BioAlliance moves on Topotarget before key US decision

Amy Brown

The all-share move that will see France's BioAlliance buy Denmark's Topotarget appears to represent a logical combination of two small, oncology-focused drug developers in search of critical mass. However, the outcome of an impending ruling by the FDA will play a big part in working out the ultimate value of the deal.

The US regulator will decide in August whether to approve belinostat, a project developed by Topotarget and licensed to Spectrum Pharmaceuticals; a green light will trigger a $25m milestone payment from Spectrum. BioAlliance's chief executive, Judith Greciet, who will remain head of the combined company, says the potential of the acquisition and of belinostat stretches far beyond this event. But it is clear that the decision becomes a big milestone on the horizon.

"Belinostat has lots of opportunities in terms of other indications, and is only one of the strengths of this deal," she tells EP Vantage. "There are lots of similarities and synergies that should allow the combined company to be more powerful and grow more quickly, and be able to attract specialised investors and have more anchorage in the US."

Paying for the pipeline

In terms of pipeline, Topotarget only has belinostat in clinical development, which will join BioAlliance's two late-stage compounds.

Most advanced is Livatag, currently in a phase III study called Relive that is seeking to recruit 400 patients with advanced hepatocellular carcinoma and who have failed to respond to Nexavar. Data showing whether the project can prolong survival are unlikely before the end of 2016.

Phase II results are due in the second half of this year on Validive, its oral mucositis treatment that received FDA fast-track status earlier this year. The disabling condition is caused by intensive radiochemotherapy regimens; the project, a mucoadhesive tablet that delivers high concentrations of the anti-inflammatory clonidine to the mouth, is being developed specifically for head and neck cancers.

BioAlliance ended 2013 with €11m ($15m) in the bank. Should the takeover proceed its coffers will be topped up with Topotarget's $15m, which was recently swelled by a $10m milestone from Spectrum, paid when belinostat’s US filing was accepted.

BioAlliance will need this cash and more as it hopes to put Validive into phase III next year and may elect to pursue further development of belinostat in Europe; Spectrum only has rights in the US and India.

The all-stock transaction “made a lot of sense for us as it doesn’t take out cash”, says Ms Greciet. "The cash that we have is dedicated as much as possible to development programmes."

Cash for stock?

With the move still requiring shareholder approval Ms Greciet was reluctant to lay out firm plans for belinostat in Europe, but said running further trials and then selling it in-house was the strategy in mind. The company intends to set up a small, oncology-focused sales force to sell all of its niche products in Europe, and belinostat would fit here.

This strategy would receive a big helping hand from the chunky $25m approval milestone, but a positive outcome is far from assured. Belinostat, now branded Beleodaq, has been filed as a treatment for relapsed peripheral T-cell lymphoma (PTCL), a rare and aggressive form of non-Hodgkin’s lymphoma, on the basis of an open-label, single-arm study.

This was run under an SPA and generated an objective response rate of 26%, above the 20% hurdle set by the FDA. But an SPA does not guarantee approval, and in the past couple of years the regulator has approved two targeted agents for this setting: Folotyn – also sold by Spectrum – and Celgene’s Isthodax (What is a special
Should Beleodaq reach the market BioAlliance would also be eligible for double-digit royalties, but analysts covering Spectrum in the US are not expecting huge revenues; Credit Suisse has pencilled in sales of $30m by 2016. As such, it is the milestone payment that would have the real impact on the French company.

And even if BioAlliance gets nothing beyond the Beleodaq milestone payments this move still has merit. True, there is current shareholder dilution – newly issued stock to complete the acquisition will enlarge BioAlliance's share capital by 50% – but further funding would have soon been needed anyway. Ms Greciet says that pre-acquisition cash “allows for 12 months of visibility”.

If the FDA gives belinostat a green light the deal could look like a smart use of stock that has risen 67% year to date.

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