U.S. Food and Drug Administration
Center of Drug Evaluation and Research
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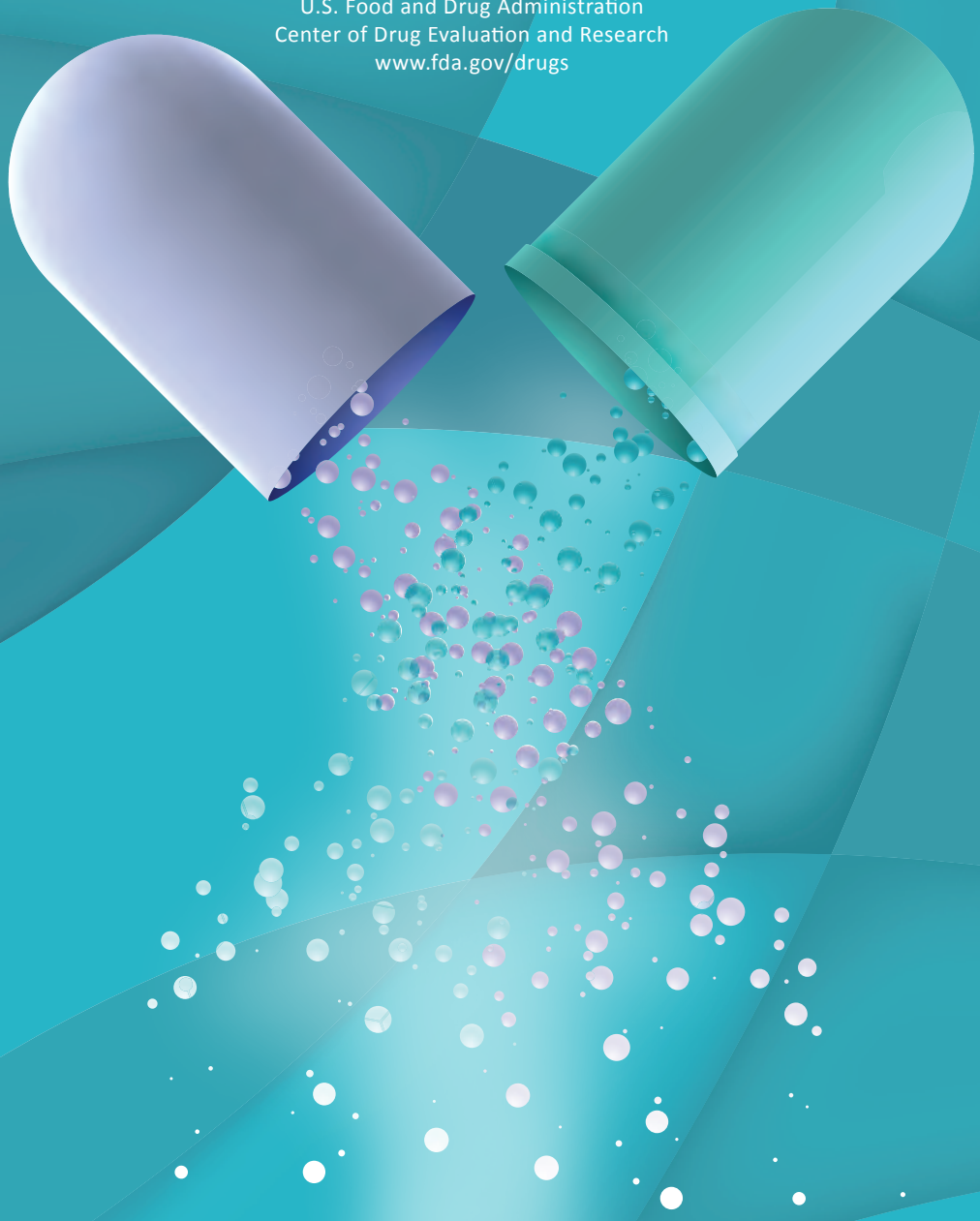


NOVEL DRUGS 2015

JANUARY 2016

S U M M A R Y

IMPACT • INNOVATION • PREDICTABILITY • ACCESS

NOVEL DRUGS 2015 SUMMARY

CONTENTS

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

For more details about the individual novel drugs, see pages 15-17.

INTRODUCTION

Welcome to the FDA's Center for Drug Evaluation and Research's (CDER's) fifth annual Novel 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, that we refer to as novel 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.

Our annual summary reports the quantity of novel drugs that we approved. However, we also focus on the quality 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.

This year's field of novel drugs will offer much to patients in need. We approved many new drugs to treat various forms of cancer, including four to treat multiple myeloma, and others to treat lung, skin, breast, brain, colorectal, and other cancers. This year's field also includes new drugs to treat heart failure and high cholesterol, as well as the first approved reversal agent for a commonly-used blood thinner. We also approved new drugs for the treatment of patients with cystic fibrosis, and irritable bowel syndrome. In the area of infectious disease, our approvals include new treatments for urinary tract infections and chronic hepatitis C. For the second consecutive year, we approved more "orphan" drugs for rare diseases than any previous year in our history.

