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Amylyx rebuff sees Europe regulators diverge from the US

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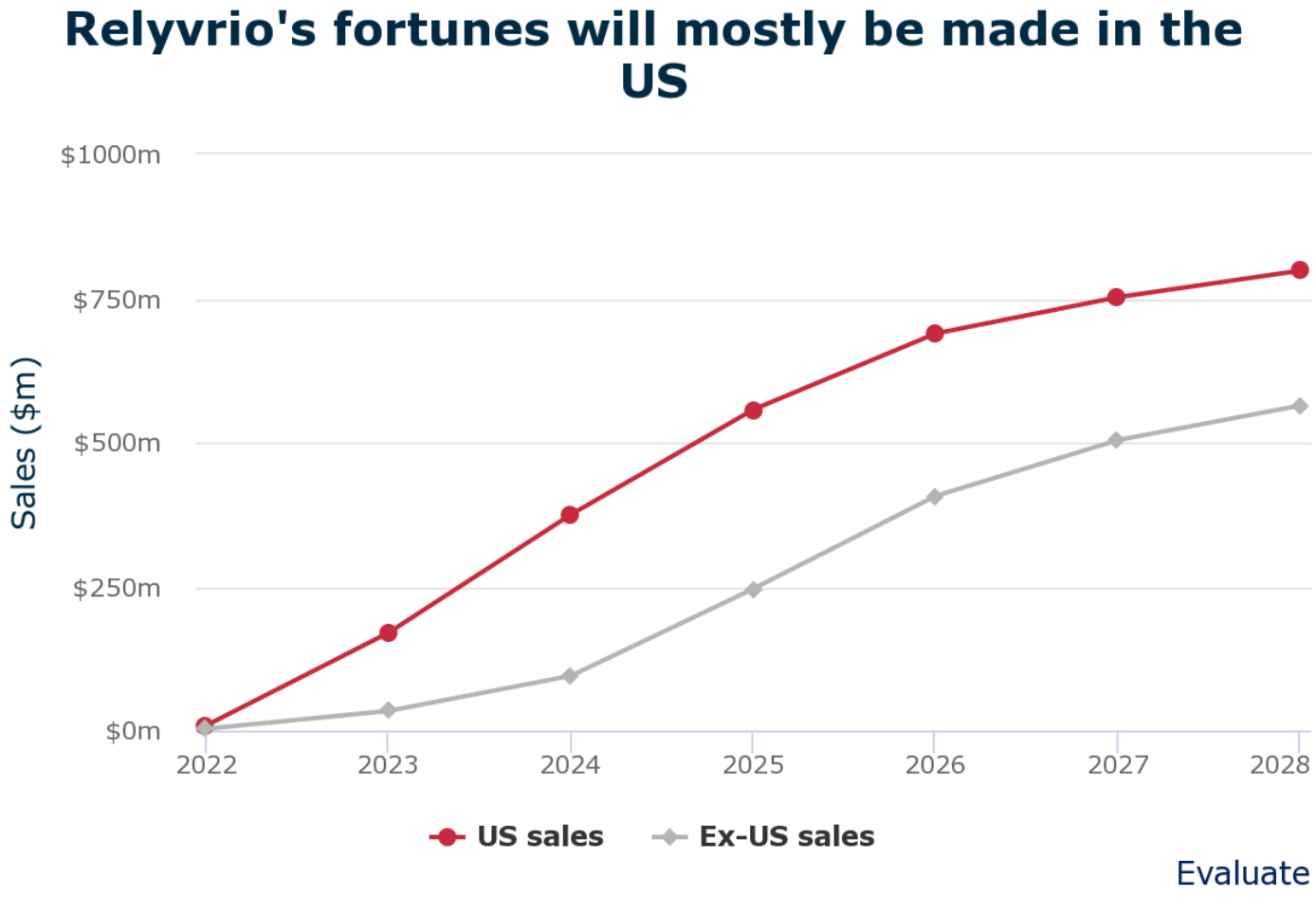
Amylyx's amyotrophic lateral sclerosis drug Relyvrio took a controversial route to the US market with an FDA green light coming after two panels, one negative and the other positive. European regulators remain unconvinced, however, with the EMA today recommending that the drug, EU-branded Albrioza, be rejected. Last month Amylyx was warned that the CHMP was trending negative, and in today's decision the EMA cited concerns that Albrioza did not convincingly slow disease progression. Neither were data on survival reliable, given the way they were collected and analysed. Amylyx has already pledged to appeal, so this is not the end of the road in Europe, though the region is not seen as commercially important. This is a rare example, outside oncology at least, of the EMA taking a harder line than its US counterpart, while the opposite has been seen many times before, with Fibrogen's roxadustat being a recent case in point. Interestingly, it was another contentious neurology agent – Biogen's Aduhelm – that the EMA also refused to approve despite the FDA's leniency; critics of the US agency's neurology division take note. Other cases involve more restrictive labels for some cancer checkpoint inhibitors in Europe.



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