Evaluate Vantage

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As FDA warns on delays, a big Novartis approval stalls – coincidence?

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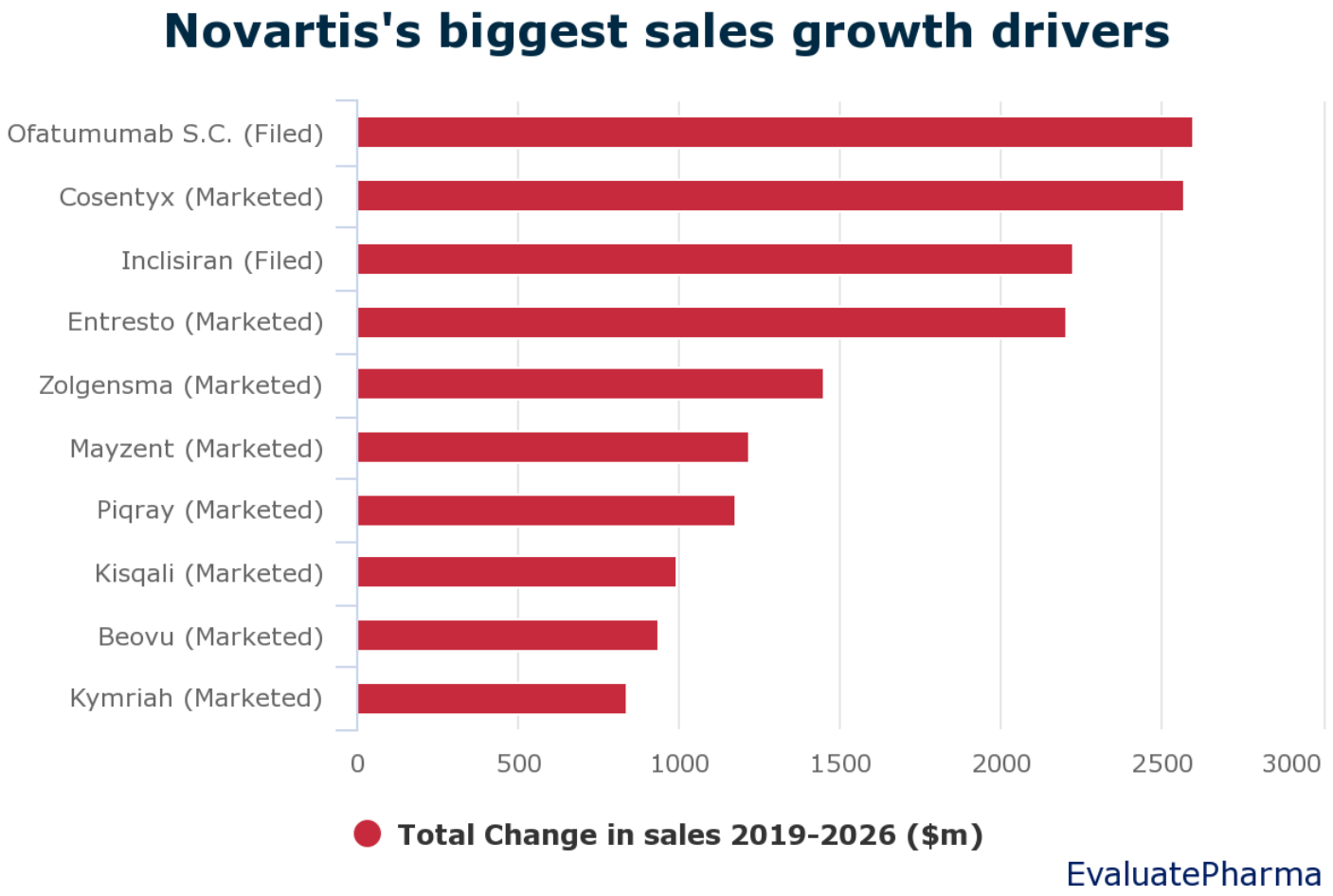
Approval of the repurposed cancer drug Arzerra (ofatumumab), which Novartis has flipped into multiple sclerosis, was slated as one of June's biggest FDA decisions. That verdict is now delayed to September, the Swiss pharma giant said this week, without providing a reason. Issues with the filing could be responsible; however, it is notable that the agency recently issued new guidance warning that PDUFA and BsUFA goals and timelines might be hit in the coming months. A considerable increase in Covid-19-related work has strained resources, which might have to be focused on applications relating to pandemic-specific treatments or other life-threatening conditions, the FDA said. It is pretty surprising that drug approvals have so far been unaffected, and investors should perhaps brace for delays in the coming months; though infections in the US do seem to be declining, it is clear that the situation in the country remains precarious. Whatever the reason for the ofatumumab delay Novartis will still hope for a green light later this year. The project, which has been reformulated for subcutaneous delivery, is pegged as the company's most important sales growth driver over the coming years, according to sellside consensus data from *EvaluatePharma*.



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