Dr Reddy’s eyes biosimilars expansion and rejigs research focus

Dr Reddy’s Laboratories is in talks with potential partners to push into regulated markets in the biosimilar segment. But the Indian firm, which claims to have sold about 1.4 million units of its biosimilar products in 12 countries so far, also says that approvals in certain emerging markets for such products are taking significantly longer than expected.

“We are preparing to expand into regulated markets and also talking to potential partners. We have also spoken to regulators. The pathways should become clearer in 2012,” Dr Reddy’s vice-chairman and CEO G V Prasad, said at a media event in Hyderabad.

Dr Reddy’s, which has seven products in various stages of development, has already launched a number of biosimilars, such as filgrastim, pegfilgrastim, darbepeptin alfa and rituximab, in India and certain emerging markets. Filgrastim and rituximab are marketed in about half a dozen countries each, with approvals pending in three and eight countries respectively.

But Mr Prasad did not provide specifics on pending approvals in emerging markets. “Wherever we’ve got approvals, we’ve done well, but approvals are taking much longer than anticipated,” he noted.

Biosimilars are seen as an important driver of future growth for the firm, with a scale-up in emerging markets projected between fiscal year 2013 and fiscal year 2017 and increasing traction in regulated markets helped by this. In 2010-11, Dr Reddy’s Redilux (rituximab) saw 75% growth in revenues to $405 million ($77.7 million) on the Indian market.

R&D shift

Meanwhile, Dr Reddy’s is “de-emphasising” its new chemical entity (NCE) R&D efforts in the cardiovascular and diabetes segments, focusing instead on areas such as anti-infectives, inflammation/pain and dermatology.

The company cited as some of the reasons for the shift the huge cost of clinical trials to go to market and the potential challenges in improving the

Continued on page 15

Amgen partners with Watson to pursue ‘new biotech frontier’

In 2010, biotechnology pioneer Amgen decided it was time to venture into what company executive Scott Foraker called the “new biotech frontier” of biosimilars, and went looking for a partner to help fund the endeavour. At about the same time, generic and specialty drug maker-Watson Pharmaceuticals was on a similar hunt for a collaborator in hopes of expanding more into the biosimilars space, with the intent of making a substantial investment in such an alliance. After much discussion with numerous other potential candidates, a partnership between the two firms has been formed.

Amgen is the latest to join a cadre of large innovator drug makers, such as Pfizer, Merck and Lilly, pursuing development of biosimilars. Parsippany, New Jersey-based Watson is putting up $400 million to help fund the worldwide deal with Amgen, which is assuming the primary responsibility for developing, manufacturing and initially commercialising biosimilar antibody products to treat cancer.

Watson President and CEO Paul Bisaro said his company is anticipating its spending commitment under the agreement to last over the next seven to eight years. “At a high level, this collaboration helps both Watson and Amgen create additional value and mitigate risks associated with the unique financial development and commercialisation challenges associated with biosimilars,” he said during a conference call with investors and analysts.

While Amgen has the capabilities on its own to pursue biosimilars and the cash on hand to fund such a programme, from a P&L standpoint – in which companies must always strike the right balance between near-term and long-term investments to keep their investors happy – the biotech decided it would be “prudent” to find a partner to share the costs, Mr Foraker told Scrip.

A co-investment partner would allow Amgen to pursue biosimilars without having to make any tradeoffs involving its innovative side of the business, said Mr Foraker, the company’s vice president and general manager of biosimilars.

Watson also brings to the collaboration its expertise in commercialising and marketing products in the “highly competitive” specialty and generic markets, Mr Foraker said.

Bringing together the “full array” of each firms’ commercial capabilities will provide the collaboration the “great flexibility” necessary to come out on top in the global biosimilars marketplace, Mr Foraker insisted.

While the products that come out of the alliance will be jointly labelled and co-branded as Amgen-Watson biosimilars, Amgen will be booking the sales worldwide, with Watson receiving royalties and sales milestones, Mr Foraker noted.

The companies did not disclose any other financial details about the deal.

Mr Foraker emphasised that the collaboration will not pursue biosimilars of Amgen’s proprietary products. He added, however, that the agreement “does not strictly prohibit” Watson from pursuing development of biosimilars of Amgen’s products outside the collaboration.

