

FDA name approvals – 2019 in review



Overview

Last year saw the FDA approve no less than 48 new molecular entities and new therapeutic biological products, so-called “novel” drugs. 21 of these treatments were designated to have “orphan” status reflecting significant advances across an extensive spectrum of rarer diseases and conditions.

And, consistent with recent years, 2019 heralded the approval of a high number of cancer and blood disorder drugs in multiple oncological and hematological areas.

A significant number of biosimilars also gained approval helping to reduce costs as well as increase patient access to important therapies.

FDA approvals 2019: select original NDAs/BLAs

ABRILADA	GLOPERBA	RECARBRIO	VYLEESI
ACCRUFER	HADLIMA	REYVOW	VYNDAMAX
ADAKVEO	HEMADY	RINVOQ	VYNDAQEL
AKLIEF	IBSRELA	ROZYLTRAK	WAKIX
AVSOLA	INREBIC	RUXIENCE	XCOPRI
BALVERSA	JEUVEAU	RUZURGI	XENLETA
BEOVU	KANJINTI	SCENESSE	XPOVIO
BRUKINSA	MAYZENT	SKYRIZI	ZIEXTENZO
CABLIVI	NOURIANZ	SPRAVATO	ZIRABEV
CAPLYTA	NUBEQA	SUNOSI	ZULRESSO
DAYVIGO	NUCALA	TALICIA	
EGATEN	ONTRUZANT	TOSYMRA	
ENHERTU	OXBRYTA	TRAZIMERA	
ETICOVO	PADCEV	TRIKAFTA	
EVENITY	PIQRAY	TURALIO	
FETROJA	POLIVY	UBRELVY	
GIVLAARI	REBLOZYL	VUMERITY	

Therapy area
Hematology/oncology
Infectious diseases
Neurology
Other

Novel drugs are shown in italics

Wide variety of name types

Different approaches to drug naming are seen within a broad range of communication and messaging strategies, including:

INN/USAN-referential tradenames such as *Trikafta* (encodes triple combination ~caf~ infixes CFTR modulators), *Brukinsa* (zanubrutinib), *Givlaari* (givosiran), *Oxbryta* (voxelotor) and *Ubrelyv* (ubrogepant) which, by echoing nonproprietary origins, can help prescribers both identify and recall drug provenance and functionality

Indication-suggestive or **condition-related** names such as *Aklief* (“acne relief”), *Ibsrela* (“irritable bowel syndrome”), *Beovu* (“better view”), *Scenesse* (“scene”, “essence”), *Dayvigo* (“overcome insomnia”), *Wakix* (“stay awake”) and *Fetroja* (embeds “Fe” [iron] and “Trojan horse” MOA cues) can offer definitive and therapy-specific benefit associations

Apparently **arbitrary/meaningless** coined names, although maybe less immediately intuitive than more identifiably apparent names, can deliver long-lasting distinctiveness and stand-out value by incorporating unorthodox or deliberately unusual letter strings or underrepresented syllables, such as *Xcopri*, *Rinvoq*, *Piqray* and *Turalio*

Aspirational, or imagery-indicative, drug names can help evoke positive and beneficial emotional, and actual, product connotations which may be relevant both to patients as well as medical professionals alike, such as *Jeuveau* (“rejuvenation”), *Mayzent* (“amazing”, MS), *Balversa* (“balance”, “versatility”) and *Skyrizi* (“sky”, “rise”), and *Vyndaqel* (“vindicate”, “quell”).

Innovation primacy

Of the 48 “novel” drug approvals in 2019, 20 were first-in-class treatments meaning they offer different mechanisms of action (MOAs) from existing therapies including *Adakveo*, *Balversa*, *Cablivi*, *Evenity*, *Givlaari*, *Ibsrela*, *Nourianz*, *Oxbryta*, *Padcev*, *Polivy*, *pretomanid*, *Reblozyl*, *Reyvow*, *Scenesse*, *Turalio*, *Vyleesi*, *Vyndaqel*, *Wakix*, *Xpovio*, and *Zulresso*.

It is widely expected that such development innovation will continue into the new decade and name creation for such pharmacologically-inventive products will need to provide equal levels of ingenuity in terms of inspiration, distinctiveness and overall impact.

To contact Purple Fire Branding, specialists in brand naming, research and design, please telephone +44 (0)20 8166 1853 or visit www.purplefirebranding.com

