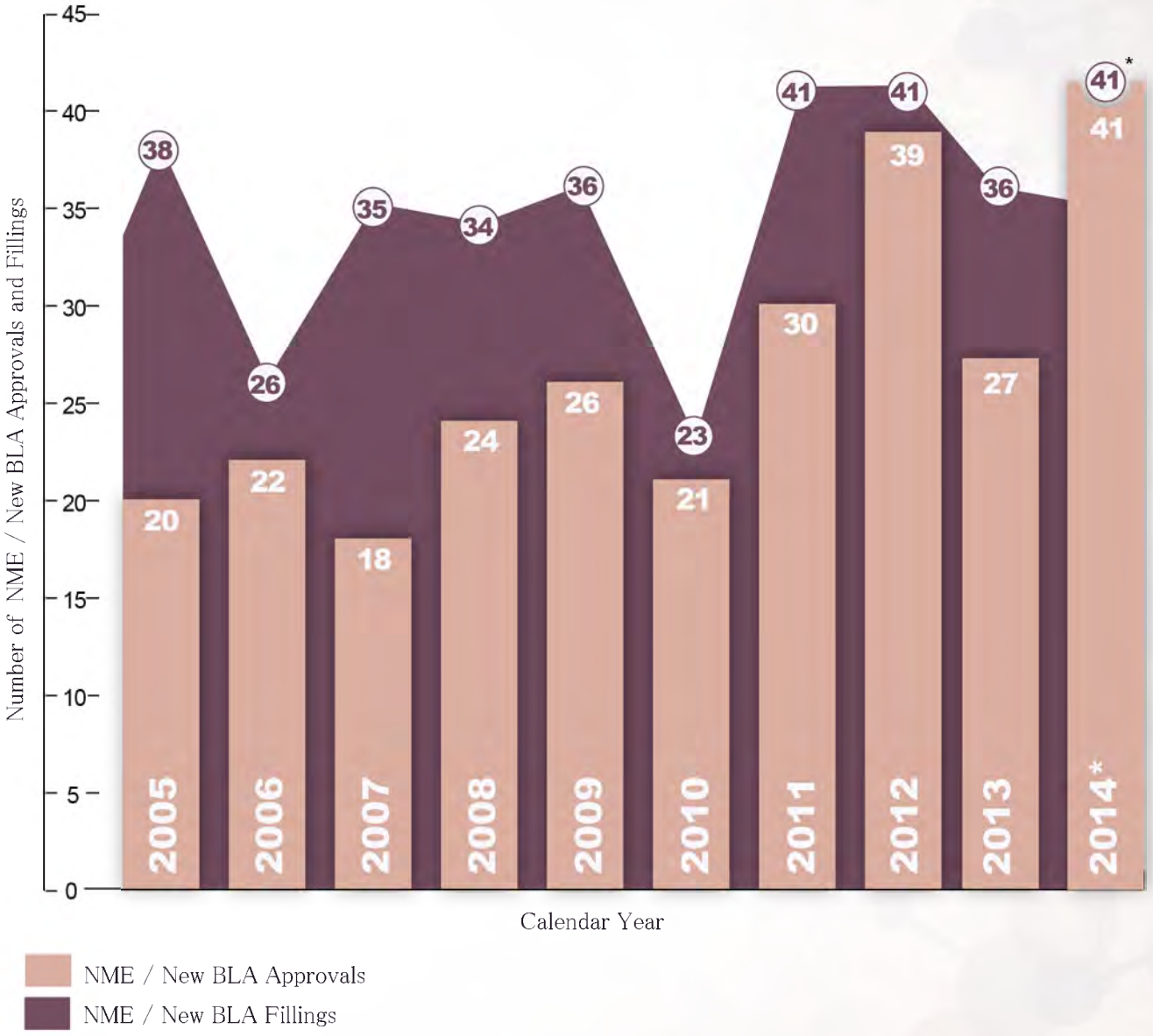
1. This total includes only novel new drug approvals by FDA's CDER. It does not include approvals by FDA's Center for Biologics Evaluation and Research (CBER).
2. One novel new drug comprised of four active ingredients: ritonavir (previously approved), and three novel new molecules: dasabuvir, ombitasvir, and paritaprevir.

41 NOVEL NEW DRUG APPROVALS IN CY 2014 IS MORE THAN THE AVERAGE NUMBER APPROVED ANNUALLY DURING THE PAST DECADE

FROM 2005 THROUGH 2013 CDER HAS AVERAGED

**25**

NOVEL NEW DRUG APPROVALS PER YEAR




* = The 2014 filed numbers include those filed in CY 2014 plus those currently pending filing (i.e., within their 60 day filing period) in CY 2014.
- Receipts that received a "Refuse to File" (RTF) or "Withdrawn before filing" (WF) identifier are excluded.
- Multiple submissions (multiple or split originals) pertaining to a single new molecular/biologic entity are only counted once.
- The filed number is not indicative of workload in the PDUFA V Program.

# Impact

## Impact on Public Health

Many of the 41 novel new drugs CDER approved in 2014 are notable for their potential positive impact and unique contributions to quality medical care and public health.

