BiVictriX Therapeutics – BVX002 Data Update

BiVictriX's lead solid tumour asset, BVX002, outperforms two clinical stage competitor ADCs in a murine model of ovarian cancer leading to nomination of development candidate.

26th June 2025

We are pleased to be able to report highly promising in vivo animal study results from our ovarian cancer Antibody-Drug Conjugate ("ADC") BVX002 study.

BVX002 is a bispecific ADC, designed through the Company's proprietary Bi-Cygni® approach, to target two tumour associated targets (B7H4 x undisclosed protein target) with a lead indication in ovarian cancer. Ovarian cancer, like many solid tumour indications, is highly heterogeneous, meaning that the tumour comprises cancerous cells with varying levels (high through to ultra-low) of expression of targeted antigens. This heterogeneity makes these cancers very challenging to treat effectively with single antigen targeted therapeutics including the typical ADC designs. BVX002, through the Bi-Cygni® approach, has been engineered specifically to address this concern by targeting *two synergistic* tumour antigens with an "AND-OR-Gated" design – meaning we can hit *either* of the *two* target antigens. And our platform allows us to pick antigen combinations which show minimal to no expression on normal cells.

Two BVX002 leads (TA-2 and TA-3) were dosed in the study at escalating doses and across differing dose schedules (single dose vs once weekly dosing for 3 weeks) and compared to the two competitor ADCs dosed according to their reported maximum dosing in similar animal studies.

In this preclinical trial against other agents that are currently showing activity in human clinical studies, BVX002 demonstrated highly statistically significant tumour regressions of up to 87% (Day 28; $p<0.001$*** versus placebo treatment) when dosed in a highly relevant, "difficult-to-treat" ultra-low target expressing mouse model of Ovarian Cancer.

- In the model, BVX002 was run head-to-head against Pfizer's SGN-B7H4V B7H4 monospecific ADC (previously in phase I) and AstraZeneca's AZD8205 B7H4 monospecific ADC (currently in phase I/II), both of which have shown some clinical activity, primarily in patients whose tumours express high levels of target (B7H4) antigen. (Note: biosimilars of both drugs were tested).

- Responses in the current model with the two competitor ADCs were generally limited to disease control, likely due to the low levels of target (B7H4) expression within the model. Indeed, recent clinical data concerning both competitors suggests that they require patient's tumours to have high levels of target expression to see a meaningful clinical benefit. In contrast, BVX002 showed statistically significant *tumour regressions* across all doses tested in the same model.

- Furthermore, one mouse in the study did not respond to AstraZeneca's AZD8205, potentially due to developing resistance to AZD8205's cytotoxic payload (a topoisomerase I-inhibitor). Of particular note, this finding is consistent with an emerging concern in the wider ADC sector where resistance to ADCs utilising topoisomerase I inhibitor-based payloads is increasingly observed. This AZD8205-treated tumour had grown to a substantial size by Day 42 (>2cm^3) and a *single dose* of BVX TA-3 (5mg/kg) was able to not only reverse the exponential growth of the tumour, but also to reduce the tumour in size by over 62% in 14 days.

- These data clearly demonstrate the superior ability of our Bi-Cygni® ADC approach to treat challenging solid tumours where target expression is below the threshold for effective monospecific ADC activity.

- The study also validates BiVictriX's proprietary site-specific conjugation technology to produce a homogeneous DAR4 (drug-to-antibody ratio of 4) product, as verified with BVX002 lead, BVX TA-3.

From these and other data, the Company is pleased to confirm that we have formally nominated BVX TA-3 as our development candidate for the BVX002 programme and will seek to continue to develop this candidate towards IND.

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