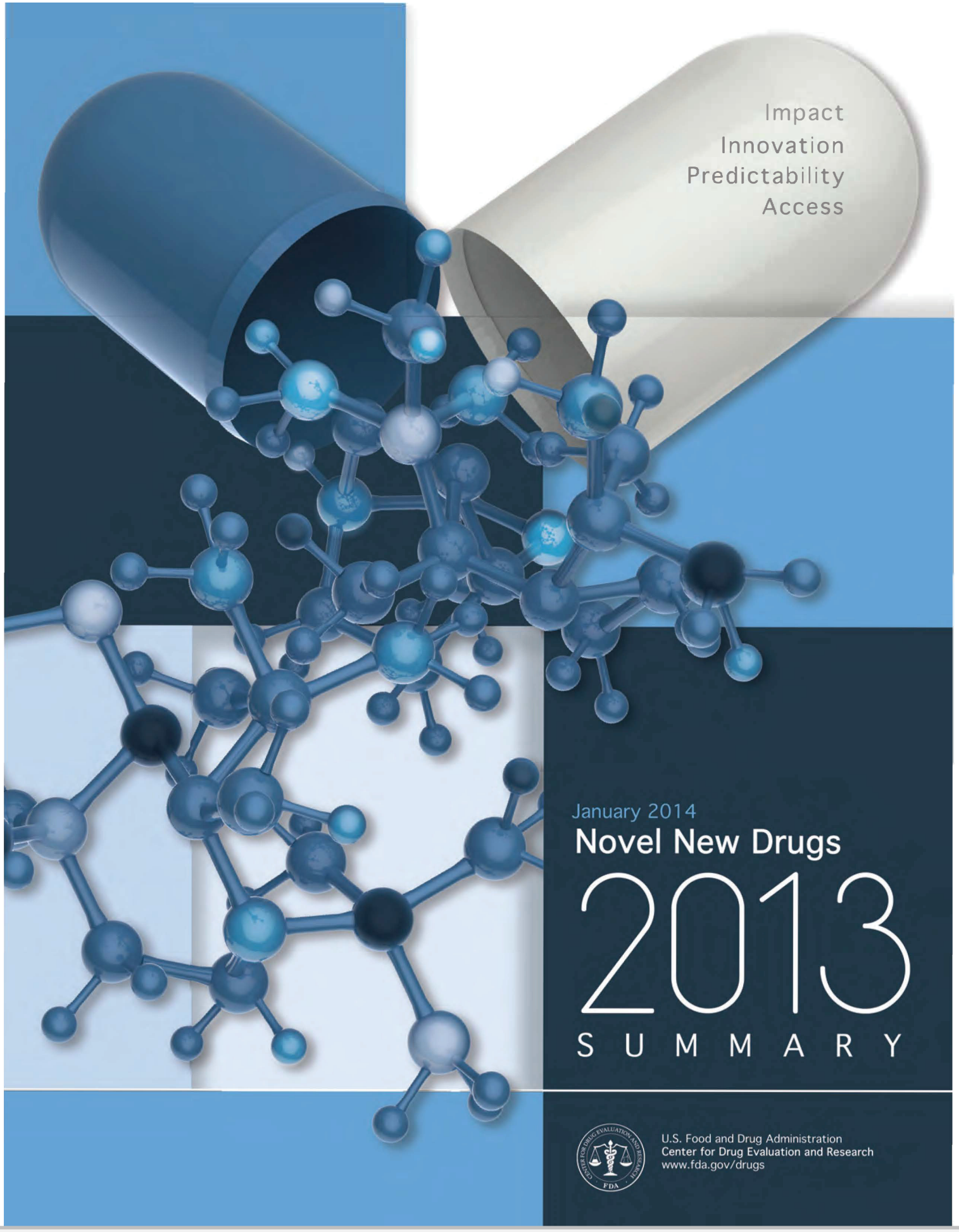


January 2014

Novel New Drugs 2013 SUMMARY

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

CDER's 2013 Novel New Drugs

27 novel new drugs in CY 2013:

In Calendar Year 2013, FDA's Center for Drug Evaluation and Research (CDER) approved 27 novel new medicines, known as new molecular entities (NMEs). For the purposes of this report, the term NME applies to novel new drugs approved under both New Drug Applications (NDAs) and Biologics License Applications (BLAs). The chart below lists CDER's 2013 NMEs.