This work in effectively reviewing and approving new drugs is meaningful to the extent that we can also effectively ensure their safety. All of these newly approved products were required to meet our rigorous premarket safety standards --- and they will all be part of a strong postmarket safety surveillance system watching how they perform after they are more widely used by larger patient populations. We will summarize our safety activities in a different report.

We hope this summary provides an appreciation of the expected impact that many of the novel drug approvals of 2015 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 2015 NOVEL DRUG APPROVALS

45 novel drugs

In calendar year 2015, FDA's Center for Drug Evaluation and Research (CDER) approved 45 novel drugs, approved as new molecular entities (NMEs) under New Drug Applications (NDAs) or as new therapeutic biologics under Biologics License Applications (BLAs). The chart below lists CDER's novel drugs of 2015.*

IN
2015
CDER APPROVED
45
NOVEL DRUGS

Novel drugs are often innovative products that serve previously unmet medical needs or otherwise significantly help to advance patient care and public health. NMEs have chemical structures that have never been approved before. However, in some cases an NME may have actions similar to earlier drugs and may not necessarily offer unique clinical advantages over existing therapies. This report summarizes all of the 2015 NME and novel BLA approvals, emphasizing those that offer new and innovative treatments to patients in need.

The vertical bars in the chart to the right indicate the number of novel drugs approved by CDER in each year of the past decade. CDER approved 45 novel drugs in 2015. From 2006 through 2014, CDER has averaged about 28 novel drug approvals per year.

Applications for new approvals remain steady

CDER approved a higher than average number of novel drugs in 2015; however, the number of applications for these drugs that sponsors have submitted over time has remained relatively stable.

The teal portion of the graph to the right 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 2006 through 2014, CDER filed an average of about 35 applications for novel drugs per year. CDER estimates 40 filings for 2015, which is consistent with previous years in this decade.

Novel Drugs Approved by CDER in Calendar Year 2015. (see pages 15-17 for their non-proprietary names, approval dates, and what these drugs are used for.)

Addyi	Alecensa	Aristada	Avycaz	Bridion	Cholbam	Corlanor	Cosentyx
Cotellic	Cresemba	Daklinza	Darzalex	Empliciti	Entresto	Farydak	Genvoya
Ibrance	Kanuma	Kengreal	Kybella	Lenvima	Lonsurf	Natpara	Ninlaro
Nucala	Odomzo	Orkambi	Portrazza	Praluent	Praxbind	Repatha	Rexulti
Savaysa	Strensiq	Tagrisso	Tresiba	Unituxin	Uptravi	Varubi	Veltassa
Viberzi	Vraylar	Xuriden	Yondelis	Zurampic			

** This information is accurate as of December 31, 2015. In rare instances, it may be necessary for FDA to change a drug's new molecular entity (NME) designation or the status of its application as a novel new biologics license application (BLA). For instance, new information may become available which could lead to a reconsideration of the original designation or status. If changes must be made to a drug's designation or the status of an application as a novel BLA, the Agency intends to communicate the nature of, and the reason for, any revisions as appropriate.*

