

Doubts grow around Omeros's kidney disease contender



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There are not many projects in development for IgA nephropathy, a serious kidney disease, and a look at the pipeline seems to show Omeros and OMS721 out in front. The company started a pivotal study earlier this year, putting it slightly ahead of a Swedish competitor, Calliditas, which is poised to start recruiting into a phase III trial with its candidate, Nefecon. However, phase II data from Omeros yesterday suggest that this apparent lead might not count for much. The study recruited 12 patients, nine of whom were randomised; no benefit was seen for OMS721 over placebo after 12 weeks, with the change in proteinuria similar between groups. Eight patients entered an extension phase and did start to see a benefit, but this was not enough to prevent a 43% crash in Omeros shares yesterday, knocking \$507m off the company's valuation. The Seattle biotech pushed into phase III on the back of IgA data in only four patients in whom impressive response rates were seen, but the new dataset adds further doubt to the reliability of that signal. Omeros has long attracted detractors, with a lack of transparency at the root of most criticisms; it is getting even harder to consider OMS721 a real IgA nephropathy contender.

Leading IgA nephropathy projects

Project	Sponsors	Trial ID (enrolment)	Notes
<i>Phase 3</i>			
OMS721	Omeros	NCT03608033 (430)	Data due 2020
Nefecon	Calliditas	NCT03643965 (450)	Trial to start enrolling imminently; data 2020.
<i>Phase 2</i>			
Bardoxolone	Reata	NCT03366337 (100)	Positive PII data reported Sep 2018, further development planned
APL-2	Apellis	NCT03453619 (48)	Phase II POC data due H2 2018
Tavalisse	Rigel	NCT02112838 (75)	Update on pivotal programme expected imminently
LNP023	Novartis	NCT03373461 (48)	Primary completion data Apr 2019
Atacicept	Merck KGaA	NCT02808429 (30)	Primary completion date Jun 2021

Source: EvaluatePharma, company statements, clinicaltrials.gov.

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