But, Mr Foraker said, “it makes for a better partnership if you are not collaborating with a partner on one hand and duking it out with them in the market on the other.”

While the regulatory landscape for biosimilars remains somewhat uncertain, with the US FDA yet to issue its general guidance documents, which the agency has committed to releasing before the end of the year, Mr Foraker said Amgen and Watson are “not waiting for anything” (scripintelligence.com, 19 December 2011).

“We are ploughing straight ahead, because we feel like we have a pretty good understanding of the product development path,” he said.

Mr Foraker acknowledged that Amgen already has had biosimilars in development and has held “several” meetings with the FDA and the European Medicines Agency on the company’s experimental medicines in its portfolio, “where we discussed specific product development plans on specific products with them.”

“ Their expectations are the same as ours, and we know exactly what we need to do in terms of product development, and we are doing it… even in the absence of the guidelines.”

donna.young@informa.com
EMA to reveal EU pharmacovigilance implementation plan mid-January

The European Medicines Agency says it will publish details of the implementation plan for the new EU pharmacovigilance legislation in mid-January. Among other things, the plan provides for the first meeting of the new Pharmacovigilance Risk Assessment Committee (PRAC) in July 2012.

The plan, which takes into account both the agency’s limited resources and the huge amount of work that needs to be done to put the new legislation into practical effect, was endorsed by the EMA’s management board at its meeting on 15 December.

As reported recently, the legislation, which was adopted in December 2010, is so far-reaching that it will need to be phased starting in July when its provisions are scheduled to come into force (scripintelligence.com, 7 December 2011).

The agency says that the highest priority will be given to activities that contribute to public health, followed by those aimed at increasing transparency and improving communications, and later the simplification measures.

urgent safety reviews

One of the key changes brought by the new legislation is the "Urgent Union Procedure". This will be used by EU member states or the European Commission when the following are being considered: suspension or revocation of a marketing authorisation, a prohibition on supply or a refusal to renew an MA, or when the MA holder has taken action to cease supplying or a new contraindication or restriction is thought necessary.

The new procedure, which the EMA now says will come into effect in September 2012, will involve an examination of the data by the PRAC. The committee will issue a recommendation, which will be followed by an opinion from the CHMP and a decision by the commission on temporary or final measures.

However, if urgent action is deemed necessary to protect public health, the member states or the commission can act at any time during this procedure decide to suspend the MA and prohibit use of the drug until the final decision is taken. The procedure can also involve public hearings.

work programme

Also at its meeting, the management board adopted the work programme and budget for 2012. The work programme forecasts a stable number of applications for centralised marketing authorisations in 2012: 52 applications are expected for new human-use medicines (compared with 47 in 2010), as well as 13 filings for orphan drugs (13 in 2010) and 39 for generics (45).

The work programme also assumes a 10% rise in the number of requests from companies for scientific advice, including an increase in the number of joint procedures conducted with health technology assessment (HTA) bodies.

The budget for 2012 has been set at €222.5 million, up by 6.5% over 2011, which includes fee revenue of €171 million (compared with €161 million in 2010) and an EU contribution of €51 million (€28 million). The special EU orphan drugs fund has been increased from €4.9 million to €6 million. The workforce will remain at the level seen in 2011, with the staff ceiling fixed at 737.

The work programme will strengthen ‘quality and the regulatory and scientific consistency’ of the agency

In order to keep within budget while undertaking a range of new responsibilities including those under the new pharmacovigilance legislation, the agency says that it will continue to pursue efficiency gains and look for ways to re-allocate resources and reprioritise activities.

The work programme, which the EMA said recently consists of those parts of its "road map" that will actually be implemented, will also see the agency strengthen the quality and the regulatory and scientific consistency of the assessment process and its outputs, and take further steps to increase transparency as well as improve communications with stakeholders.

The board discussed a revised policy for handling conflicts of interest for its members, which will be adopted at its next meeting in March 2012, endorsed a reflection paper on ethical and GCP aspects of clinical trials conducted outside the EU, and initiated a new framework to increase interactions with healthcare professionals and their involvement in agency activities.

Discussions also began on a reflection paper on lessons learnt from shortages caused by manufacturing and GMP compliance problems, and actions to be taken to prevent, mitigate or manage such shortages in future.