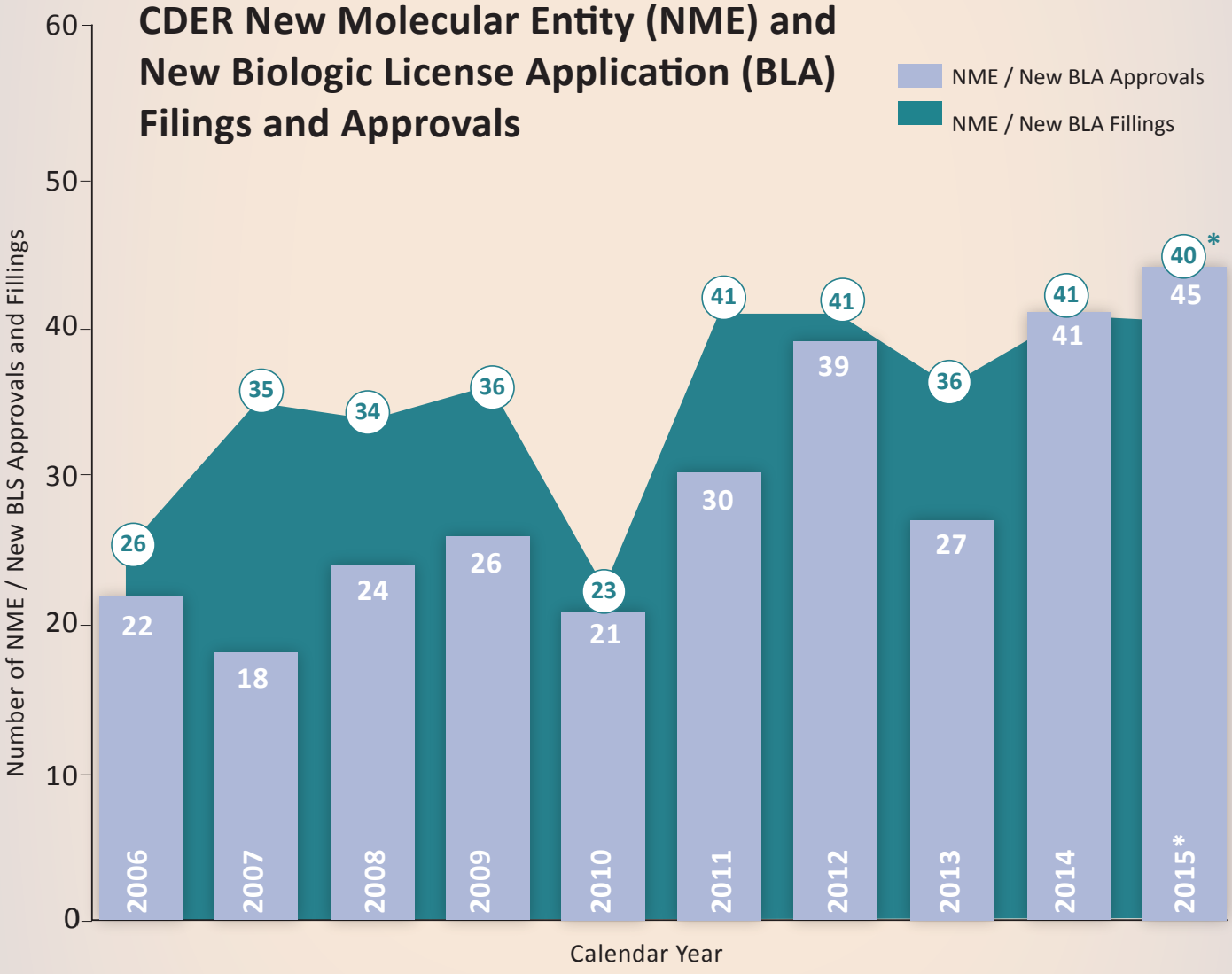
45

novel drug approvals in CY 2015 is more than the average number approved annually during the past decade

From 2006 through 2014 CDER averaged about

28

novel drug approvals per year



*The 2015 filed numbers include those filed in CY 2015 plus those currently pending filing (i.e., within their 60 day filing period) in CY 2015.

- 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.

For more details about the individual novel drugs, see pages 15-17.

IMPACT

Impact on Public Health

Many of the 45 novel drugs CDER approved in 2015 are notable for their potential positive impact and unique contributions to quality medical care and public health.

First-in-Class

CDER identified 16 of the 45 novel drugs approved in 2015 (36%) as First-in-Class, one indicator of the innovative nature of a drug. These drugs often have mechanisms of action different from those of existing therapies. This First-in-Class approval rate is one factor that suggests the 2015 group of novel new approvals is a field comprised of many

Addyi	Bridion	Corlanor	Cosentyx
Darzalex	Empliciti	Entresto	Ibrance
Kanuma	Nucala	Orkambi	Praluent
Praxbind	Strensiq	Unituxin	Xuriden

Noteworthy First-in-Class products include:

Bridion – To reverse post-surgical neuromuscular blockade caused by certain kinds of anesthesia

Ibrance - To treat advanced (metastatic) breast cancer

Praxbind – To reverse adverse anticoagulant effects caused by the blood-thinner drug, dabigatran

For more details about the individual novel drugs, see pages 15-17.

Drugs for Rare Diseases

About 47% of the novel drugs approved in 2015 (21 of 45) 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.

Alecensa	Cholbam	Cotellic
Cresemba	Darzalex	Empliciti
Farydak	Kanuma	Lenvima
Natpara	Ninlaro	Orkambi
Portrazza	Praxbind	Repatha*
Strensiq	Tagrisso	Unituxin
Uptravi	Xuriden	Yondelis

Noteworthy examples of drugs to treat rare diseases among the 2015 novel drugs include:

Kanuma – To treat lysosomal acid lipase deficiency, a rare inherited genetic disorder that does not allow the body to produce an enzyme responsible for breaking down fats, and can lead to liver disease, cardiovascular disease, and life-threatening organ damage.

Orkambi – A therapy for the lung disease, cystic fibrosis.

Strensiq - Long-term enzyme replacement therapy in patients with infantile- and juvenile - onset hypophosphatasia, a serious and sometimes fatal bone disease.

Unituxin - To treat pediatric patients with high-risk neuroblastoma (brain tumors).

