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Speedy EU Assessment On Cards For AZ's Durvalumab

by Maureen Kenny

AstraZeneca is hoping that when it files for approval in the EU of its PD-L1 blocker, *Imfinzi* (durvalumab), for Stage III lung cancer, it will be given accelerated assessment on the back of the PACIFIC data.

AstraZeneca will find out this week whether its key immuno-oncology drug, *Imfinzi* (durvalumab), will be granted speedy assessment in the EU for the treatment of Stage III lung cancer.

The European Medicines Agency's drug evaluation committee, the CHMP, will consider at its July meeting which is taking place this week the company's request for accelerated assessment of durvalumab for the treatment of patients with locally advanced, unresectable Stage III non-small cell lung carcinoma (NSCLC) whose disease has not progressed following platinum-based chemoradiation therapy.

AstraZeneca UK Ltd. has not yet filed for approval – the EMA advises companies to submit their requests for accelerated assessment two to three months before they submit their marketing authorization application – but it seems the company is moving quickly to capitalize on the early and positive results that it reported in May from its Phase III PACIFIC study of durvalumab – the newest PD-L1 blocker on the market – in Stage III lung cancer.

In terms of near-term direct competition, there is nothing in this space. It therefore seems likely speedy approval will be granted. This would mean the assessment timetable for durvalumab being reduced from 210 to 150 days. This mechanism is used for medicines that are of major interest for public health or can be considered a therapeutic innovation.

AstraZeneca's Imfinzi Steals March Into Untapped IO Lung Cancer Territory

By Alex Shimmings

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AstraZeneca said at the time of the PACIFIC results that it would work with regulatory agencies to make Imfinzi available quickly to unresectable Stage III lung cancer patients. Analysts have suggested that PACIFIC's success could bring an extra $1.7bn in sales for the product.

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While most eyes were on AstraZeneca's keenly awaited MYSTIC lung cancer study of Imfinzi, its PACIFIC trial has ducked under the radar and hit investors with the nicest kind of surprise. The results could have wider implications for IO in earlier-stage cancers.

Read the full article here

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AstraZeneca received its first approval for Imfinzi in May – in the US under the Food and Drug Administration's accelerated approval pathway for the treatment of advanced bladder cancer. Imfinzi, which the company describes at the "cornerstone of our extensive immuno-oncology programme", is in development across many tumor types, as monotherapy and in combination.

Roche's Tecentriq up for approval recommendation

The CHMP's July *meeting* started on Monday and runs until Thursday. Among many other things, the committee is expected to decide whether a dozen or so new medicines that are in the final stages of the evaluation process should be approved for marketing across the EU.

Roche is among the companies hoping for good news. It is looking to secure a positive opinion for its own anti-PD-L1 cancer immunotherapy, *Tecentriq* (atezolizumab), for the treatment of locally advanced or metastatic urothelial carcinoma (bladder cancer) and for the treatment of Stage IV NSCLC. However, the company was recently left disappointed by the failure of a confirmatory Phase III trial IMVigor211 in second-line advanced/metastatic urothelial cancer which has cast a cloud over its prospects in this indication. (Also see "*Bladder Cancer Market Wide Open As Tecentriq Fails Confirmatory 2L Trial*" - Scrip, 10 May, 2017.)