Evaluate Vantage

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Tanezumab pain only deepens for Pfizer and Lilly

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Given the strength of negativity directed at tanezumab by both the FDA and an advisory committee this week, it is remarkable that the sellside did not instantly write off the Pfizer and Lilly pain project. Not that many still harbour hopes for the antibody, of course, but huge need for novel pain mechanisms means that some expectations linger. SVB Leerink, for example, lowered tanezumab's chance of reaching the market from 65% to 35% after yesterday's panel, estimating that at least two more years of work could be needed to satisfy the safety-conscious regulator. Many might wonder how even that lower figure makes sense, but then it is equally perplexing that Pfizer and Lilly have pushed on for this long, ploughing billions into development for almost 20 years. The FDA's final verdict is now awaited, but anything other than a complete response letter would be a huge surprise. It is hard to see how the partners could justify any further investment in the project, thus the end of the road surely beckons. Regeneron's plans for fasinumab are also awaited, but having seen the response to tanezumab few could blame this company for raising a white flag.

The anti-NGF antibodies: a painful development path	
2006	Clinical development of the class begins
2010	FDA halts all clinical work on concern about rapidly progressing arthritis
2012	FDA adcom recommends clinical work to resume, with certain exclusions
2012	New clinical hold is placed on tanezumab, after peripheral nervous system effects are seen in animal studies
2013	Lilly opts in to tanezumab in 50:50 costs and profit share, paying $200m up front
2015	Tanezumab clinical hold finally lifted; developers resume phase 3 programmes
2016	J&J abandons fulranumab citing "strategic portfolio prioritisation"
2016	Teva opts in to Regeneron's fasinumab, paying $250m up front and $1bn in R&D support
2016	One month after Teva deal, fasinumab trial in lower back pain is halted after a case of joint damage
2018	Tanezumab phase 3 trials start to report
2020	Regeneron discontinues dosing after IDMC recommends terminating fasinumab; decision due in 2021
2021	FDA adcom votes 19-1 against a REMS proposed by Pfizer to support tanezumab's approval

A shrinking pipeline of anti-NGF antibodies			
Project	**Company**	**Status**	**2026e sales**
Tanezumab	Pfizer/Lilly	Mar 2021: US adcom votes 19-1 against a REMS proposed by Pfizer; PDUFA date unknown	$186m
Fasinumab	Regeneron/Teva	Pivotal programme completed in 2018 and long-term safety data being gathered; decision on filing due 2021	$84m
Fulranumab	Johnson & Johnson	Abandoned in ph3 in 2016	-
ABT-110	Abbvie	Abandoned in ph1 in 2013	-
ASP6294	Astellas Pharma	Assumed abandoned in ph2 in 2020, no ongoing trials	-
MEDI-578	Astrazeneca	Abandoned in ph1 in 2012	-
Source: Evaluate Pharma.			

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