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Physician Views: Oncologist reaction to Roche's Gazyva – US approval and new late-stage data versus Rituxan

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Abstracts

Roche’s efforts to enhance its dominance of the haematological cancer market received notable momentum last week when the company gained FDA approval for Gazyva as a first-line treatment for chronic lymphocytic leukemia (CLL) - see ViewPoints: Roche ticks another box in biosimilar defence/cancer domination strategy as FDA approves 'son of Rituxan' Gazyva.

In addition to this regulatory milestone – which occurred some 7 weeks earlier than expected – abstracts released ahead of next month’s American Society of Hematology (ASH) meeting demonstrated significant superiority for Gazyva over Roche’s Rituxan in front-line CLL patients.

Analysts at Goldman Sachs commented that although positive data from stage 2 of the CLL11 study was anticipated, the “magnitude of improvement re-affirms Gazyva as a superior therapy in CLL, which could significantly improve the current standard of care”. Progression free survival in the Gazyva arm was 26.7 months versus 15.2 months in the Rituxan arm, while Gazyva also demonstrated a higher complete response rate (21 percent versus 7 percent) and a notably higher minimal residual disease rate of 29.4 percent (versus 2.5 percent); the latter being a surrogate endpoint that Roche was keen to discuss at its recent R&D open day.

Gazyva has become the first product to demonstrate superiority to Rituxan in blood cancer, thus approval sets a very high bar for competitors note analysts. Following the launches of Perjeta and Kadcyla (designed to enhance and ultimately displace Roche’s Herceptin for the treatment of HER2 positive breast cancer), this first approval for Gazyva sets in motion the initial stages of a similar strategy for the Rituxan franchise.

CLL accounts for approximately 20 percent of Rituxan revenues and additional late stage studies for Gazyva are ongoing.

This week's FirstWord Physician Views poll aims to gauge initial oncologist reaction to the data for, and approval of, Gazyva and ascertain how quickly uptake will occur in the first-line CLL setting. Specifically oncologists based in the US and EU5 will be asked:

> What percentage of chronic lymphocytic leukemia (CLL) patients do you initially treat with Rituxan/MabThera (rituximab) and fludarabine and cyclophosphamide (FC)?
>
> Based on available clinical data, what percentage of first-line CLL patients would you anticipate treating with Roche's Gazyva (obinutuzumab) and chlorambucil six months after launch?
>
> What factor would most likely cause you to prescribe Rituxan/MabThera in favour of Gazyva for initial treatment of CLL patients?
>
> How comfortable would you be 'extrapolating' usage of Gazyva into combination with other, more potent, chemotherapies such as FC, prior to the publication of additional clinical data?
>
> In your opinion what would be the key driver of use for an approved biosimilar version of rituximab over branded Rituxan and Gazyva?

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