Xuriden – To treat patients with hereditary orotic aciduria, a condition that can result in blood abnormalities (anemia, decreased white blood cell count, decreased neutrophil count), urinary tract obstruction, failure to thrive, and developmental delays.

47%
Rare or "Orphan" Diseases

** Repatha was submitted with two indications. One indication received Orphan designation while the other did not.*

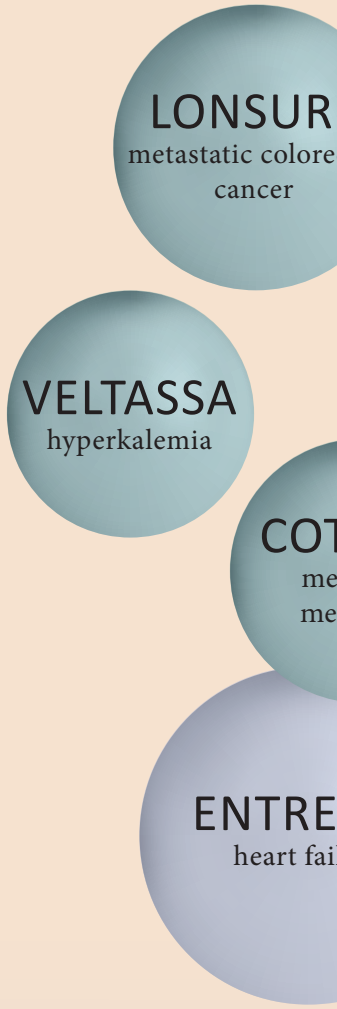
OTHER NOTABLE NOVEL DRUGS OF 2015:

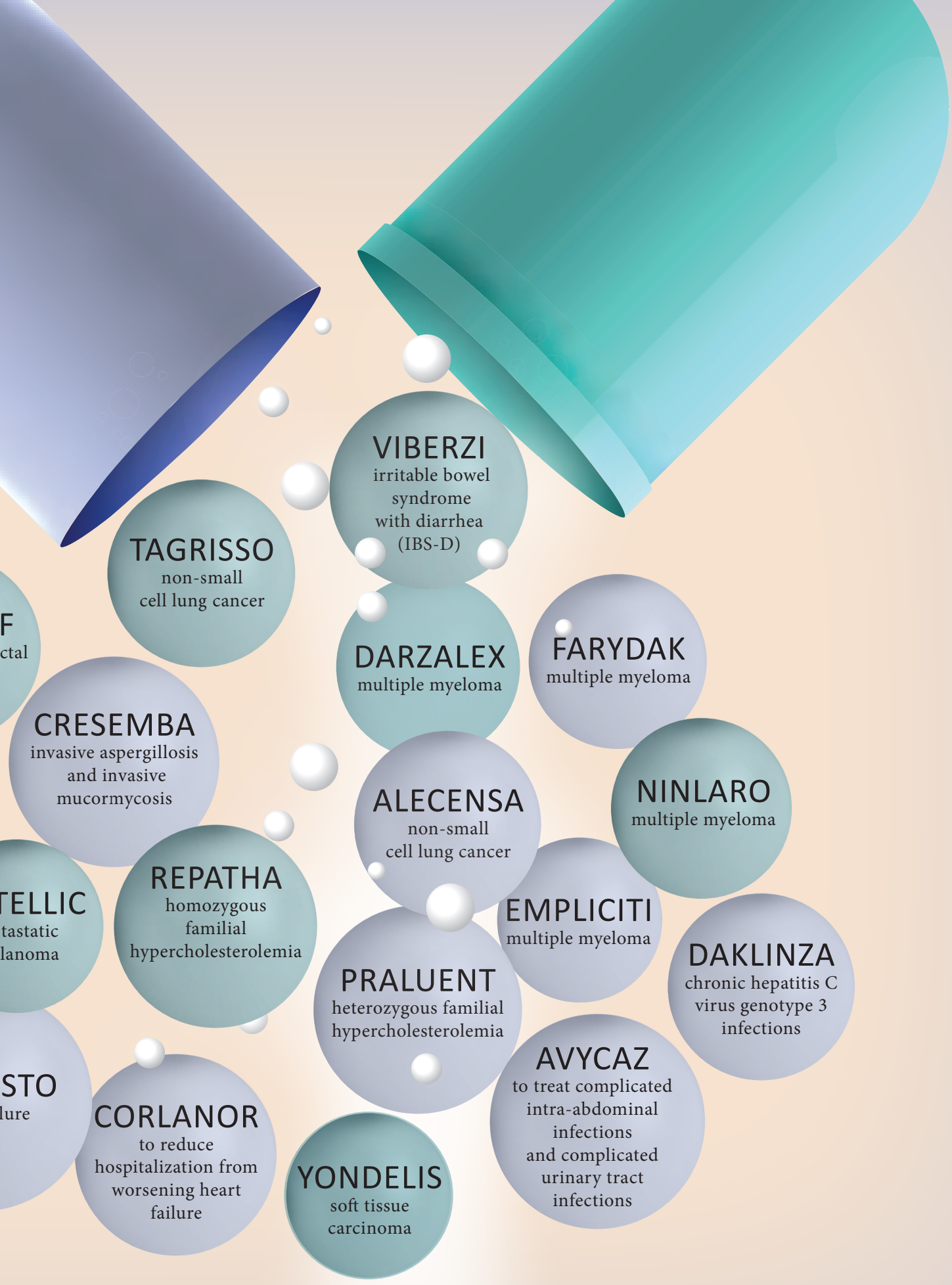
Another strong year for quality

In addition to the noteworthy examples of innovative First-in-Class and "orphan" new products mentioned on pages 4 and 5, the 2015 novel drug field also includes a variety of other notable drugs. These include the antibacterial drug **Avycaz,** to treat complicated intra-abdominal infections and complicated urinary tract infections, and the antifungal product **Cresemba**, to treat invasive aspergillosis and invasive mucormycosis, rare but serious infections. Also, the heart drugs, **Entresto**, to treat heart failure, and **Corlanor,** to reduce hospitalization from worsening heart failure; and the hypercholesterolemia (high cholesterol) treatments, **Praluent,** to treat certain patients with hard to treat heterozygous familial hypercholesterolemia and **Repatha,** to treat this same condition as well as homozygous familial hypercholesterolemia (a rare disease).

Additional noteworthy cancer treatments include **Darzalex, Empliciti, Farydak,** and **Ninlaro,** to treat patients with multiple myeloma (a type of bone cancer), **Alecensa** and **Tagrisso,** to treat certain patients with non-small cell lung cancer, **Cotellic,** to treat certain patients with metastatic melanoma (skin cancer), **Lonsurf,** for the treatment of certain patients with metastatic colorectal cancer, and, **Yondelis,** for treatment of soft tissue carcinoma (cancer of the inner or outer surfaces of the body).

The year's notable approvals also include **Viberzi,** to treat patients who have irritable bowel syndrome with diarrhea (IBS-D), **Veltassa,** to treat hyperkalemia (elevated potassium in the blood), and **Daklinza,** to treat chronic hepatitis C virus genotype 3 infections.





For more details about the individual novel drugs, see pages 15-17.

INNOVATION

Methods for expediting innovative novel drugs to market

CDER used a number of regulatory methods to expedite the approval of novel drugs in 2015. These involved the following four expedited development and review pathways: Fast Track, Breakthrough, Priority Review, and Accelerated Approval.

Fast Track

Fourteen of the 2015 novel drugs (31%) 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.

Avycaz	Corlanor	Cotellic	Daklinza
Darzalex	Entresto	Genvoya	Kanuma
Lonsurf	Orkambi	Portrazza	Strensiq
Tagrisso	Viberzi		

Breakthrough

CDER designated ten of the 2015 novel 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 potential new therapy.

Alecensa	Darzalex	Empliciti	Ibrance	Kanuma
Orkambi	Praxbind	Strensiq	Tagrisso	Xuriden

Priority Review

Twenty-four of the 2015 novel drugs (53%) were designated Priority Review, in which CDER determined that the drug could 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.*

Alecensa	Avycaz	Bridion	Cholbam	Corlanor	Cotellic
Cresemba	Daklinza	Darzalex	Empliciti	Entresto	Farydak
Ibrance	Kanuma	Lenvima	Ninlaro	Orkambi	Praxbind
Strensiq	Tagrisso	Unituxin	Viberzi	Xuriden	Yondelis

**In some instances, priority review is assigned as a result of the sponsor redeeming a voucher for priority review under CDER's Priority Review Voucher program, which may mean the drug does not potentially provide a significant advance. Such drugs are not included in the list above.*

For more details about the individual novel drugs, see pages 15-17.

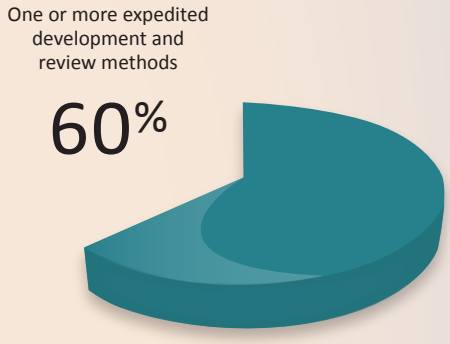
Accelerated Approval

CDER approved six of the 2015 novel drugs (13%) 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.

Alecensa Darzalex Farydak Ibrance Tagrisso Praxbind

Overall use of expedited development and review methods

Twenty-seven of the 2015 novel drugs (60%) were designated in one or more expedited 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.