In 2013 CDER approved 27 NMEs

NMEs are often innovative new products that serve previously unmet medical needs or otherwise significantly help to advance patient care and public health. However, in some cases, while categorized as novel for technical and/or administrative purposes, a particular NME may not necessarily offer unique clinical advantages over existing therapies. This report summarizes all NMEs of 2013, with an emphasis on those that offer new and innovative treatments to patients in need.

The dark blue bars in the chart to the right indicate the number of NMEs approved by CDER in each year of the past decade. CDER approved 27 NMEs in 2013, which is similar to average totals of other years from this time period. For instance from 2004 through 2012, CDER has averaged about 26 NME approvals per year. In 2012, CDER approved 39 NMEs, but this was an unusually high number compared to any other total in more than a decade.

Applications for new approvals remain steady

The number of applications CDER has been receiving for NMEs has not been consistently and significantly increasing. The light blue portion of the graph to the right indicates the number of new NDA and BLA applications for NMEs CDER has filed over the last ten years. From 2004 through 2012, CDER filed an average of about 34 applications for NMEs per year. Although all applications submitted in 2013 had not yet been accepted for filing as of 12/31/13, CDER projects about 36 for 2013, which is consistent with previous years in this decade.

With a relatively steady number of applications coming in over time, it is noteworthy that FDA cannot expect a continuing upward trend for NME approvals until a sustained increase in the number of applications for NMEs submitted for approval is also demonstrated.

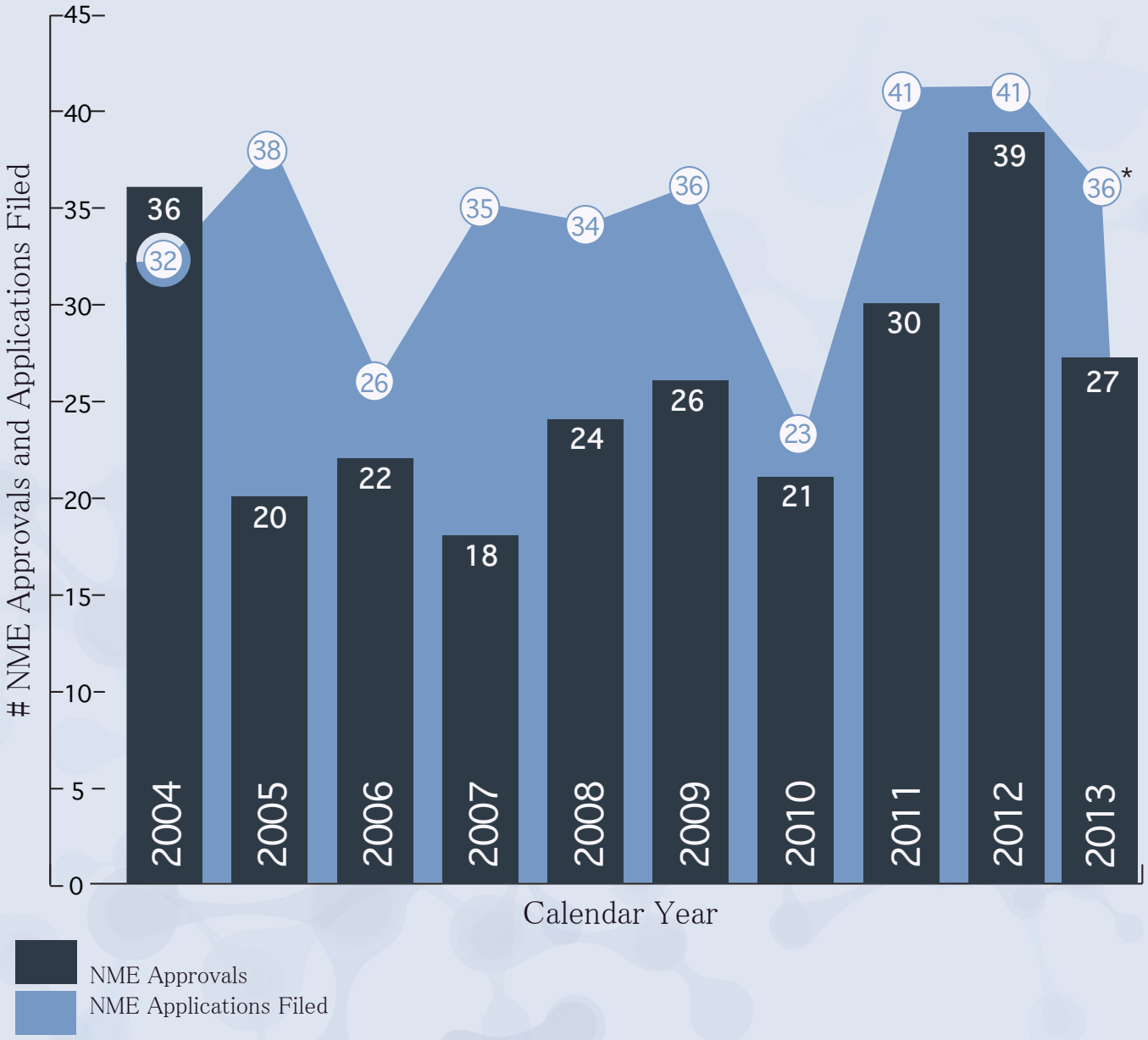
CDER's NMEs of CY 2013: see pages 14 & 15 for what these drugs are used for.								
Adempas	Anoro Ellipta	Aptiom	Breo Ellipta	Brintellix	Dotarem	Duavee	Gazyva	Gilotrif
Imbruvica	Invokana	Kadcyla	Kynamro	Luzu	Lymphoseek	Mekinist	Nesina	Olysio
Opsumit	Osphena	Pomalyst	Sovaldi	Tafinlar	Tecfidera	Tivicay	Vizamyl	Xofigo