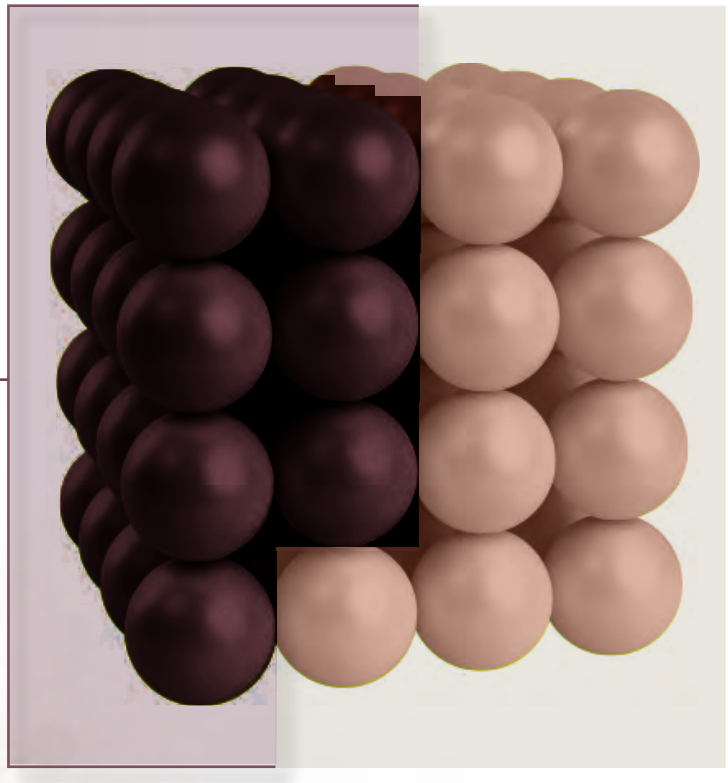
## First-in-Class

1. BELSOMRA
2. BLINCYTO
3. ESBRIET
4. HARVONI
5. IMPAVIDO
6. KERYDIN
7. KEYTRUDA
8. LYNPARZA
9. MYALEPT
10. NORTHERA
11. OFEV
12. OTEZLA
13. SYLVANT
14. VIEKIRA PAK
15. VIMIZIM
16. ZONTIVITY
17. ZYDELIG

CDER identified more than one-third of the novel new drugs approved in 2014 (17 of 41 or about 41%) as First-in-Class, one indicator of the innovative nature of a drug. For example, these drugs might use new or unique mechanisms of action for treating medical conditions over existing therapies. A First-in-Class approval rate of about four in 10 is one factor that suggests the 2014 group of novel new approvals is a field with many innovative products.

### Noteworthy First-in-Class products include:

Harvoni – to treat certain patients with chronic hepatitis C.
Keytruda – for patients with unresectable or metastatic melanoma, a type of skin cancer that has spread to other parts of the body.
Zontivity – to reduce risk of thrombotic cardiovascular events in certain patients with heart conditions.



41%
First-in-Class Drugs

For more details about the individual novel new drugs, see pages 14–16.

About 41% of the novel new drugs approved in 2014 (17 of 41) were approved to treat rare or "orphan" diseases that affect 200,000 or fewer Americans. This is significant because patients with rare diseases often have few or no drugs available to treat their conditions.

## Rare Diseases

1. Beleodaq
2. Blincyto
3. Cerdelga
4. Cyramza
5. Esbriet
6. Hetlioz
7. Impavido
8. Keytruda
9. Lynparza
10. Myalept
11. Northera
12. Ofev
13. Opdivo
14. Sylvant
15. Vimizim
16. Zydelig
17. Zykadia

## Noteworthy examples of drugs to treat rare diseases among the 2014 novel new drugs include:

Vimizim – to treat mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome), a rare genetic disorder resulting in skeletal deformities, growth retardation, and heart problems.

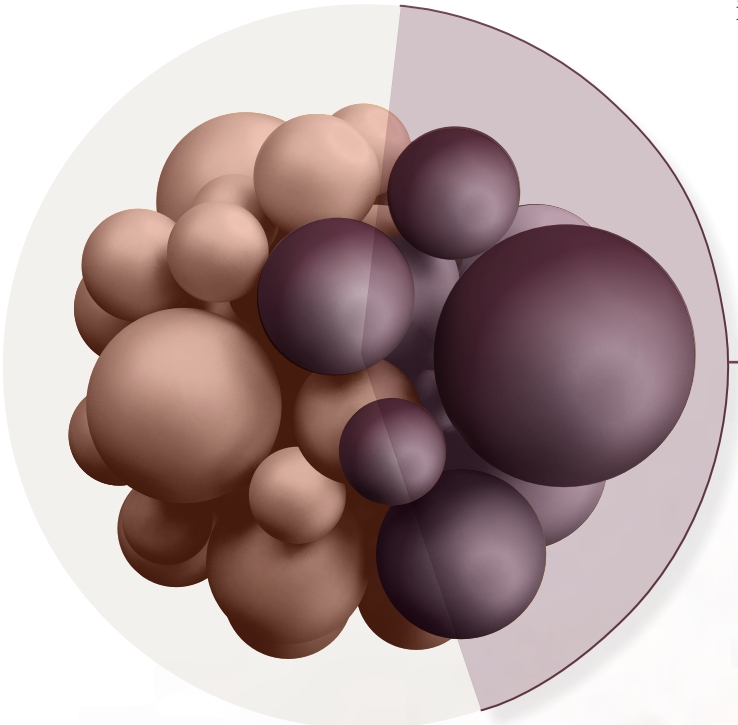
Impavido – to treat forms of the rare tropical disease called leishmaniasis.

