Evaluate Vantage

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EP Vantage interview – Backers place €55m bet on Glycotope technology

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Private German developer Glycotope has banked €55m ($76m) in one of the biggest European fundraisings of the last couple of years to push three fully humanised, glycosylised biologics through mid- and late-stage trials. The group hopes its focus on glycosylation will improve on the specificity and bioavailability of currently-available therapies.

Continuing funding from biotech cultivators the Strüngmann brothers and Andreas Eckert, rather than traditional venture capital firms, has provided Glycotope the stability necessary to think long-term about their compounds, two in cancer care and one in fertility treatment. “They said, ‘We would like to build a big biotech company. We are not looking for a fast exit,’” Franzpeter Bracht, Glycotope’s chief operating officer, says of its benefactors.

Better and bio-better

Glycotope believes its technology can help to achieve clinical responses at lower dosing levels and reduce side effects for a number of well-established drug classes. Its most-advanced product is FSH-GEX – the suffix is an abbreviation for the “glycoexpress” platform that modifies key features of existing drugs by changing glycosylation parameters that affect bioactivity, bioavailability and immunogenicity.

FSH-GEX is a variant on follicle stimulating hormones like Gonal-F and Elnova; the company is preparing to enrol the first women into a 1,000-patient, phase III trial in mid-2014 in the US and Europe. A 240-patient phase II trial against Merck KGaA’s Gonal-F found a statistically significant increase in the number of eggs successfully retrieved in patients taking FSH-GEX while having a lower rate of ovarian hyperstimulation syndrome, a sometimes severe response to fertility treatment.

Mr Bracht reckons the trial should take 15 months from first patient to conclusion, allowing for a submission in late 2015 or early 2016. He says the drug can be filed on biochemical confirmation of pregnancy, so Glycotope would not need to wait for live birth data.

Shepherding a compound through phase III would be no mean feat for a private biotech, and the new funding will be key in achieving that. But the company probably will be able to generate more interest in its oncology platform of three compounds, two of which it intends to push through to the end of phase II, thanks to the new funding.

The first is one of two “biosuperior” drugs. CetuGEX is version of Bristol-Myers Squibb and Eli Lilly’s antibody Erbitux, but developed in a human cell line that can reduce off-target effects.

“Erbitux has some strange glycosylation due to the fact that it’s made in a rat cell,” Mr Bracht says. “This leads to a high rate of side effects. In some regions of the world, especially the Bible Belt in the US for example, people have a very high immune system answer to this non-human carbohydrate. So we now have a human cell line and we don’t have a side effect. That means we now have many more patients we can bring a benefit to.”

The patent for Erbitux, the fourth-oldest monoclonal antibody used in oncology, is due to fall in 2018 and companies like Amgen, Actavis and Celltrion are developing biosimilar versions, so CetuGEX will need to show clear differentiation.

In a 250-patient phase IIb trial of CetuGEX Glycotope hopes to show that it can improve progression free survival when tested against Erbitux in head and neck cancer; the study should start this year.

A second biosuperior drug in the form of Herceptin, a compound it calls TrasGEX, has recently completed a phase I/IIa trial. Late phase II work has yet to begin.

The novel PankoMab-GEX, meanwhile, is a tumour-associated MUC1 antibody that Gylcotope has in a 240-patient phase IIb maintenance study for ovarian cancer, where no competition currently exists.

A look ahead

The phase IIb trials of CetuGEX and PankoMab-GEX are expected to wrap up in 2016. Mr Bracht says the group wants to partner one of those to enable clinical research on candidates that it cannot currently fund.

Outside of the large but tranched VC-backed rounds of Symphogen and Circassia, this financing is the biggest private biotech fundraising in Europe since CureVac raised €80m in 2012. And the sum would rank it among the biggest private rounds raised last year (*Soon-to-be-publics top VC rounds of 2013 while seed funding shows an uptick, February 5, 2014*).

Mr Bracht gives credit to the long-term support of its investors – Eckert through the Eckert Life Science Accelerator that provided seed funding and majority backers the Strüngmanns through Jossa Arznei GmbH, which has been involved since 2008 - and says a different biotech fundraising environment is emerging in Europe.

“I think there are now some really advanced biotech companies showing very good technologies and very promising drugs and that’s the reason why financing will become a little bit easier than in the past,” Mr Bracht says.

Trial	**ID**
FSH-GEX	NCT01794208 (concluded)
CetuGEX	NCT02052960 (not yet recruiting)
PankoMab-GEX	NCT01899599 (underway)

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