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Editorial Open Access

2015 Pharmaceutical Industry Roundup

Prathap Nagaraja Shastri*

ADME/DMPK, Wil Research, 1407 George Road, Ashland, Ohio 44805, USA

***Corresponding author:** Prathap Nagaraja Shastri, ADME/DMPK, Wil Research, 1407 George Road, Ashland, Ohio 44805, USA, Tel: 404-259-4973; E-mail: Prathap.shastri@wilresearch.com

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Editorial

2015 was yet another dynamic year for Pharmaceuticals with the Pharma industry witnessing tremendous investment on drug development. The year saw 45 new molecular entity (NME) approvals from US FDA Centre for Drug Evaluation and Research (CDER), which is the highest number of approvals since 1996 [1]. NMEs are those products containing active moieties that have been never approved by FDA previously, either as a single ingredient drug or as a part of a combination product.

As identified by CDER, 16 of the 45 drugs were approved as First-in-Class, which are categorized based on the fact that the mechanism of action for these drugs is different from those of existing therapies [1]. Some of the noteworthy first-in-class products include Bridion, a product from Merck, used to the reversal of neuromuscular blockade induced by Rocuronium bromide and Vecuronium bromide in adults undergoing surgery [2]; Ibrance, marketed by Pfizer, used for the treatment of breast cancer [3]; and Praxbind, a product from Boehringer-ingelheim, used to reverse the action of anticoagulant Pradaxa in case of emergency situation [4]. Another key aspect to note is that 17 and of the novel drugs approved in 2015, were approved to treat rare or orphan disease that affect 200000 or fewer Americans [1].

Although the year saw highest number of drug approvals, only time has to tell how many of these drugs will make blockbluster gains and make a big difference to the pharma industry. Some of the big pharma players including Novartis, Pfizer, Amgen and Sanofi succeeded with interesting drug approvals with great potential. In particular, Entresto from Novartis is already coveted to become the next block buster drug based on its outstanding performance during the clinical trials. Entresto demonstrated significant reduction in the rate of cardiovascular death and hospitalizations among thousands of patients with a particular form of heart failure in a late-stage study, successfully treating a condition that afflicts some 5 million-plus Interestingly, the agency also approved Entresto 6 weeks ahead of their scheduled deadline, which further added to the buzz around it [5].

In addition to having the highest number of new drug approval, 2015 also saw the approval of first Biosimilar in USA [6]. Biosimilars is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Biologics, being complex in comparison to small molecule, are prone to degradation and modification due to small changes in manufacturing process. It is observed that even a well - defined production process to express protein in living organism and purify cannot avoid in - identical protein generation, which exemplify the challenges to prove similarity with totality of evidences. Although, biosimilars were approved several years ago in India, Europe, and other places in the world, there was no US FDA approved biosimilar until last year. US pharmaceutical market being one of the largest, had the pharmaceutical company waiting for number of years, who now are anticipating number of biosimilar approvals in the coming years. In March 2015, US FDA approved Zarxio, a Novartis - Sandoz product as a biosimilar with the same indication to Neupogen, an Amgen product. The decision to approval was made based on evidences to support similarity in terms of physical, chemical, biological, preclinical, pharmacokinetic, pharmacodynamic, clinical safety, and immunogenicity comparisons. However, Zarxio is not approved as an interchangeable or switchable which would have given an ultimate liberty to select between the candidates without specific prescription. So, the wait is still on to see if pharmaceutical industry take a step ahead and further invest in R&D to fulfil regulatory requirements for interchangeability.

Overall, 2015 yet again supported that there has been significant investment made in the field of biologics which is evident by the fact that biologics made larger share of the First-in-Class new molecular entity approvals. As the biologics market continues to grow, collaboration and acquisitions continue to play a major role in the industry, and pharmaceuticals are poised for another dynamic year looking ahead.

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