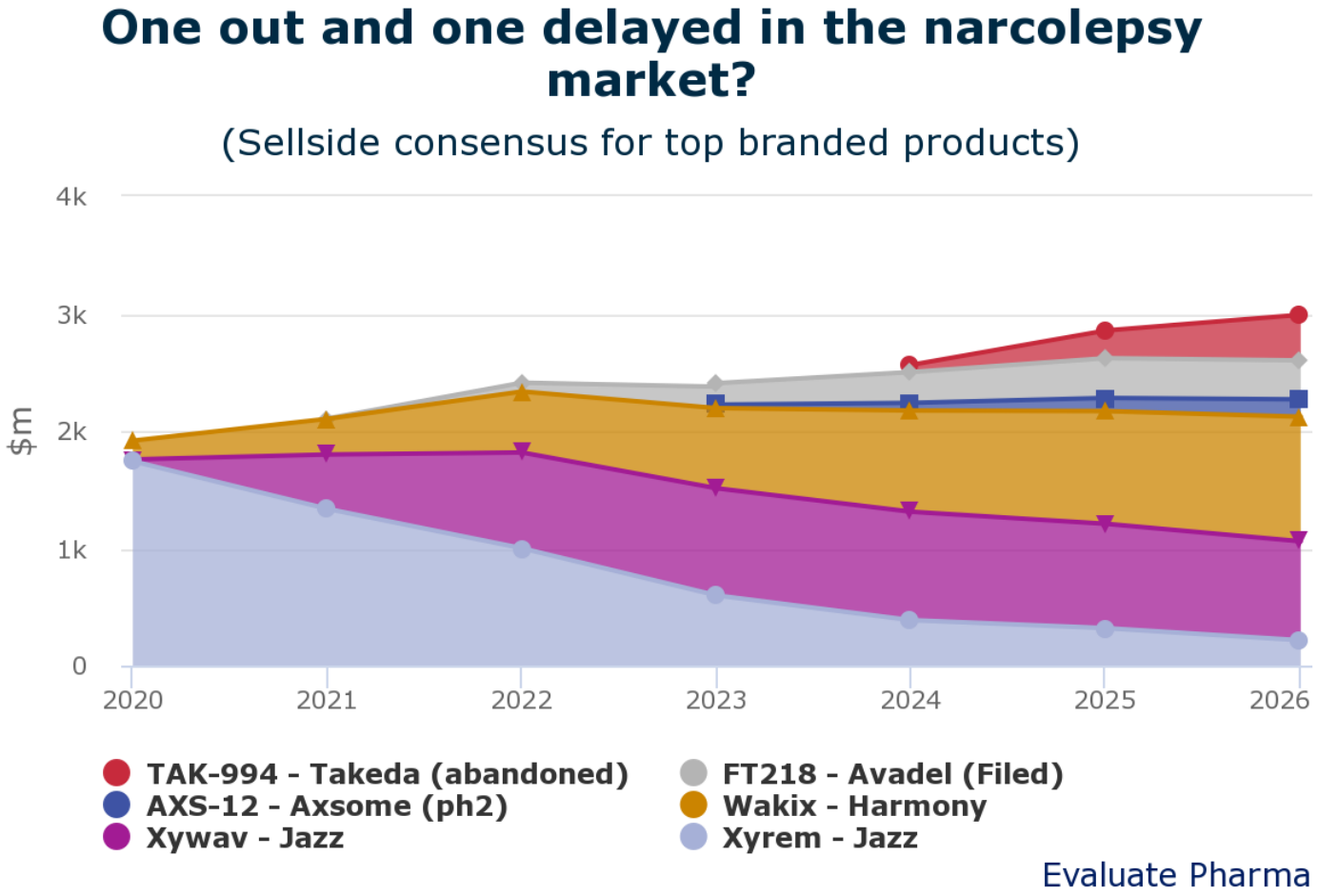
Evaluate Vantage

October 18, 2021

Avadel delay hands Jazz another narcolepsy boost

Amy Brown

A delay to the FDA's decision on Avadel's narcolepsy project, FT218, allows Jazz investors a second bout of schadenfreude in as many weeks. The once-a-night pill could become a big competitor to Jazz's twice-a-night Xyrem/Xyway franchise; the news follows the exit of another potential rival, Takeda's TAK-994, recently abandoned on safety concerns. When the FDA's verdict on FT218, which had a Pdufa date of October 15, might emerge is unclear. Avadel insists the regulator made no new information requests, saying only that action was unlikely in October. A short delay due to a lack of resources at the agency would be the best case scenario. However, the FDA could be mulling more serious issues, Stifel analysts mooted: firstly that Avadel might need to go down the generic filing route – Xyrem/Xyway and FT218 contain the same active ingredient – a scenario that would lead to a 30-month stay to approval. Or perhaps the agency is considering whether FT218 really deserves orphan drug exclusivity, which is largely based on its dosage advantage. A 15% drop in Avadel's stock this morning suggests investors are cautiously optimistic that the delay will be short. The outlook for the narcolepsy market, below, shows what is in play.



Evaluate Americas
+1-617-573-9450

Evaluate APAC
+81-(0)80-1164-4754