

Horizon eyes 2020 approval for Grave's orbitopathy



[Elizabeth Cairns](#)

Horizon's Grave's orbitopathy antibody HZN-001 (teprotumumab) is so effective that doctors would be afraid not to offer it, Stifel analysts wrote yesterday after it hit in its [phase III trial, Optic](#). That might be hyperbole, but the trial hit is real enough, with 82.9% of HZN-001 patients seeing a reduction of 2mm or more in proptosis – eye bulging – at six months, versus 9.5% on placebo ($p < 0.001$). Safety was clean, with three of the 83 patients in the trial having serious adverse events; only one of these, an infusion reaction that led to discontinuation, was drug-related. A BLA filing is pencilled in for mid-2019. If teprotumumab is approved Stifel analysts claim that sales in excess of \$750m are achievable, which would represent a vote of confidence in Horizon's business development nous: it got teprotumumab through the [\\$145m acquisition of River Vision Development](#). There is little else to challenge Horizon's product: its closest competitor, Novartis and Xoma's CFZ533, was in [a phase II trial](#) in Grave's disease, but the completion date for the study was April 2017 and nothing has been heard since. Horizon's stock closed up 33% yesterday.

Quiet as: the Grave's disease pipeline

| Status | Project | Company | Mechanism of action | 2024e sales (\$m) |
|-----------|-----------|-----------------------|-------------------------|-------------------|
| Phase III | HZN-001 | Horizon Pharma | IGF-1R antibody | 81 |
| Phase II | CFZ533 | Xoma/Novartis | TNFRSF5 antibody | 2 |
| Phase I | K1-70 | AV7 | TSH receptor antagonist | - |
| Phase I | ATX-GD-59 | Apitope International | Thyrotropin stimulant | - |

Source: EvaluatePharma.

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