Sylvant – to treat multicentric Castleman's disease (MCD), which results in excessive lymph node growth.

Cerdelga – to treat Gaucher disease, a rare genetic disorder resulting in enlargement of the liver and spleen, a low number of red blood cells, easy bruising caused by a decrease in blood platelets, lung disease, and bone problems.

Esbriet and Ofev – to treat idiopathic pulmonary fibrosis, which results in decreasing lung function and breathing failure.

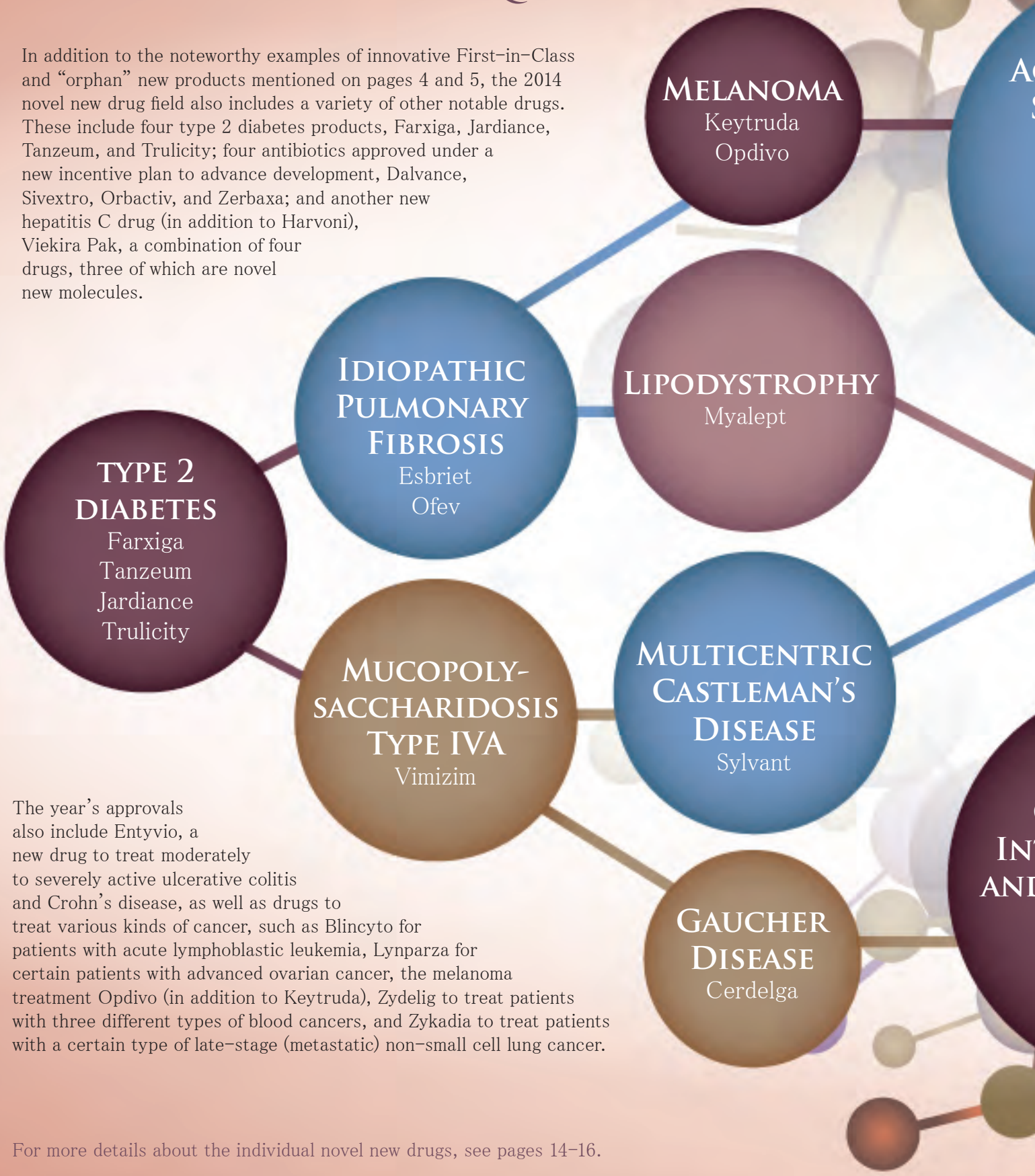
Myalept – to treat complications of lipodystrophy associated with a deficiency of the important hormone leptin.