27 NMEs approved in CY 2013 is similar to the average totals approved in the past decade

From 2004 through 2012, CDER has averaged

26

NME approvals per year



* – The filed numbers include those filed in CY 2013 plus those currently pending filing (i.e., within their 60 day filing period) in CY 2013.
– 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.
– There is a BLA included that does not currently have a review schedule but is known to contain a new active ingredient.

Impact

Impact on Public Health

Many of the 27 NMEs approved by CDER in CY 2013 are notable for their potential positive impact and unique contributions to quality care and public health.

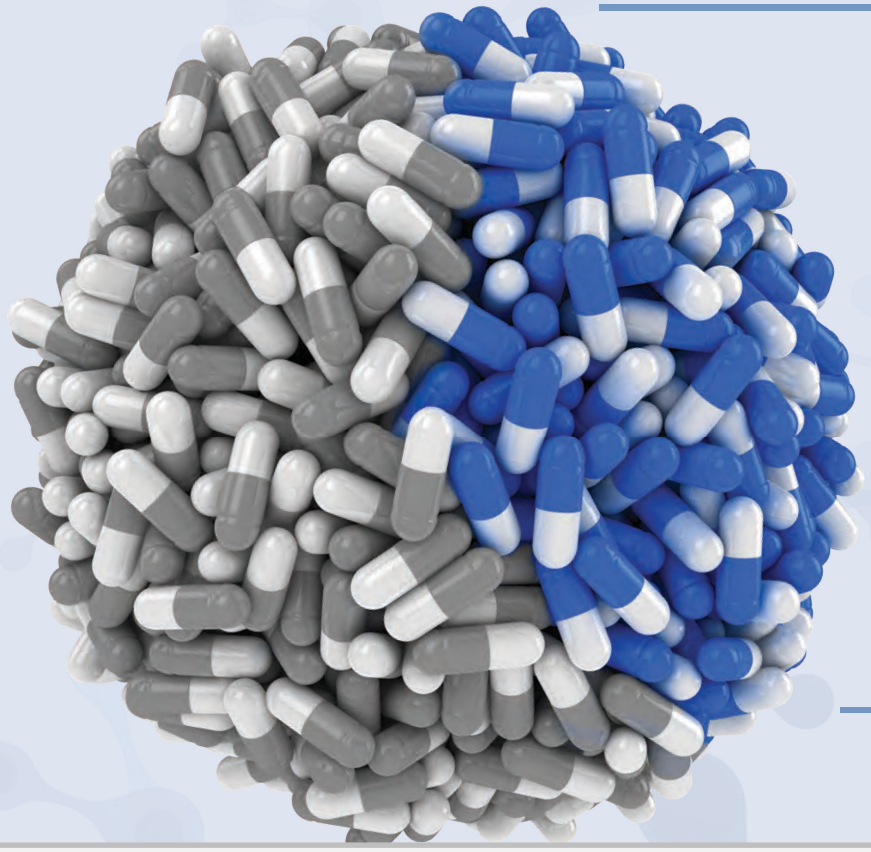
First-in-Class

Adempas
Imbruvica
Invokana
Kadcyla
Kynamro
Mekinist
Sovaldi
Tecfidera
Xofigo

One-third (33%) of the NMEs approved in CY 2013 (9 of 27) were identified by FDA as First-in-Class, meaning drugs which, for example, use a new and unique mechanism of action for treating a medical condition. First-in-Class is one indicator of the innovative nature of a drug and a 33% First-in-Class approval rate suggests that the group of CY 2013 NMEs is a field of innovative new products.

