2014年度、USFDAが承認した新規医薬品の概要

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CDER’s 2014 Novel New Drugs
41 Novel New Drugs

2014年、FDAが承認した新規医薬品の承認、マーケットの概要をまとめた。

参考文献

• Overview of FDA Support for Innovation (PDF - 683KB)

http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM433161.pdf

• Nature REVIEWS DRUG DISCOVERY, VOLUME 14, FEBRUARY 2015

FDAは2014年　41の新規医薬品を承認した。

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.)

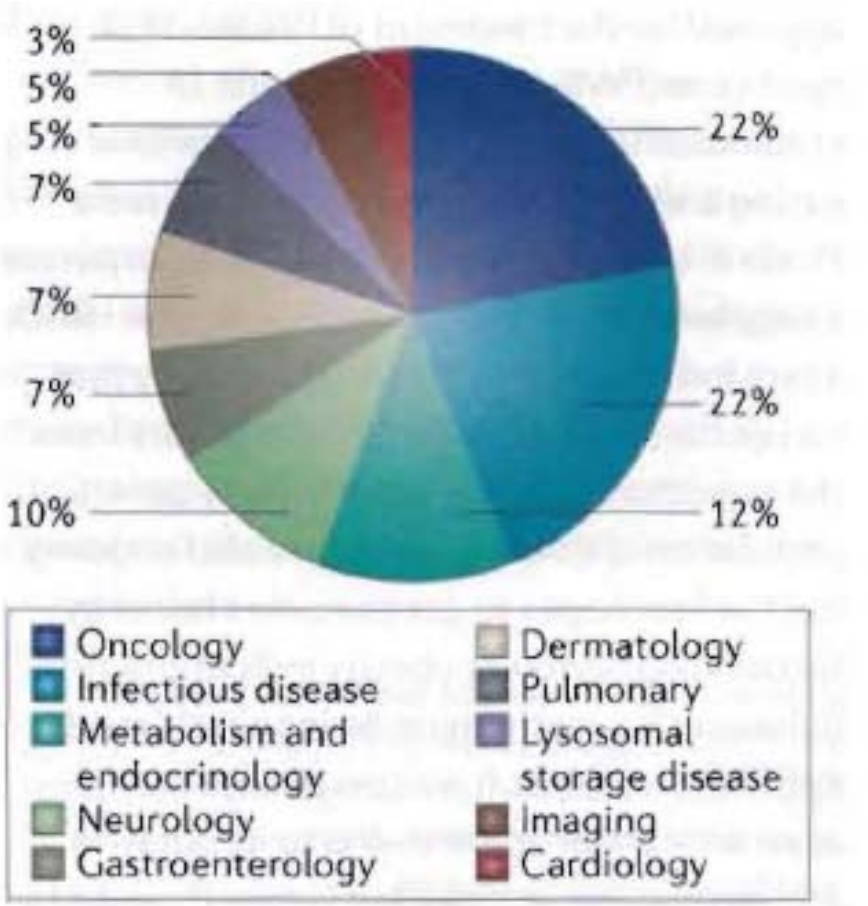
Akynzeo	Dalvance	Impavido	Lynparza	Opdivo	Striverdi Respimat	Xtoro
Beleodaq	Entyvio	Jardiance	Movantik	Orbactiv	Sylvant	Zerbaxa
Belsomra	Esbriet	Jublia	Myalept	Otezla	Tanzeum	Zontivity
Blincyto	Farxiga	Kerydin	Neuraceq	Plegridy	Trulicity	Zydelig
Cerdelga	Harvoni	Keytruda	Northera	Rapivab	Viekira Pak[2]	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.

新規医薬品**41**品目の内、**17**品目が**first –in-class**で、新規な作用機序を有した医薬品が多く承認された。

希少疾病薬が17品目が承認された（オーファンドラッグは9品目

領域別でみると、制がん剤が多く(9品目)、次いで、感染症が9品目



ファーストトラックに17品目が指定される

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*.

ブレイクスルーに9品目が指定される。ブレイクスルーに指定された品目の多くは、ブロックバスターに育つと期待されている。

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

優先審査　25品目承認される

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

- 初回の承認率は67％で、承認審査が厳しくなっており、当局のレギュラトリーサイエンスの理解や相談がますます重要になってきています。