Alecensa Avycaz Bridion Cholbam Corlanor Cotellic
Cresemba Daklinza Darzalex Empliciti Entresto Farydak
Genvoya Ibrance Kanuma Lenvima Lonsurf Ninlaro
Orkambi Portrazza Praxbind Strensiq Tagrisso Unituxin
Viberzi Xuriden Yondelis


Fast Track 31%


Priority Review 53%


Breakthrough 22%


Accelerated Approval 13%

Qualified Infectious Disease Program Designations

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 2015, CDER approved two novel drugs with this designation.

Avycaz Cresemba

PREDICTABILITY

Addyi	Alecensa
Avycaz	Bridion
Corlanor	Cosentyx
Cotellic	Cresemba
Daklinza	Darzalex
Empliciti	Entresto
Farydak	Genvoya
Ibrance	Kanuma
Kengreal	Kybella
Lenvima	Lonsurf
Natpara	Ninlaro
Nucala	Odomzo
Orkambi	Portrazza
Praluent	Praxbind
Repatha	Rexulti
Savaysa	Strensiq
Tagrisso	Tresiba
Unituxin	Uptravi
Varubi	Veltassa
Viberzi	Vraylar,
Xuriden	Yondelis
Zurampic	

PDUFA Goals 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 2015, CDER met its PDUFA goals for 96% of the novel drugs approved (43 of 45).

IN
2015
CDER MET ITS PDUFA GOAL FOR
96%
OF THE NOVEL DRUGS APPROVED IN
2015

For more details about novel drugs, see pages 15-17

ACCESS

First Cycle Approval

CDER approved most of the novel drugs of 2015 (39 of 45, 87%) on the "first cycle" of review, meaning without requests for additional information that would delay approval and lead to another cycle of review.

Alecensa	Aristada	Avycaz	Cholbam	Corlanor	Cosentyx	Cotellic	Cresemba
Darzalex	Empliciti	Entresto	Farydak	Genvoya	Ibrance	Kanuma	Kybella
Lenvima	Lonsurf	Natpara	Ninlaro	Nucala,	Odomzo	Orkambi	Portrazza
Praluent	Praxbind	Repatha	Rexulti	Savaysa	Strensiq	Tagrisso	Unituxin
Uptravi	Varubi	Veltassa	Viberzi	Xuriden	Yondelis	Zurampic	

Approval in the U.S. before other countries

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, about two-thirds of the novel drugs approved in 2015 (29 of 45, 64%) were approved in the United States before receiving approval in any other country.

Addyi	Aristada	Avycaz	Cresemba	Darzalex	Empliciti
Entresto	Farydak	Genvoya	Ibrance	Kybella	Lenvima
Natpara	Ninlaro	Nucala	Orkambi	Portrazza	Praluent
Praxbind	Rexulti	Tagrisso	Unituxin	Uptravi	Varubi
Veltassa	Viberzi	Vraylar	Xuriden	Zurampic	

87%
First Cycle Approval

64%
Approved First in U.S.

For more details about the individual novel drugs, see pages 15-17.

OVERVIEW

This document represents a broad overview of CDER approvals of novel drugs for calendar year 2015.

A continuing upward trend for the annual number of CDER's novel drug approvals necessarily relies on a corresponding increase in the number of drug applications submitted for approval. 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 drugs approved in 2015 are the qualities of the novel 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 novel drugs, CDER maintains its rigorous standards for demonstration of effectiveness and safety in the process.

> More important than the quantity of novel drugs approved by CDER in 2015 is their quality and the important new roles they are serving to advance medical care.

For more details about the individual novel drugs, see pages 15-17.