41%
Rare Disease Drugs

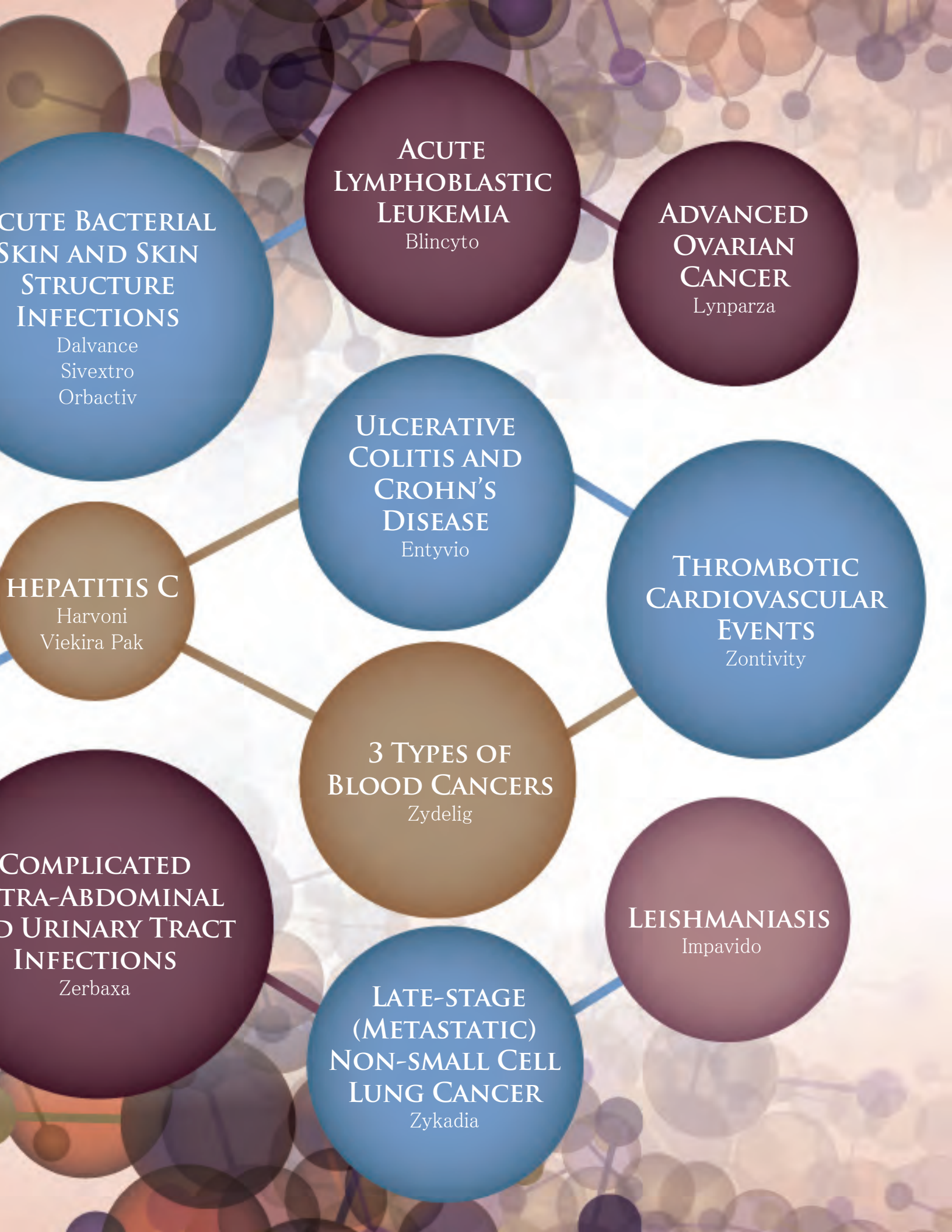
# Notable Novel Drugs of 2014:
## Another strong year for quality

In addition to the noteworthy examples of innovative First-in-Class and "orphan" new products mentioned on pages 4 and 5, the 2014 novel new drug field also includes a variety of other notable drugs. These include four type 2 diabetes products, Farxiga, Jardiance, Tanzeum, and Trulicity; four antibiotics approved under a new incentive plan to advance development, Dalvance, Sivextro, Orbactiv, and Zerbaxa; and another new hepatitis C drug (in addition to Harvoni), Viekira Pak, a combination of four drugs, three of which are novel new molecules.




The year's approvals also include Entyvio, a new drug to treat moderately to severely active ulcerative colitis and Crohn's disease, as well as drugs to treat various kinds of cancer, such as Blincyto for patients with acute lymphoblastic leukemia, Lynparza for certain patients with advanced ovarian cancer, the melanoma treatment Opdivo (in addition to Keytruda), Zydelig to treat patients with three different types of blood cancers, and Zykadia to treat patients with a certain type of late-stage (metastatic) non-small cell lung cancer.

For more details about the individual novel new drugs, see pages 14–16.


Acute Lymphoblastic Leukemia
Blincyto
Advanced Ovarian Cancer
Lynparza
cute Bacterial Skin and Skin Structure Infections
Dalvance
Sivextro
Orbactiv
Ulcerative Colitis and Crohn's Disease
Entyvio
Thrombotic Cardiovascular Events
Zontivity
hepatitis C
Harvoni
Viekira Pak
3 Types of Blood Cancers
Zydelig
Complicated tra-Abdominal d Urinary Tract Infections
Zerbaxa
Leishmaniasis
Impavido
Late-stage (Metastatic) Non-small Cell Lung Cancer
Zykadia

# Innovation

## Methods For Expediting Innovative Novel New Drugs To Market

CDER used a number of regulatory methods to expedite the approval of novel new drugs in 2014. These involved the following four expedited development and review pathways: Fast Track, Breakthrough, Priority Review, and Accelerated Approval.

