Evaluate Vantage

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Resurgent Arqule climbs on targeted therapy hope

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You might be forgiven for thinking that Arqule was down and out, but since the 2013 failure of tivantinib the group has enjoyed an amazing turnaround. This is thanks to repositioning itself around five targeted oncology projects, one of which, the BTK inhibitor ARQ 531, caused its stock to surge 67% yesterday. It is hoped that ARQ 531 could treat patients with the C481S resistance mutation that can develop in response to treatment with a BTK inhibitor like Imbruvica or Calquence. While Arqule reckons the project could treat wild-type patients as well as C481S mutants, the latter represents its fastest route to market, and it was this that helped send the stock up yesterday: a single Calquence-relapsed leukaemia subject treated with ARQ 531 was documented to harbour this mutation, and reported a partial remission, with an 88% tumour burden reduction. Apart from the obvious caveat that this was just a response in one patient, the high ARQ 531 dose involved, 65mg, was associated with serious rash, a dose-limiting toxicity, in another subject. Nevertheless, Arqule today boasts a $593m market cap, and its stock is back where it was before a safety scare spelled the beginning of the end of tivantinib.

Selected Arqule targeted oncology assets

Project	Mechanism	2024e sales ($m)	Oncology focus	Trial ID
Miransertib/ARQ 092	Pan-AKT inhibitor	220	AKT or PI3kmut pts	NCT02476955
ARQ 531	W/T & C481Smut BTK inhibitor	140	Post-BTK inhibitor pts	NCT03162536
Derazantinib/ARQ 087	FGFR inhibitor	22	FGFR2 fusion cholangiocarcinoma	NCT03230318
ARQ 761	NQO1 inhibitor	0	NQO1-high pts	NCT02514031
ARQ 751	Next-gen AKT inhibitor	0	AKT, PI3k & PTENmut pts	NCT02761694

Source: EvaluatePharma & clinicaltrials.gov.