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Red flags for Abbvie’s elagolix green light

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US approval of Abbvie’s elagolix, one of the company’s biggest hopes, will be a huge relief after previous delays. But the drug, now brand named Orilissa, will only go part of the way to filling a looming Humira-shaped hole – and several red flags raised today might hinder Orilissa’s progress towards blockbuster status. The FDA has approved two doses of the drug for endometriosis-related pain: 200mg twice daily, designed to be given alongside oestrogen, which counteracts the menopause-like symptoms resulting from treatment; and 150mg once daily, which does not require this “add-back” therapy. Because of the risk of lowering patients’ bone mineral density, the higher dose of Orilissa can only be given for up to six months, while even the lower dose is only recommended for up to 24 months – not ideal for a long-term condition that primarily affects women in their 20s and 30s. Also worrying is a link between Orilissa and depression and suicidal thoughts. Still, any safety concerns have not stopped analysts predicting that the product will become the biggest endometriosis therapy by 2024. Abbvie has also reported phase III success in uterine fibroids, an indication that could add another $600m that year, according to EvaluatePharma sellside consensus.

Top five endometriosis therapies in 2024

			Indication sales ($m)			
Product	**Company**	**Pharma class**	**2018**	**2020**	**2022**	**2024**
Elagolix	Abbvie	GnRH antagonist	33	294	576	842
Visanne	Bayer/Mochida Pharmaceutical	Progestogen agonist	195	224	253	282
Linzagolix	Obseva	GnRH antagonist	-	-	35	220
Leuplin	Abbvie/Takeda	LHRH analogue	241	217	198	180
BAY 1128688	Bayer	AKR1C3 inhibitor	-	-	18	55

Source: EvaluatePharma.