## Fast Track

Seventeen of the 2014 novel new drugs (41%) were designated by CDER as Fast Track, meaning drugs with the potential to address unmet medical needs. Fast Track speeds new drug development and review, for instance, by increasing the level of communication FDA allocates to drug developers and by enabling CDER to review portions of a drug application ahead of the submission of the complete application.

1. BELEODAQ
2. CYRAMZA
3. DALVANCE
4. ENTYVIO
5. ESBRIET
6. HARVONI
7. IMPAVIDO
8. MYALEPT
9. NORTHERA
10. OFEV
11. OPDIVO
12. RAPIVAB
13. VIEKIRA PAK
14. VIMIZIM
15. ZERBAXA
16. ZONTIVITY
17. ZYDELIG*.

## Breakthrough

CDER designated nine of the 2014 novel new drugs (22%) as Breakthrough therapies, meaning drugs with preliminary clinical evidence demonstrating that the drug may result in substantial improvement on at least one clinically significant endpoint (i.e., study result) over other available therapies. A breakthrough therapy designation includes all of the Fast Track program features, as well as more intensive FDA guidance on an efficient drug development program. Breakthrough status is designed to help shorten the development time of a promising new therapy.

1. BLINCYTO
2. ESBRIET
3. HARVONI
4. KEYTRUDA
5. OFEV
6. OPDIVO
7. VIEKIRA PAK
8. ZYDELIG*
9. ZYKADIA

## Priority Review

Twenty-five of the 2014 novel new drugs (61%) were designated Priority Review, in which CDER determined the drug to potentially provide a significant advance in medical care and set a target to review the drug within six months instead of the standard 10 months.

1. BELEODAQ
2. BLINCYTO
3. CERDELGA
4. CYRAMZA
5. DALVANCE
6. ENTYVIO
7. ESBRIET
8. HARVONI
9. HETLIOZ
10. IMPAVIDO
11. KEYTRUDA
12. LYNPARZA
13. MYALEPT
14. NORTHERA
15. OFEV
16. OPDIVO
17. ORBACTIV
18. SIVEXTRO
19. SYLVANT
20. VIEKIRA PAK
21. VIMIZIM
22. XTORO
23. ZERBAXA
24. ZYDELIG*
25. ZYKADIA

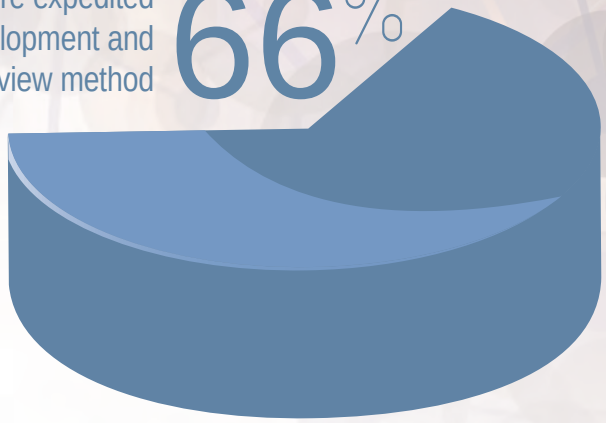
## Accelerated Approval

CDER approved eight of the 2014 novel new drugs (20%) under FDA's Accelerated Approval program, which allows early approval of a drug for a serious or life-threatening illness that offers a benefit over current treatments. This approval is based on a "surrogate endpoint" (e.g., a laboratory measure) or other clinical measure that we consider reasonably likely to predict a clinical benefit of the drug. Once Accelerated Approval is granted, the drug must undergo additional testing to confirm that benefit; this speeds the availability of the drug to patients who need it.

1. BELEODAQ
2. BLINCYTO
3. KEYTRUDA
4. LYNPARZA
5. NORTHERA
6. OPDIVO
7. ZYDELIG*
8. ZYKADIA

* ZYDELIG was submitted with two indications of which one of the indications was granted a Breakthrough Therapy, Fast Track and Priority Review; the other was granted Accelerated Approval.

One or more expedited development and review method 66%



## Overall Use Of Expedited Development And Review Methods

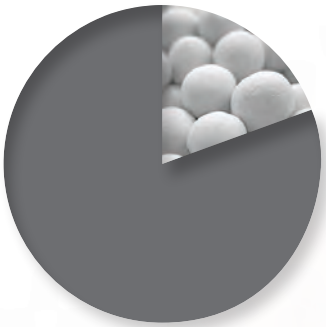
Two-thirds of the 2014 novel new drugs (27 of 41 or 66%) were designated in one or more categories of Fast Track, Breakthrough, Priority Review, and/or Accelerated Approval. Each of these designations helps expedite the speed of the development and/or approval process and is designed to help bring important medications to the market as quickly as possible.

