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Argenx accelerates despite burying its own good news

Amy Brown

On Monday Argenx managed to scoop its own presentation of encouraging early data in acute myeloid leukaemia at the Ash conference with a hit with a novel myasthenia gravis candidate – a questionable communications strategy for a Belgian company flying relatively low under the radar.

Fortunately investors still took notice – the Euronext and Nasdaq-listed company has more than doubled in value so far this week, to €1.2bn ($1.4bn). Even the immediate launch of a $150m sale of its ADSs has not halted its share price surge, and hopes are building ahead of further data in the coming months.

Most hotly anticipated are further updates on ARGX-113, the candidate that yielded such encouraging results in myasthenia gravis (MG). The neonatal Fc receptor (FcRn) protects pathogenic immunoglobulin G antibodies (IgG) by rescuing them from lysosomal degradation. ARGX-113, an antibody fragment, binds to FcRn and inhibits this process. IgG drives several autoimmune diseases such as MG, immune thrombocytopenia and pemphigus vulgaris.

The data unveiled on Monday showed that this mechanism of action produced dramatic clinical responses – 75% of patients had statistically significant improvements on MG-ADL scores, a measure of MG symptoms, over placebo. Responses were seen one week after the first infusion and the duration of responses was surprising, Argenx's chief executive Tim Van Hauwermeiren said on a conference call. No serious safety or tolerability issues were raised.

Top-line results in immune thrombocytopenia and interim data in pemphigus vulgaris are due around the middle of next year.

Competition

Argenx is not alone is this field – only a few months ago Alexion won approval for Soliris in MG, although it is restricted to a small subset of patients who are anti-acetylcholine receptor antibody-positive, about 5-10% of patients.

And UCB has perhaps a more direct competitor with rozanolixizumab, a monoclonal antibody against FcRn. The company presented interim data from a phase II immune thrombocytopenia trial at Ash which Mr Van Hauwermeiren brushed off, saying data revealed some dose-limiting toxicities.

"While data are still emerging, we believe we have a compound with a unique PK/PD profile when it comes to its interaction with FcRn, as compared to high affinity, multivalent, interacting monoclonal antibodies like we see from UCB," he told analysts and investors on the call.

Still, UCB has more comparable data in MG patients due next year, and also importantly Argenx has yet to disclose the exact extent to which ARGX-113 removed circulating IgG. A 30-60% reduction can put patients into remission, Mr Van Hauwermeiren said, pointing out that plasma exchange – which typically takes five days of continual transfusion – induces a reduction of around 80%.

And another thing…

With MG patients sorely in need of new treatments and in the rare disease sweet spot, it is perhaps not surprising that these data overshadowed the company's Ash presentation of ARGX-110 in AML. However these were also highly encouraging, showing intriguing signs of efficacy with a novel mechanism of action.

The monoclonal antibody targets the ligand CD70 and its receptor CD27 on leukaemic stem cells, which are responsible for disease relapse in AML. At Ash Argenx presented results from an ongoing proof-of-concept study – of six evaluable patients all responded, including three with complete remissions, one of whom went on to have a successful stem cell transplant.

The company admits there is still a long way to go with this project – the correct dose still needs to be ascertained before a larger study can be initiated. But with safety seemingly manageable, the possibility of exploring combinations remains on the table, important in this cancer type.

But it is clear that Argenx has had a good week – it is notable that ARGX-110 and '113 are two of three wholly-owned assets in its clinical stage pipeline. And in one busy day, the company convinced investors that both deserved to be re-valued.

To contact the writer of this story email Amy Brown in London at AmyB@epvantage.com or follow @ByAmyBrown on Twitter.