Evaluate Vantage

September 13, 2019

Sakura blossoms for Roche, setting up Soliris battle

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A phase III win for Roche’s satralizumab has added to Alexion’s Soliris woes.

Last week Alexion’s attempt to extend the life of its bestseller Soliris came to nothing when the European Patent Office rejected its applications for pharmaceutical composition and composition of matter patents.

Now the decent data Roche’s anti-IL-6 biological satralizumab has posted in the autoimmune condition neuromyelitis optica might position it as a potential competitor to Soliris. This disorder is only forecast to be the fourth most lucrative of Soliris’s indications, but with the latter unable to fend off approaching biosimilars satra’s success is not what Alexion needed.

Data from the SakuraStar trial, which pit satralizumab as monotherapy against placebo in 95 patients with neuromyelitis optica spectrum disorder, were presented yesterday at Ectrims. The disease causes severe, immune-mediated demyelination and axonal damage of the optic nerves and spinal cord, and can lead to blindness or paralysis.

Star dreck

In SakuraStar, 120mg of satra, administered subcutaneously every two weeks for three doses followed by monthly injections thereafter, caused a statistically significant 55% reduction in relapse risk compared with placebo.

In the two-thirds of trial patients seropositive for aquaporin 4 (AQP4)-IgG antibodies – patients who tend to have more severe disease – the effect was greater, with a 74% reduction relapse risk versus placebo; again this was significant.

The data are good, but arguably not as good as the results from the Prevent trial, on the strength of which Soliris, a complement component 5 inhibitor, was approved in the same disease. In this trial, which only enrolled patients with AQP4-IgG antibodies, the relapse risk was reduced by 94% versus placebo.

The data are summarised below, though a comparison of two different trials is indicative at best. It should be noted that around three quarters of patients in Alexion’s trial were receiving background immunosuppressants, unlike those in SakuraStar.

Satralizumab versus Soliris in neuromyelitis optica spectrum disorder						
	SakuraStar				Prevent	
	All subjects		AQP4-positive		AQP4-positive	
	Satralizumab	Placebo	Satralizumab	Placebo	Soliris	Placebo
% reduction in risk of relapse vs placebo	55		74		94	
% relapse-free at wk 48	76	62	83	55	98	63
% relapse-free at wk 96	72	51	76	41	-	-
% relapse-free at wk 144	-	-	-	-	96	45
AQP4: Aquaporin 4 antibody. Source: company releases.						

With Soliris looking more effective in this disorder Roche's hopes for satralizumab rest partly on its better dosing profile; Soliris is dosed intravenously once-weekly for five weeks and every fortnight after that.

The other advantage is its effect, mild but significant, in AQP4-IgG-negative patients. Soliris is not approved for this population and there are no other disease-modifying drugs.

Even so, satra is forecast to trail Soliris commercially in neuromyelitis optica, with 2024 sales of $396m to Soliris's $643m, according to *EvaluatePharma* consensus. Alexion's drug is forecast to have 2024 sales of $3.4bn when its other indications are taken into account.

That is why Alexion has been so keen to shore up its intellectual property around its antibody, and why the decision that went against it last week was such a blow. Biosimilars could appear in Europe in 2022, and will pose more of a threat than satralizumab.