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# FDA okays only 25 new biotech drugs in 2013

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**FDA okays only 25 new biotech drugs in 2013**



After a high of 33 approvals in 2012, the US regulator FDA gave its nod to only 25 new drugs in 2013. FDA also approved just two biological licenses (BLA) last year, according to data compiled by the annual Global Biotechnology Report by EY. The report was released at the annual BIO International Convention in San Diego, USA, in June.

The highest annual drug approvals in recent decades happened in 1996 when US FDA approved 53 drugs. Otherwise, the annual average approvals have hovered around 24.

Releasing the report, EY's Global Life Science Practice leader, Mr Glen Gionavetti, noted that among the 25 new drugs approved in 2013, two are already on the way to become blockbusters with annual sales topping $1 billion.

bsi-july-2014-europe-orphan-drug-approvals
Gilead Sciences got a lucky winner in Sovaldi, which got approved very late in 2013. Its sales in the first quarter of 2014 itself has topped $2 billion. Sovaldi is an interferon-free oral treatment to contain Hepatitis C infection. Biogen Idec hit the blockbuster jackpot with Tecfidera, an oral therapy to treat relapsing forms of multiple sclerosis. Both Tecfidera and Sovaldi are biotech drugs.

EY report said there are three other promising biotech drugs which got approved in 2013. These are: Ibruvica, developed by Pharmacylcis in partnership with Johnson & Johnson, Opsumit by Actelion and Pomalyst from Celgene.

bsi-july-2014-other-selected-ema-approvals
Ibruvica and Pomalyst are anti-cancer drugs. Ibruvica is used to treat mantle cell lymphoma cancer condition and also chronic lymphocytic leukemia. Pomalyst is successful in treating another form of cancer called multiple myeloma. Opsumit is used to reduce the effect of pulmonary hypertension (high blood pressure) in adults, which if untreated leads to lung collapse.

EY said companies took advantage of FDA's expedited review process for Breakthrough Therapy and got approvals faster. In fact, more than half the 25 drugs approved last year came through some of FDA's new fast track approval process.

Overall GSK was the table topper getting five new biotech drugs approved in 2013. These include Mekinist and Tafinlar, both anti-cancer drugs, Trivacy, an anti-HIV treatment method developed through Viiv Healthcare.
EY said biotech companies have played a key role in the approval of many other drugs such as cancer treatment Kadcyla which used an important technology from biotech company Immunogen. Prostate cancer medicine Xofigo by Bayer Healthcare was developed by biotech company Algeta. In fact Bayer bought Algeta for this drug.

Overall one-third of the 25 new drugs approved were to treat some forms of cancer.