1. BELEODAQ
2. BLINCYTO
3. CERDELGA
4. CYRAMZA
5. DALVANCE
6. ENTYVIO
7. ESBRIET
8. HARVONI
9. HETLIOZ
10. IMPAVIDO
11. KEYTRUDA
12. LYNPARZA
13. MYALEPT
14. NORTHERA
15. OFEV
16. OPDIVO
17. ORBACTIV
18. RAPIVAB
19. SIVEXTRO
20. SYLVANT
21. VIEKIRA PAK
22. VIMIZIM
23. XTORO
24. ZERBAXA
25. ZONTIVITY
26. ZYDELIG
27. ZYKADIA

Fast Track 41%

Priority Review 61%

Breakthrough 22%



Accelerated Approval 20%

## Qualified Infectious Disease Program Designations

1. DALVANCE
2. ORBACTIV
3. SIVEXTRO
4. ZERBAXA

The Generating Antibiotics Incentives Now Act (GAIN Act) provides incentives to help bring new antibiotics and other antimicrobials to market. A drug with particular promise can be designated as a Qualified Infectious Disease Product (QIDP) by authority of the GAIN Act. In 2014, CDER approved four new antibiotics with this designation, the first four QIDP-designated novel new drugs approved by FDA.

# Predictability

**98%** Drugs That Met Their PDUFA Goal Date

## Nearly All PDUFA Goal Dates Met

Under the Prescription Drug User Fee Act (PDUFA), sponsors are assessed user fees that provide FDA with the additional resources needed to meet performance goals. Throughout the year, CDER was able to meet or exceed most PDUFA goal dates for application review, agreed to with the pharmaceutical industry and approved by Congress. In 2014, CDER met its PDUFA goal dates for 98% of the novel new drugs approved (40 of 41).

## PDUFA Goal Dates Met

1. BELEODAQ
2. BELSOMRA
3. BLINCYTO
4. CERDELGA
5. CYRAMZA
6. DALVANCE
7. ENTYVIO
8. ESBRIET
9. FARXIGA
10. HARVONI
11. HETLIOZ
12. IMPAVIDO
13. JARDIANCE
14. JUBLIA
15. KERYDIN
16. KEYTRUDA
17. LUMASON
18. LYNPARZA
19. MOVANTIK
20. MYALEPT
21. NEURACEQ
22. NORTHERA
23. OFEV
24. OPDIVO
25. ORBACTIV
26. OTEZLA
27. PLEGRIDY
28. RAPIVAB
29. SIVEXTRO
30. STRIVERDI RESPIMAT
31. SYLVANT
32. TANZEUM
33. TRULICITY
34. VIEKIRA PAK
35. VIMIZIM
36. XTORO
37. ZERBAXA
38. ZONTIVITY
39. ZYDELIG
40. ZYKADIA

For more details about the individual novel new drugs, see pages 14–16.

# Access

CDER approved a majority of the novel new drugs of 2014 (32 of 41, 78%) on the "first cycle" of review, meaning without requests for additional information that would delay approval and lead to another cycle of review.

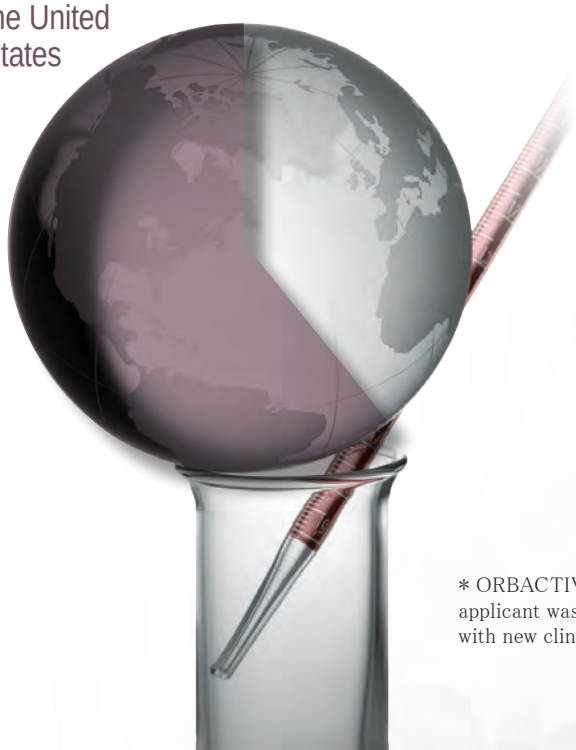
## First Cycle Approval

1. AKYNZEO
2. BELEODAQ
3. BLINCYTO
4. CERDELGA
5. CYRAMZA
6. ENTYVIO
7. HARVONI
8. HETLIOZ
9. IMPAVIDO
10. KERYDIN
11. KEYTRUDA
12. LYNPARZA
13. MOVANTIK
14. MYALEPT
15. NEURACEQ
16. OFEV
17. OPDIVO
18. ORBACTIV*
19. OTEZLA
20. PLEGRIDY
21. RAPIVAB
22. SIVEXTRO
23. SYLVANT
24. TANZEUM
25. TRULICITY
26. VIEKIRA PAK
27. VIMIZIM
28. XTORO
29. ZERBAXA
30. ZONTIVITY
31. ZYDELIG
32. ZYKADIA

**78%**
First Cycle Approval

**63%**
First Approved in the United States

Comparing approval to other countries offers another measure of approval efficiency. Although regulatory processes differ widely between FDA and those of regulatory agencies in other countries, almost two-thirds of the novel new drugs approved in 2014 (26 of 41, 63%) were approved in the United States before receiving approval in any other country.