Drug Designation Summary

Approval Date	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
8/18	Addyi	■						■		■		Tablet
12/11	Alecensa		■		■	■	■	■	■			Capsule
10/6	Aristada								■	■		Injection
2/25	Avycaz			■		■		■	■	■	■	Injection
12/15	Bridion	■				■		■				Injection
3/17	Cholbam		■			■			■			Capsule
4/15	Corlanor	■		■		■		■	■			Tablet
12/1	Cosentyx	■						■	■			Injection
11/10	Cotellic		■	■		■		■	■			Tablet
3/6	Cresemba		■			■		■	■	■	■	Capsule
7/24	Daklinza			■		■		■				Tablet
11/16	Darzalex	■	■	■	■	■	■	■	■	■		Injection
11/30	Empliciti	■	■		■	■		■	■	■		Injection
7/7	Entresto	■		■		■		■	■	■		Tablet
2/23	Farydak		■			■	■	■	■	■		Capsule
11/5	Genvoya			■				■	■	■		Tablet
2/3	Ibrance	■			■	■	■	■	■	■		Capsule
12/8	Kanuma	■	■	■	■	■		■	■			Injection
6/22	Kengreal							■				Injection
4/29	Kybella							■	■	■		Injection
2/13	Lenvima		■			■		■	■	■		Capsule
9/22	Lonsurf			■				■	■			Tablet
1/23	Natpara		■					■	■	■		Injection
11/20	Ninlaro		■			■		■	■	■		Capsule
11/4	Nucala	■						■	■	■		Injection
7/24	Odomzo							■	■			Capsule
7/2	Orkambi	■	■	■	■	■		■	■	■		Tablet
11/24	Portrazza		■	■				■	■	■		Injection
7/24	Praluent	■						■	■	■		Injection
10/16	Praxbind	■	■		■	■	■	■	■	■		Injection
8/27	Repatha		■					■	■			Injection
7/13	Rexulti							■	■	■		Tablet
1/8	Savaysa							■	■			Tablet
10/23	Strensiq	■	■	■	■	■		■	■			Injection
11/13	Tagrisso		■	■	■	■	■	■	■	■		Tablet
9/25	Tresiba							■				Injection
3/10	Unituxin	■	■			■		■	■	■		Injection
12/22	Uptravi		■					■	■	■		tablet
9/2	Varubi							■	■	■		Tablet
10/21	Veltassa							■	■	■		Oral Suspension
5/27	Viberzi			■		■		■	■	■		Tablet
9/17	Vraylar							■		■		Capsule
9/4	Xuriden	■	■		■	■		■	■	■		Oral granules
10/23	Yondelis		■			■		■	■			Injection
12/22	Zurampic							■	■	■		Tablet

DRUG DESIGNATION SUMMARY

First-in-Class

Drugs with a new and unique mechanism for treating a medical condition

Orphan Drugs

Drugs approved for small populations of patients with rare diseases

Breakthrough

A drug with preliminary clinical evidence demonstrating that it may result in substantial improvement on at least one clinically significant endpoint over available therapies.

Fast Track

Drugs that can treat unmet medical needs

Priority Review

A drug is given a priority review if there is potential to provide a significant advance in existing medical care. Drugs assigned priority review under CDER's Priority Review Voucher program are not included in this summary.

Accelerated Approval

Early approval based on markers that predict a reasonable benefit, with more testing to confirm clinical benefit after approval

PDUFA Goal Date

The goal date for application review determined by the Prescription Drug User Fee Act (PDUFA).

First Cycle

Drugs that were approved without request for additional information that could delay approval and lead to another cycle of review

First Approved in U.S.

Drugs that were approved in the United States before approval in other country

Qualified Infectious Disease Program Designation

A drug with particular promise can be designated as a Qualified Infectious Disease Product (QIDP) by authority of the Generating Antibiotics Incentives Now Act (GAIN Act)

THE NOVEL DRUGS OF 2015

CDER's Novel Drug Approvals of 2015, backward from the most recently approved.

Drug Name	Active Ingredient	Approval Date	What it is used for
Zurampic	lesinurad	12/22/2015	To treat high blood uric acid levels associated with gout
Uptravi	selexipag	12/22/2015	To treat pulmonary arterial hypertension
Bridion	sugammadex	12/15/2015	To reverse effects of neuromuscular blocking drugs used during surgery
Alecensa	alectinib	12/11/2015	To treat ALK-positive lung cancer
Kanuma	sebelipase alfa	12/8/2015	To treat patients with a rare disease known as lysosomal acid lipase (LAL) deficiency
Empliciti	elotuzumab	11/30/2015	To treat people with multiple myeloma who have received one to three prior medications
Portrazza	necitumumab	11/24/2015	To treat patients with advanced (metastatic) squamous non-small cell lung cancer (NSCLC) who have not previously received medication specifically for treating their advanced lung cancer
Ninlaro	ixazomib	11/20/2015	To treat people with multiple myeloma who have received at least one prior therapy
Darzalex	daratumumab	11/16/2015	To treat patients with multiple myeloma who have received at least three prior treatments.
Tagrisso	osimertinib	11/13/2015	To treat certain patients with non-small cell lung cancer
Cotellic	cobimetinib	11/10/2015	To be used in combination with vemurafenib to treat advanced melanoma that has spread to other parts of the body or can't be removed by surgery, and that has a certain type of abnormal gene (BRAF V600E or V600K mutation)
Genvoya	a fixed-dose combination tablet containing elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide	11/5/2015	For use as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients 12 years of age and older
Nucala	mepolizumab	11/4/2015	For use with other asthma medicines for the maintenance treatment of asthma in patients age 12 years and older.
Strensiq	asfotase alfa	10/23/2015	To treat perinatal, infantile and juvenile-onset hypophosphatasia (HPP).

For more details about the individual novel drugs, see pages 15-17.

CONTINUED NOVEL DRUGS OF 2015

CDER's Novel Drug Approvals of 2015, backward from the most recently approved.

