Evaluate Vantage

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Momenta confirms its place in FcRn race

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A successful mid-stage read out from Momenta's anti-FcRn project, nipocalimab, confirms that the project is a viable competitor in this closely watched novel mechanism. The Vivacity-MG study compared four different dosing schedules of the antibody against placebo in patients with advanced myasthenia gravis (MG), an IgG-driven autoimmune condition. The primary efficacy endpoint was change on a symptom scale called MG-ADL, and when pooled across the arms the placebo-adjusted response rate came out remarkably close to that achieved by Argenx last month with its leading anti-FcRn project, efgartigimod: 36.5% vs 40% respectively. Safety also looked clean, reassuring given some signals seen in phase I; Momenta shares jumped 15% on the news. Seeking a competitive edge the company hopes to take monthly or longer dosing into phase III trials, which are slated to start later this year. Subcutaneous delivery remains the real goal, however, and both Argenx and Momenta are working on switching to SC from their current IV formulations. One wild card here is Immunovant, which is gearing up to release phase IIa data on its SC project, IMVT-1401, in the coming months.

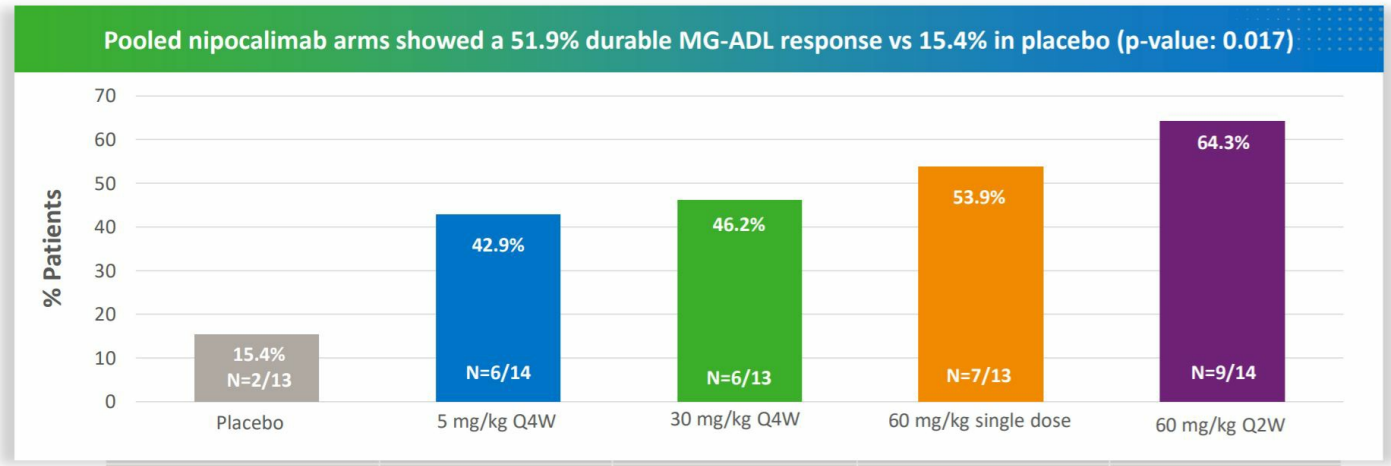
FcRn targeted projects: the progress so far

Project	Pharmacology	Company	Next steps
Efgartigimod	Anti-FcRn Ab fragment; IV and SC in earlier development	Argenx	US filing due by year end
Rozanolixizumab	Anti-FcRn MAb; SC	UCB	Phase III readout expected H1 2021
Nipocalimab	Anti-FcRn MAb; IV and SC in earlier development	Momenta	Phase II MG trial positive, phase III to start by YE'20
IMVT-1401	Anti-FcRn MAb; SC	Immunovant/ Hanall Biopharma/ Harbour Biomed	Phase IIa in MG read-out Q3'20; thyroid eye disease over next 12 mth
ALXN1830	Anti-FcRn MAb; IV and SC in earlier development	Alexion (Syntimmune)	Paused owing to Covid-19, to restart 2021, SC formulation prioritised
ABY-039	Anti-FcRn bivalent Ab mimetic; SC	Affibody	Alexion handed back rights in Feb 2020; phase I ongoing

Source: EvaluatePharma, company statements.

Vivacity-MG phase II trial

Durable MG-ADL Responses at All Doses



Difference vs Placebo:	27.5%	30.8%	38.5%	48.9%
p-value:	0.1044	0.1008	0.0484	0.0092

Durable response is defined as improvement in MG-ADL >= 2 points for at least 4 consecutive weeks during the 1st 8 weeks; p-values are one sided

Momenta