## Approval in U.S. before Other Countries

1. AKYNZEO
2. BELEODAQ
3. BELSOMRA
4. BLINCYTO
5. CERDELGA
6. CYRAMZA
7. DALVANCE
8. ENTYVIO
9. HARVONI
10. HETLIOZ
11. KERYDIN
12. KEYTRUDA
13. MOVANTIK
14. OFEV
15. ORBACTIV
16. OTEZLA
17. SIVEXTRO
18. SYLVANT
19. TRULICITY
20. VIEKIRA PAK
21. VIMIZIM
22. XTORO
23. ZERBAXA
24. ZONTIVITY
25. ZYDELIG
26. ZYKADIA

* ORBACTIV was originally submitted in 2008 and received a complete response. The original applicant was purchased by another company and ORBACTIV was resubmitted under a new NDA with new clinical trials and was approved.

# Overview

## This document represents a broad overview of CDER approvals of new novel drugs for calendar year 2014.

A continuing upward trend for the annual number of CDER's novel new drug approvals necessarily relies on a corresponding increase in the number of drug applications submitted. During the past decade, submissions of applications for NMEs and novel new BLAs by the pharmaceutical and biotechnology industry have remained relatively stable.

More important than the quantity of novel new drugs approved in 2014 are the qualities of the new drugs the pharmaceutical industry has developed and the important new roles these drugs are serving to advance medical care.

Also noteworthy is the efficiency with which most of these drugs were reviewed and approved. CDER used a variety of expedited development and review regulatory tools in an effort to help speed these drugs to market.

In all cases, while striving for efficiency of review and approval of applications for new drugs, CDER maintains its rigorous standards for demonstration of effectiveness and safety in the process.

More important than the quantity of novel new drugs approved by CDER in 2014 is their quality and the important new roles they are serving to advance medical care.

# DRUG DESIGNATION SUMMARY

| Trade Name | First-in-Class | Orphan | Fast Track | Breakthrough | Priority Review | Accelerated Approval | Met PDUFA Goal Dates | First Cycle | First Approved in U.S. | Qualified Infectious Disease Pro. | Dosage Form |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Akynzeo | | | | | | | | | | | Capsule |
| Beleodaq | | | | | | | | | | | Injection |
| Belsomra | | | | | | | | | | | Tablet |
| Blincyto | | | | | | | | | | | Injection |
| Cerdelga | | | | | | | | | | | Capsule |
| Cyramza | | | | | | | | | | | Injection |
| Dalvance | | | | | | | | | | | Injection |
| Entyvio | | | | | | | | | | | Injection |
| Esbriet | | | | | | | | | | | Capsule |
| Farxiga | | | | | | | | | | | Tablet |
| Harvoni | | | | | | | | | | | Tablet |
| Hetlioz | | | | | | | | | | | Capsule |
| Impavido | | | | | | | | | | | Capsule |
| Jardiance | | | | | | | | | | | Tablet |
| Jublia | | | | | | | | | | | Topical solution |
| Kerydin | | | | | | | | | | | Topical solution |
| Keytruda | | | | | | | | | | | Injection |
| Lumason | | | | | | | | | | | Injection |
| Lynparza | | | | | | | | | | | Capsule |
| Movantik | | | | | | | | | | | Tablet |
| Myalept | | | | | | | | | | | Injection |
| Neuraceq | | | | | | | | | | | Injection |
| Northera | | | | | | | | | | | Capsule |
| Ofev | | | | | | | | | | | Capsule |
| Opdivo | | | | | | | | | | | Injection |
| Orbactiv | | | | | | | | | | | Injection |
| Otezla | | | | | | | | | | | Tablet |
| Plegridy | | | | | | | | | | | Injection |
| Rapivab | | | | | | | | | | | Injection |
| Sivextro | | | | | | | | | | | Tablet |
| Striverdi Respimat | | | | | | | | | | | Inhalation Spray |
| Sylvant | | | | | | | | | | | Injection |
| Tanzeum | | | | | | | | | | | Injection |
| Trulicity | | | | | | | | | | | Injection |
| Viekira Pak | | | | | | | | | | | Tablets |
| Vimizim | | | | | | | | | | | Injection |
| Xtoro | | | | | | | | | | | Otic Suspension |
| Zerbaxa | | | | | | | | | | | Injection |
| Zontivity | | | | | | | | | | | Tablet |
| Zydelig | | | | | | | | | | | Tablet |
| Zykadia | | | | | | | | | | | Capsule |

# The Novel New Drugs of 2014

Drugs are listed by the date of approval in 2014, backward from the most recently approved.

