

Pharmaceutical companies increasingly looking to innovate high-risk, first-in-class products

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With the cost of bringing a single novel drug to market estimated to be \$2.6 billion in 2015, pharmaceutical companies are increasingly looking towards developing first-in-class treatments to maximize revenue and stay ahead of competition, according to business intelligence provider GBI Research.

The company's latest report states that the growth in drug research and development (R&D) costs appears to stem from an increased clinical failure rate and emphasis on proving superiority over comparator drugs in technology assessments, as well as an increasing level of sophistication from payers when assessing the cost-effectiveness of drugs.

Mr Dominic Trewartha, Managing Analyst for GBI Research, explains: "Due to the inherently limited life cycle of a patented drug and growing R&D costs as a percentage of net sales, the pharmaceutical industry has the highest R&D expenditure of all industries. As such, imperatives for pharmaceutical companies include reducing product development costs, maximizing the annual product revenue, and optimizing the life cycle of a drug, primarily by minimizing the impact of the entry of generics. Together, these factors favor the inclusion of first-in-class pipeline products within a balanced pipeline portfolio."

Higher-risk programs for innovative first-in-class products remain attractive and have led to some of the most clinically and commercially successful products over the past decade, and the 4,964 first-in-class products currently in development

represent 37.9% of pharmaceutical pipeline products with a disclosed molecular target.

Overall, 'me-too' drugs, which are structurally very similar to already-established drugs, have traditionally been highly commercially and clinically successful.

These products continue to provide a well-established pathway for promising product developments due to a lower risk profile based on safer and more cost-effective incremental innovation.

Dr Trewartha concludes, however: "Some of the most successful products of the previous ten years have been first-in-class therapies, including Avastin (bevacizumab), Rituxan (rituximab), Herceptin (trastuzumab) and Gleevec (imatinib). Additionally, when 2015 FDA approvals are analyzed, first-in-class products have far higher average projected sales than non-first-in-class products, indicating that this trend is set to continue in the future.

"GBI Research believes that despite the high risks involved in developing first-in-class products, pharmaceutical companies stand to earn high rewards through innovative development strategies."