Evaluate Vantage

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Eyes return to the prize for Protagonist's rusfertide

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When the FDA halted all clinical work with Protagonist's rusfertide over cancer concerns, investors feared the worst. The lifting of that hold a mere three weeks later therefore prompted a similarly dramatic reaction: the stock surged 94% yesterday. But the shares still sit some 25% below levels seen before the clinical hold. Aside from requiring enhanced monitoring for skin cancer, the FDA seems comfortable for the programme to continue largely as before. Such a swift resolution is reassuring, though confidence in rusfertide's potential has clearly taken a knock. More data will help, and two presentations before year end are now keenly awaited. The first is at the Liver Meeting, concerning a second indication for the project: hereditary haemochromatosis, a rare inherited disorder that causes iron build-up. Phlebotomy is the effective but burdensome standard of care. The abstract points to a dramatic reduction in phlebotomies as well as improvements in various pharmacological markers. The latest cut from an ongoing phase 2 trial in polycythemia vera is also due, possibly at Ash. Protagoinst confirmed yesterday that it still plans to start phase 3 in polycythemia vera early next year.

Rusfertide (PTG-300) clinical programme in disorders of iron overload/excessive red blood cell production

Setting	Trial	Next steps
Polycythemia vera (rare chronic blood disorder that affects about 160,000 US patients)	Phase 2 in phlebotomy-requiring PV	Latest cut of data could be at Ash; previous presentation at EHA
	Phase 2 in PV patients with elevated haematocrit	Data could come 2022
Hereditary haemochromatosis (inherited iron overload blood disorder affecting over a million US people)	Open label phase 2 study fully recruited	Data to be presented in oral session at AASLD November 13th
Third indication	–	To be announced by YE 2021
Source: Company statements & clinicaltrials.gov.		