Evaluate Vantage

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Novartis’s Paragon perseverance pays off – perhaps

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Two years ago Novartis’s decision to push on with Entresto in heart failure with preserved ejection fraction (HFpEF) looked questionable: the product had just failed, albeit narrowly, in the Paragon trial. But US approval now looks within reach after an advisory committee voted 12-1 yesterday that the available data support the use of Entresto in HFpEF. However, a broad HFpEF label looks unlikely, with the panellists more convinced of Entresto's efficacy in an intermediate ejection fraction population. Entresto is already marketed for heart failure with reduced ejection fraction, defined as <40%. Paragon enrolled patients with an ejection fraction of 45% or higher, but the benefit was most pronounced in those with an ejection fraction below 57%. However, the panellists did not agree on any potential new cut-off, leaving the ball in the FDA's court. The agency is set to decide in the first quarter of next year. *EvaluatePharma* sellside consensus puts 2026 Entresto sales at $4bn; Jefferies analysts reckon HFpEF could add another $1bn at peak, although this surely depends on the breadth of any new label. And HFpEF data are coming soon with the SGLT2 inhibitors, so Entresto might not have this market to itself for long.