Allergy Therapeutics

G309 exploratory grass trial on course for H221 read-out

6 May 2021

- Allergy Therapeutics has announced the completion of the treatment period for all patients in the G309 exploratory field study of Grass MATA MPL. This has been achieved despite the myriad COVID-19 restrictions and challenges in performing such a study in both Europe and the US. The lack of delay means the data readout remains on track for H221.
- Grass MATA MPL is a short course, aluminium-free, allergen-specific, subcutaneous immunotherapy (SCIT), in seasonal allergic rhinitis and/or rhinoconjunctivitis induced by grass pollen. The commercial importance of the timelines being maintained is high as the ultra-short Pollinex Quattro SCIT platform underpins future growth prospects in Europe and will enable entry into the commercially important US market.
- G309 is a double-blind, placebo controlled, randomised study designed to evaluate the efficacy and safety of an optimized Phase III dose of 27,600 SU Grass MATA MPL. The trial will run for one year, capturing the 2020/21 allergy season, and has recruited c 150 patients over 12 sites in Germany and the US. The primary endpoint is the combined symptom medication score (CSMS) averaged over the peak grass pollen season.
- Data from G309 will help inform and optimise the design of the pivotal Phase III study (G306), required for FDA filing and potential US approval. G306 will also be run in Europe and the US, and is expected to start in H222, over the 2022/23 allergy season. Had there been any delay to G309, there would have been knock-on effects, with the start of G306 potentially being delayed beyond its patient recruitment window.
- G306 is expected to recruit 900-1200 patients over more than 100 trial sites. A successful outcome will support registration of Grass MATA MPL under the TAV (Therapy Allergy Ordinance) process in Germany, and hence over time across Europe, and should pave the way for registration via a Biological License Application (BLA) in the USA.

Trinity Delta view: The successful completion of the treatment period for Allergy Therapeutics' G309 Grass MATA MPL trial and continued expectation of H221 top-line results means that the timeline for the G306 pivotal trial remains intact. It is the G306 study that will support European and, importantly, US approvals. In Europe this approval will broaden prescribing beyond 'named patient' basis; in the US, Grass MATA MPL will likely become the first short-course, subcutaneous, and aluminium-free grass allergy therapy available. We value Allergy Therapeutics at £344.5m (53.8p/share), based on sum of the parts including a DCF of the commercial operations (£89.7m or 14.0p/share), an rNPV of the R&D pipeline (£210.3m, or 32.8p/share), and net cash.

Price	21.5p
Market Cap	£137.8m
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.

Analysts

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