Evaluate Vantage

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Bayer puts the brakes on vilaprisan trials following safety concerns

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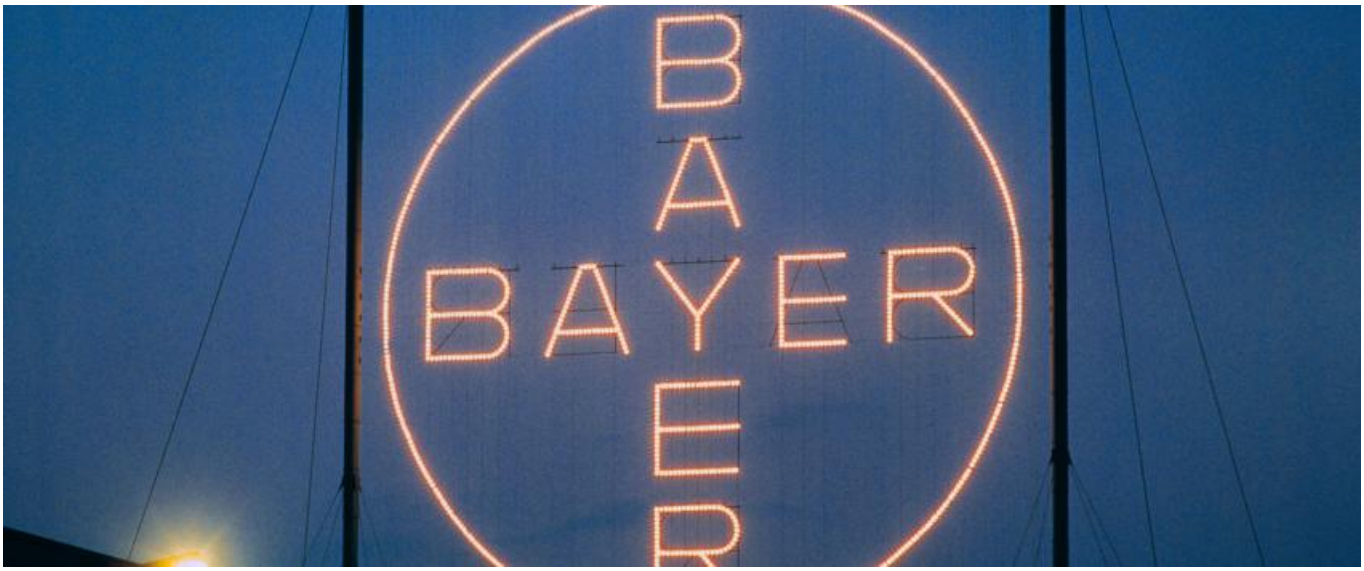

The decision to halt trials for the uterine fibroid product marks another setback in an area where there are few suitable solutions for patients.

Yesterday Bayer joined a small but growing band of drug developers struggling with the issue of how to safely treat uterine fibroids. The German group announced that it would be stopping recruitment into trials of vilaprisan, after finding safety signals in animal toxicology studies.

With Bayer now temporarily on the sidelines as it investigates these safety issues, the path is clear for Abbvie to establish dominance in uterine fibroids. Abbvie's Orilissa was approved for endometriosis in July and following positive phase III data is on track for an approval in fibroids in by the end of 2019.

Learning from the past

While the reported toxicology issues might have only been found in rodents, the group's caution can probably be attributed to Allergan's recent experiences with Esyma.

Hopes for Esmya were obliterated after new patient starts were halted in May following concerns over potential liver damage. For those already on the drug, which is only approved in Europe, monthly liver checks have been mandated.

Allergan has insisted that it has seen no link between its drug and liver damage, but the fact that four people using the drug have had to have liver transplants will have eroded consumer confidence. The FDA, which had extended its review period for Esmya, also dealt the product another body blow in the shape of a complete response letter, citing safety concerns, in August.

By halting recruitment into vilaprisan trials now, Bayer is no doubt hoping to get to the bottom of the preclinical safety signals before the product suffers any reputational damage, especially as there have so far been no reported problems in human patients. Sellside analysts had been forecasting sales of $278m in 2024.

New kids on the block?

Beyond Orlissa's potential approval next year, there is little on the horizon for fibroids outside of the usual treatments of surgery and largely ineffective contraception pills.

Selected late-stage fibroid products		
Product	**Company**	**Phase**
Relugolix	Takeda/Myovant Sciences	Filed
Orilissa	AbbVie/Neurocrine Biosciences	Phase III
Vilaprisan	Bayer	Phase III
Linzagolix	ObsEva/Kissei Pharmaceutical	Phase III

The next best hope is Takeda's Relugolix, which is also being studied in prostate cancer, and could come to market for fibroids by mid-2019. Obseva's Linzagolix is due to report phase III fibroid data next year. For patients, this latest setback from Bayer means new treatments cannot come soon enough.