Drug Name	Active Ingredient	Approval Date	What it is used for
Yondelis	trabectedin	10/23/2015	To treat specific soft tissue sarcomas (STS) – liposarcoma and leiomyosarcoma – that cannot be removed by surgery (unresectable) or is advanced (metastatic).
Veltassa	patiromer for oral suspension	10/21/2015	To treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high.
Praxbind	idarucizumab	10/16/2015	For use in patients who are taking the anticoagulant Pradaxa (dabigatran) during emergency situations when there is a need to reverse Pradaxa's blood-thinning effects.
Aristada	aripiprazole lauroxil	10/6/2015	To treat adults with schizophrenia
Tresiba	insulin degludec injection	9/25/2015	To improve blood sugar (glucose) control in adults with diabetes mellitus
Lonsurf	trifluridine and tipiracil	9/22/2015	To treat patients with an advanced form of colorectal cancer who are no longer responding to other therapies
Vraylar	cariprazine	9/17/2015	To treat schizophrenia and bipolar disorder in adults
Xuriden	uridine triacetate	9/4/2015	To treat patients with hereditary orotic aciduria
Varubi	rolapitant	9/2/2015	To prevent delayed phase chemotherapy-induced nausea and vomiting (emesis)
Repatha	evolocumab	8/27/2015	To treat certain patients with high cholesterol
Addyi	flibanserin	8/18/2015	To treat acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women
Daklinza	daclatasvir	7/24/2015	To treat chronic hepatitis C virus (HCV) genotype 3 infections
Odomzo	sonidegib	7/24/2015	To treat patients with locally advanced basal cell carcinoma that has recurred following surgery or radiation therapy, or who are not candidates for surgery or radiation therapy.
Praluent	alirocumab	7/24/2015	To treat certain patients with high cholesterol
Rexulti	brexpiprazole	7/10/2015	To treat schizophrenia and as an add on to an antidepressant to treat major depressive disorder
Entresto	sacubitril/valsartan	7/7/2015	To treat heart failure
Orkambi	lumacaftor 200 mg/ ivacaftor 125 mg	7/2/2015	To treat cystic fibrosis

For more details about the individual novel drugs, see pages 15-17.

CONTINUED NOVEL DRUGS OF 2015

CDER's Novel Drug Approvals of 2015, backward from the most recently approved.

Drug Name	Active Ingredient	Approval Date	What it is used for
Kengreal	canegrelor	6/22/2015	To prevent the formation of harmful blood clots in the coronary arteries for adult patients undergoing percutaneous coronary intervention
Viberzi	eluxadoline	5/27/2015	To treat irritable bowel syndrome with diarrhea (IBS-D) in adult men and women.
Kybella	deoxycholic acid	4/29/2015	To treat adults with moderate-to-severe fat below the chin, known as submental fat
Corlanor	ivabradine	4/15/2015	To reduce hospitalization from worsening heart failure.
Cholbam	cholic acid	3/17/2015	To treat pediatric and adult patients with bile acid synthesis disorders due to single enzyme defects, and for patients with peroxisomal disorders
Unituxin	dinutuximab	3/10/2015	To treat pediatric patients with high-risk neuroblastoma
Cresemba	isavuconazonium sulfate	3/6/2015	To treat adults with invasive aspergillosis and invasive mucormycosis, rare but serious infections
Avycaz	ceftazidime-avibactam	2/25/2015	To treat adults with complicated intra-abdominal infections (cIAI), in combination with metronidazole, and complicated urinary tract infections (cUTI), including kidney infections (pyelonephritis), who have limited or no alternative treatment options.
Farydak	panobinostat	2/23/2015	To treat patients with multiple myeloma
Lenvima	lenvatinib	2/13/2015	To treat patients with progressive, differentiated thyroid cancer (DTC) whose disease progressed despite receiving radioactive iodine therapy (radioactive iodine refractory disease).
Ibrance	palbociclib	2/3/2015	To treat advanced (metastatic) breast cancer
Natpara	parathyroid horomone	1/23/2015	To control hypocalcemia (low blood calcium levels) in patients with hypoparathyroidism
Cosentyx	secukinumab	1/21/2015	To treat adults with moderate-to-severe plaque psoriasis

New Molecular Entity and New Therapeutic Biological Product Approvals for 2015

http://www.fda.gov/DevelopmentApprovalProcess/DrugInnovation/default.htm.

NOVEL DRUGS 2015

Addyi
Alecensa
Avycaz
Bridion
Corlanor
Cosentyx
Cotellic
Cresemba
Daklinza
Darzalex
Empliciti
Entresto
Farydak
Genvoya
Ibrance
Kanuma
Kengreal
Kybella
Lenvima
Lonsurf
Natpara
Ninlaro
Nucala
Odomzo
Orkambi
Portrazza
Praluent
Praxbind
Repatha
Rexulti
Savaysa
Strensiq
Tagrisso
Tresiba
Unituxin
Uptravi
Varubi
Veltassa
Viberzi
Vraylar
Xuriden
Yondelis
Zurampic

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