

Alexion adds to rare disease pipeline



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Projects targeting the neonatal Fc receptor (FcRn) are already attracting much attention: Argenx's efgartigimod, which only recently moved into phase III, has already attracted [blockbuster sales forecasts](#). So Alexion's swoop on Syntimmune today, for \$400m up front, could yet be seen as a bargain; the private biotech's anti-FcRn antibody SYNT001 is one of the few assets in the class in clinical trials. Aggressive clinical plans for the project were unveiled: even though a phase Ia/Ib trial has yet to be completed, pivotal studies in warm autoimmune haemolytic anaemia (WAIHA) and another as-yet-undisclosed indication will commence next year. In terms of the competition, executives pointed to SYNT001's fast onset of action and what could be a lower potential for immunogenicity than other agents in development. Many of the illnesses being pursued by developers of anti-FcRn agents are chronic, so confirmation of long-term safety and tolerability remains crucial. However, the mechanism could plausibly revolutionise the treatment of a broad range of IgG-mediated autoimmune conditions, so the enthusiasm here is understandable. As owners of the only unencumbered clinical stage assets – assuming Argenx is intent on going it alone – Momenta and Affibody could well start to attract more interest.

The FcRn pipeline

Project	Pharmacology class	Company	Notes
Phase III			
ARGX-113 (efgartigimod)	Anti-FcRn antibody fragment	Argenx	Plans to initiate phase III trials in second indication, ITP
Phase II			
Rozanolixizumab	Anti-FcRn MAb	UCB	Final phase II results expected at Ash in Dec 2017
Synt001	Anti-FcRn MAb	Syntimmune	Company bought by Alexion for \$400m up front in Sep 2018, primarily for Synt001
Phase I			
M281	Anti-FcRn MAb	Momenta	Plans to initiate phase II trials in Q4 2018
ABY-039	Anti-FcRn antagonist (antibody mimetic)	Affibody	P1 proof of principle study started in Mar 2018
RVT-1401/HL161	Anti-FcRn MAb	Immunovant/Hanall	Licensed from Hanall in Dec 2017 for \$30m up front in deal worth up to \$503m

Source: EvaluatePharma.

