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Physician Views: Can GlaxoSmithKline strike early with Anoro? / What role will dosing, inhaler type play in uptake of LAMA/LABA combinations for COPD?

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Abstracts

This year looks set to be one of notable evolution for the US chronic obstructive pulmonary disease (COPD) market and GlaxoSmithKline's respiratory franchise in particular.

The company secured FDA approval for its once-daily LABA/ICS therapy Breo Ellipta in May and its proposed once-daily LAMA/LABA combination Anoro Ellipta has been set a PDUFA date of December 18. Before securing an early Christmas present, however, GlaxoSmithKline will have to negotiate an advisory committee meeting next month (September 10).

With progression of Novartis' QVA149 delayed in the US, Anoro is poised to be the first LAMA/LABA combination to reach the market in the country, although a number of key questions await GlaxoSmithKline at September's AdCom.

Most pertinently, suggested analysts at JP Morgan last week, could be the AdCom's view towards the dosing profile of Anoro. JP Morgan analyst James Gordon postulates that based on "noisy dose response data," the panel could question whether the optimal dose and dosing frequency for the umeclidinium LABA component has been identified. Furthermore, could the panel recommend that twice-daily dosing may be better?

Such an outcome would seemingly have significant commercial implications, given that the race to bring LABA/LAMA combinations to market is notably focused on once-daily products. Not so, argues Pearl Therapeutics CEO Charles Bramlage, who recently told FirstWord that he believes significant commercial opportunity exists for a twice-daily LAMA/LABA combination, given the risk that the efficacy of a once-daily product will

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wane over a 24-hour period (see In Focus: Can Pearl Therapeutics support AstraZeneca's late dash in the respiratory market? - FirstWord speaks to CEO Charles Bramlage).

AstraZeneca is banking on Bramlage being right. The UK drugmaker recently acquired Pearl for a potential cost of up to $1 billion; a move that is designed to accelerate its own efforts to expand its respiratory portfolio. AstraZeneca and Pearl's PT003 is expected to reach the market by around 2016, potentially some time behind competing LAMA/LABA combinations.

A key differentiator for PT003 – despite its later market entry and confirmed twice-daily dosing – will be the inhaler device, noted AstraZeneca CEO Pascal Soriot at the beginning of the month when the company announced its Q2 results. PT003 will be delivered in a pressured metered dose inhaler (pMDI) instead of a dry powder inhaler (DPI), the type of device being used by other LAMA/LABA developers. A pMDI inhaler could offer an ease-of-use/convenience advantage, particularly in older or frail COPD patients, note analysts at JP Morgan.

Combined with a porous particle formulation technology, Pearl is confident that PT003 will deliver the necessary efficacy at lower doses, a potential advantage suited to the pMDI approach (management has previously suggested the challenge in delivering a small dose via a DPI as the drug is not always uniformly dispersed).

This week's FirstWord Physician Views poll will ask:

> To what percentage of COPD patients they currently prescribe both a LABA monotherapy and a LAMA monotherapy?
>
> What percentage of patients currently receiving a LABA therapy would they expect to switch to a combination LABA/LAMA product two years after the first product of this type gains approval?
>
> What percentage of patients currently receiving a LABA/ICS therapy they would anticipate switching to a combination LABA/LAMA product?
>
> To what percentage of COPD patients they would favour prescribing a twice-daily therapy for fear that a once-daily treatment would have a diminished effect later in the day?

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In what percentage of patients being prescribed a LABA/LAMA combination therapy they would prefer to prescribe a pMDI instead of a DPI?

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