| Drug Name | Active Ingredients | Approval Date | What it is used for |
|---|---|---|---|
| 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. |
| Rapivab | peramivir | 12/19/2014 | To treat influenza infection in adults. |
| Zerbaxa | ceftolozane/ tazobactam | 12/19/2014 | To treat adults with complicated intra-abdominal infections (cIAI) and complicated urinary tract infections (cUTI). |
| 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. |
| Lynparza | olaparib | 12/19/2014 | To treat advanced ovarian cancer. |
| Xtoro | finafloxacin otic suspension | 12/17/2014 | To treat acute otitis externa, commonly known as swimmer's ear. |
| Blincyto | blinatumomab | 12/3/2014 | To treat patients with Philadelphia chromosome-negative precursor B-cell acute lymphoblastic leukemia (B-cell ALL). |
| Esbriet | pirfenidone | 10/15/2014 | For the treatment of idiopathic pulmonary fibrosis (IPF). |
| Ofev | nintedanib | 10/15/2014 | For the treatment of idiopathic pulmonary fibrosis (IPF). |
| Lumason | sulfur hexafluoride lipid microsphere | 10/10/2014 | For patients whose ultrasound image of the heart (echocardiograms) are hard to see with ultrasound waves. |
| Akynzeo | netupitant and palonosetron | 10/10/2014 | To treat nausea and vomiting in patients undergoing cancer chemotherapy. |
| Harvoni | ledipasvir/ sofosbuvir | 10/10/2014 | To treat chronic hepatitis C virus (HCV) genotype 1 infection. |
| Trulicity | dulaglutide | 9/18/2014 | To treat adults with type 2 diabetes. |
| Movantik | naloxegol | 9/16/2014 | To treat opioid-induced constipation in adults with chronic non-cancer pain. |

| Drug Name | Active Ingredients | Approval Date | What it is used for |
|---|---|---|---|
| Keytruda | pembrolizumab | 9/4/2014 | For treatment of patients with advanced or unresectable melanoma who are no longer responding to other drugs. |
| Cerdelga | eliglustat | 8/19/2014 | For the long-term treatment of adult patients with the Type 1 form of Gaucher disease. |
| Plegridy | peginterferon beta-1a | 8/15/2014 | For the treatment of patients with relapsing forms of multiple sclerosis. |
| Belsomra | suvorexant | 8/13/2014 | To treat difficulty in falling and staying asleep (insomnia). |
| Orbactiv | oritavancin | 8/6/2014 | To treat adults with skin infections. |
| Jardiance | empagliflozin | 8/1/2104 | To improve gylcemic control in adults with type 2 diabetes. |
| Striverdi Respimat | olodaterol | 7/31/2014 | To treat chronic obstructive pulmonary disease. |
| Zydelig | idelalisib | 7/23/2014 | To treat patients with three types of blood cancers. |
| Kerydin | tavaborole | 7/7/2014 | For the topical treatment of onychomycosis of the toenails. |
| Beleodaq | belinostat | 7/3/2014 | To treat patients with peripheral T-cell lymphoma (PTCL). |
| Sivextro (tablet) | tedizolid phosphate | 6/20/2014 | To treat adults with skin infections. |
| Sivextro (injection) | tedizolid phosphate | 6/20/2014 | To treat adults with skin infections. |
| Jublia | efinaconazole | 6/6/2014 | To treat mild to moderate onychomycosis (fungal infection). |
| Dalvance | dalbavancin | 5/23/2014 | To treat adults with skin infections. |
| 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. |

## Continued Novel New Drugs of 2014

Drugs are listed by the date of approval in 2014, backward from the most recently approved.

| Drug Name | Active Ingredients | Approval Date | What it is used for |
|---|---|---|---|
| Zontivity | vorapaxar | 5/8/2014 | To reduce the risk of heart attacks and strokes in high-risk patients. |
| Zykadia | ceritinib | 4/29/2014 | To treat patients with a certain type of late-stage (metastatic) non-small cell lung cancer (NSCLC). |
| 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). |
| Cyramza | ramucirumab | 4/21/2014 | To treat patients with advanced stomach cancer or gastroesophageal junction adenocarcinoma. |
| Tanzeum | albiglutide | 4/15/2014 | To improve glycemic control, along with diet and exercise, in adults with type 2 diabetes. |
| Otezla | apremilast | 3/21/2014 | To treat adults with active psoriatic arthritis (PsA). |
| Impavido | miltefosine | 3/19/2014 | To treat a tropical disease called leishmaniasis. |
| Neuraceq | florbetaben F 18 injection | 3/19/2014 | For Positron Emission Tomography (PET) imaging of the brain. |
| Myalept | metreleptin for injection | 2/24/2014 | To treat the complications of leptin deficiency. |
| Northera | droxidopa | 2/18/2014 | To treat neurogenic orthostatic hypotension (NOH). |
| Vimizim | elosulfase alfa | 2/14/2014 | Treatment for Mucopolysaccharidosis Type IVA (Morquio A syndrome). |
| 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. |
| Farxiga | dapaglifozin | 1/8/2014 | To improve glycemic control, along with diet and exercise, in adults with type 2 diabetes. |

To view this full summary online please visit the CDER web page spotlight on Drug Innovation http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/default.htm.

Many novel new drugs significantly help patient care and public health.

# Novel New Drugs

# 2014

AKYNZEO
BELEODAQ
BELSOMRA
BLINCYTO
CERDELGA
CYRAMZA
DALVANCE
ENTYVIO
ESBRIET
FARXIGA
HARVONI
HETLIOZ
IMPAVIDO
JARDIANCE
JUBLIA
KERYDIN
KEYTRUDA
LUMASON
LYNPARZA
MOVANTIK
MYALEPT
NEURACEQ
NORTHERA
OFEV
OPDIVO
ORBACTIV
OTEZLA
PLEGRIDY
RAPIVAB
SIVEXTRO
STRIVERDI RESPIMAT
SYLVANT
TANZEUM
TRULICITY
VIEKIRA PAK
VIMIZIM
XTORO
ZERBAXA
ZONTIVITY
ZYDELIG
ZYKADIA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