

## Interview - A biosimilars springboard for Innovent



[Jacob Plieth](#)

For a young Chinese company about which relatively little has been made public Innovent Biologics has done pretty well, attracting Western funding, raising \$100m in a series C round this year and following this with a Lilly tie-up worth \$56m up front.

At the Asco meeting *EP Vantage* spoke to Linda Pullan, Innovent's vice-president of business development, who put the group's key strengths down to Western-quality biomanufacturing and a focus she describes as "one third biosimilars and two thirds novel drugs". While others have found achieving US-quality production tough, the Lilly endorsement suggests that Innovent is on the right track.

Ms Pullan agrees that developing-world manufacturing has been patchy, as a focus on speed led to shortcuts and early biologicals that clearly did not meet Western standards. Many so-called biosimilars would actually not meet the standards for similarity and comparability.

"Innovent's real focus has been [on] facilities and quality of product that would meet EMA and FDA standards to provide biologics for the world," says Ms Pullan. The series C investors, including Fidelity and Lilly's venture arm, "all saw the opportunity here, and the Lilly deal is a nice validation" ([Biotech first-quarter venture haul unprecedented since crash, April 22, 2015](#)).

Is Lilly Innovent's partner for the West, or does Lilly see Innovent as a gateway into China? The deal certainly started out with Lilly's interest in Innovent's lead project, IBI301, a biosimilar version of Rituxan, says Ms Pullan, but then the idea was conceived of an asset swap - IBI301 for Chinese rights to Lilly's phase II c-Met antibody emibetuzumab.

And finally the US group "became aware of the innovation that Innovent had begun", and an undisclosed Innovent immuno-oncology project - presumably IBI308 - was [thrown into the bargain](#).

### Domestic advantage

"I think Lilly recognised the tremendous advantage in China that is given to domestic companies, which can use a 'green channel' - a faster approval path that comes with greater government reimbursement," says Ms Pullan.

Moreover, in China it is the manufacturer that holds the licence - there is no role for a CRO - so it is critical to pick the right manufacturer. "Lilly recognised that early on and went looking for the best biologics company in China."

As for the rest of the pipeline Innovent's website is sketchy, though Ms Pullan is happy to disclose more, highlighting among novel projects an anti-VEGF/anti-complement bispecific MAb for ophthalmology, as well as IBI306, a high-affinity anti-PCSK9 MAb. PCSK9 "doesn't fall within our sweet spot so we really do need a partner, both for China and the rest of the world".

Further biosimilars include IBI303, a version of Humira. That said, both IBI303 and IBI301 are early in development, with INDs filed but clinical trials in China yet to begin. At the same time, numerous groups including Amgen, Boehringer, Sandoz and Hospira are in the pivotal stages of developing Rituxan and Humira biosimilars.

Thus Innovent, which has no plans to build a rest-of-world sales force, is basically a play on low-cost, high-quality biomanufacturing, and product characterisation. Rituxan is the best-selling MAb in China, but only a tiny proportion of eligible patients get it owing to the high price of imported products.

The Roche drug has no patent protection in China, and while there are lots of anti-CD20 MAbs in the local market none is rigorously comparable. "There is huge untapped scope for a more affordable, domestically reimbursed product," says Ms Pullan, and the hope is that IBI301 will be China's first "truly comparable" Rituxan biosimilar.

So is this all about first-mover advantage? Yes, that is huge in China, says Ms Pullan, but so is the ability to draw in key people from the West, since unlike in the US you cannot just raid experienced staff from companies around you. Innovent's C-suite includes execs formerly at Genentech and Abbott.

Meanwhile, its chief executive is Michael Yu, the inventor of the world's first approved oncolytic virus product, Oncorine.

If Innovent is capable of complex biomanufacturing to US standards then the Rituxan biosimilar could just be a first step on a longer path to becoming a truly innovative business.

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