Allergy Therapeutics

Positive top line G309 results for Grass MATA MPL

25 October 2021

- Allergy Therapeutics has reported highly encouraging top line data from its G309 exploratory field trial of Grass MATA MPL. Both treatment arms demonstrated statistically significant improvement over placebo on the primary endpoint, the combined symptom and medication score (CSMS). The six-week arm showed a 29.1% improvement (p=0.0367), with this rising to 36.8% (p=0.0088) in the 14-week arm. These represent a significant reduction in both daily symptoms and the use of relief medication. Both dosing regimens were shown to be safe and well tolerated. Additionally, European and US study centre data were comparable. Analysis of secondary endpoints, including quality of life measures and allergy biomarkers, is yet to be completed. Full G309 results will be presented at a future conference.
- G309 is an innovative double-blind, placebo controlled, randomised study that evaluated the efficacy and safety of an optimized Phase III dose of 27,600 SU Grass MATA MPL. Two short courses of six injections with treatment durations of six and 14 weeks were tested. The trial ran for one year, over the 2020/21 allergy season, and recruited c 150 patients over 12 sites in Germany and the US.
- The G309 results will help inform and optimise the design of the pivotal Phase III study (G306), which is the key step for FDA filing and potential approval in the US. G306 will also be run in Europe and the US, and is planned to start in H222, capturing the 2022/23 allergy season. It is expected to involve 900-1,200 patients and more than 100 trial sites.
- The Grass MATA MPL development programme is a key element in Allergy Therapeutics medium-term strategy. These trials, assuming the positive G309 results are replicated in G306, are set to demonstrate the clinical benefits of Pollinex Quattro (PQ) ultra-short courses. In Europe, the PQ range is currently only available on a "named patient" basis; regulatory approval would remove marketing restrictions allowing promotion of the clinical benefits to the medical community. In the US, an FDA approval would make it the first short course, subcutaneous and aluminium-free allergy immunotherapy available in the US.

Price	33.5p
Market Cap	£215.0m
Primary exchange	AIM
Sector	Healthcare
Company Code	AGY
Corporate client	Yes

Company description:

Allergy Therapeutics specialises in the diagnosis and treatment of allergy. The existing European business generates c £80m annual sales. Near-term R&D efforts are focussed on the Pollinex Quattro platform, whilst in the medium-term the VLP platform is highly promising.

Trinity Delta view: The positive top line results of the Grass MATA MPL G309 exploratory field study represent a major de-risking of the planned G306 pivotal trial. In turn, we view the G306 results as the gatekeeper to Allergy Therapeutics medium-term prospects, as subsequent regulatory filings and potential approvals will underpin Europe growth expectations and allow entry into the commercially significant US market. G309 results complement recent encouraging data from the VLP Peanut preclinical programme. Continued progress with both the VLP Peanut and Grass MATA MPL programmes will clearly unlock further valuation upside. We currently value Allergy Therapeutics at £350.7m, or 54.7p per share. Net of cash, the existing commercial business contributes £91.1m (14.2p/share) and the R&D pipeline £222.8m (34.7p/share).

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