Momenta steadies the ship with Baxter biosimilar deal

Jonathan Gardner

Momenta Pharmaceuticals is finding the world of biosimilars to be a bit rough and tumble. It has had to fight off competitive threats to its copy of the blood-thinner Lovenox whilst taking on generics giant Teva in a legal battle over MS drug Copaxone, all at the same time as some major pharma players were signing global deals in preparation for a new biosimilar pathway to be defined in US regulation.

So it was with some relief to shareholders that the Massachusetts group announced it had signed a $33m deal with Baxter International to develop and commercialise up to six biosimilar products. Shares rose 4% to $17.76, near a five month high, as investors saw an opportunity for Momenta to take advantage of Baxter’s global commercial power and become a biosimilar player. Having a partner with a presence in the hospitals where these products will be sold will be a big advantage, chief executive Craig Wheeler told EP Vantage.

Interchangeable

The deal trades Baxter’s commercialisation power and experience in manufacturing and sterile injectables for Momenta’s technologies in analytics, characterisation and product and process development. No specific products have been named, although the aim is to produce “interchangeable” biosimilars, or the ones that under emerging FDA regulations can be substituted by pharmacists without a prescriber’s intervention.

These products are likely to be more competitive in the marketplace as patients on established medicines can be switched from a branded biologic to interchangeable biosimilar, an important consideration for patients with chronic conditions. Of course, they will need to meet a higher standard for approval.

The $33m upfront payment will pay for Momenta to begin work on the first two products under the partnership, chief executive Craig Wheeler told EP Vantage. The deal specifies up to $91m in technical milestones across all six products and $50m per product - $300m in total contingent payments should Momenta show its technology significantly reduces the necessity for clinical trials.

There are also $28m in option payments specified under the deal; the company would be eligible for royalties, and would have the option to seek a 30% co-marketing pact on the final four products under the deal.

Amongst the strengths of the partnership is Baxter’s marketing muscle in hospitals and managed-care organisations, where most of the buying decisions are made in biologicals, as well as global marketing and manufacturing capabilities, Mr Wheeler said. As biogenerics will be a low-margin business, sales strategy will be crucial to establishing a profitable market share, he said.

“Baxter has a tremendous presence in managed care and hospital settings where most of these products will be sold,” Mr Wheeler said.

Right now Momenta has just the Lovenox copy on the market, which is expected to earn the group a tidy $263m in 2011 in royalties from its partnership with Novartis, according to EvaluatePharma data; significant erosion is forecast through 2016 as a result of competition, although with Sanofi having withdrawn its authorised generic and Momenta claiming Watson and Amphastar’s entry violated its patents, those forecasts may be adjusted. Its generic Copaxone is forecast to hit the market in 2014 and earn $154m in 2016.

Dealmaking flurry

This is the third such deal on biosimilars in December. Biogen Idec and Samsung struck a $300m partnership early in the month, and just this week Amgen and Watson Pharmaceuticals agreed to work on biosimilar cancer drugs.

The dealmaking comes at a propitious time in the evolution of the biosimilar market. Long without a clear regulatory pathway as with generic small molecules, the FDA is expected almost any day now to release
guidance advising biosimilar companies on the data that will be necessary to validate biological likeness, a condition of health care reform law enacted in 2010 (US biosimilar rules due by year end, November 23, 2011).

Among the questions waiting to be resolved will be those issues of interchangeability – what evidence will be necessary to qualify for that higher standard of marketing authorisation.

In addition, there have been signals from senior-ranking FDA officials that safety and efficacy similar to the reference product may need to be demonstrated in clinical trials for protein therapeutics; for others, “fingerprint-like” identification of similar molecular patterns may be sufficient, as occurred with Momenta’s Lovenox copy.

Thus the regulation will help to define the market. And in the meantime the deal-making is likely far from over, as companies wanting to launch biogenerics pair off with partners offering complementary capabilities.