Evaluate Vantage

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One win, one delay for Alexion's lifecycle management

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Alexion’s creeping domination of complement inhibition took another step forward today with EU approval for Ultomiris in haemolytic uremic syndrome. This is the second EU use for the group’s Soliris follow-on, which already has a label for paroxysmal nocturnal haemoglobinuria (PNH). Still, investors are naturally more focused on the US, where a franchise-extension plan suffered a quiet delay last week. This concerned Ultomiris’s subcutaneous version, which Alexion said met the primary goal of a phase III study, demonstrating pharmacokinetic non-inferiority versus the approved IV form in 136 PNH subjects previously given Soliris. However, Alexion revealed that a US filing for SC Ultomiris would now not be made until the third quarter of 2021, after the regulator said it wanted 12-month data from an extension trial. This would result in approval in mid-2022, versus an earlier 2021 timeline. While IV delivery is seen as less patient-friendly than SC, a further complication is that Ultomiris in the latter form is given weekly, while the former is injected only once every eight weeks. A separate angle to the Ultomiris story is a phase III trial in Covid-19, measuring 29-day survival, based on anecdotal reports of complement involvement in acute lung injury.

Alexion's lifecycle management

	2019 sales ($m)			2026e sales ($m)	
Indication	**Soliris**	**Ultomiris (IV & SC)**		**Soliris**	**Ultomiris (IV & SC)**
Paroxysmal nocturnal haemoglobinuria	1,940	339		852	978
Haemolytic uremic syndrome	1,380	0		711	874
Myasthenia gravis	612	0		934	794
Neuromyelitis optica	15	0		450	261

Source: EvaluatePharma sellside consensus.