Noteworthy First-in-Class products include:

Invokana - for type 2 diabetes glycemic control
Kadcyla - for HER2-positive late-stage (metastatic) breast cancer
Sovaldi - an interferon-free oral treatment option for some patients with chronic hepatitis C
Mekinist - for metastatic melanoma



33%
First-in-Class Drugs

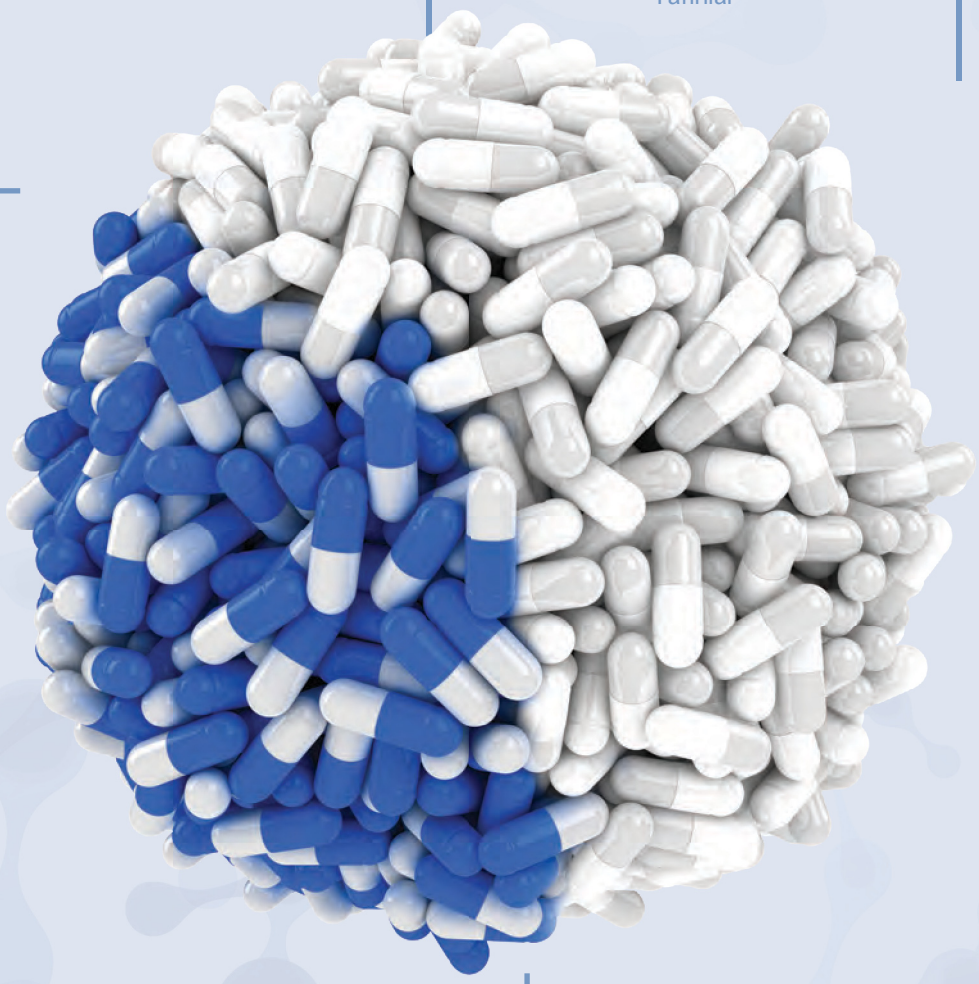
One-third (33%) of the NMEs approved in CY 2013 (9 of 27) were approved to treat rare or "orphan" diseases that affect 200,000 or fewer Americans. This is significant because patients with rare diseases often have few or no drug treatment options.

Noteworthy examples of rare diseases that now have new or additional effective treatment options include:

Mantle cell lymphoma - Imbruvica
Chronic lymphocytic leukemia - Gazyva
Homozygous familial hypercholesterolemia - Kynamro
Pulmonary arterial hypertension - Adempas and Opsumit

Orphan Drugs

Adempas
Gazyva
Gilotrif
Imbruvica
Kynamro
Mekinist
Opsumit
Pomalyst
Tafinlar



33%
Orphan Drugs

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