Evaluate Vantage

January 06, 2010

Notable events over the Christmas period

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After all the excitement during 2009 that saw the pharma and biotech sector hammered by the markets at the start of the year and then stage a remarkable recovery towards the end, it is perhaps unsurprising that Christmas was quiet allowing everyone to catch their breath.

As such, the number of notable events over the holidays were rather thin on the ground.

Financings

December 30

Following a flurry of fundraising towards the end of the year, the only notable financing during the Christmas period was Compugen, which managed to add $19m after expenses to its bank account thanks to a controlled equity offering, that saw it issue 4.1m shares priced at $4.91. The move came a few days after it struck a deal with Pfizer to develop three compounds, allowing Compugen to take full advantage of the share price rise.

Meanwhile Summit fell slightly short in its ambitions to raise £8.2m, but instead managed to convince investors to give it £5.4m ($8.6m) in a placing of new shares. The UK company expects this sum to last until December 2011 before it has to tap the market again.

December 24

In contrast to Summit, Australian biotech, Avexa, found its offer oversubscribed allowing it to raise A$15m ($13.8m) for general corporate purposes.

Deals

December 29

Ranbaxy Laboratories announced that it would be selling its entire stake in the Ranbaxy Guangzhou China Limited (RGCL) joint venture to HNG Chembio Pharmacy Co for an undisclosed amount. Ranbaxy said the transaction was part of an effort to develop a new business model for China.

December 24

While Ranbaxy was getting out of China, Teva Pharmaceutical Industries was extending its reach in the Japanese market. Its joint venture with KOWA Company, Teva-KOWA Pharma Co, signed an agreement to acquire a majority stake in Taisho Pharmaceutical Industries for an undisclosed sum. The transaction, which closed last month, leaves Teva-KOWA Pharma with 66.7% of Taisho's shares.

December 23

In the only complete buyout of the season Novartis announced that it would be paying $120m to purchase Corthera, primarily to gain rights to phase III vasodilator Relaxin, a treatment for acute decompensated heart failure. In what looked to be a Christmas bonus Corthera shareholders will be eligible for additional payments of up to $500m if Relaxin meets development and commercialisation milestones.

Regulatory

December 30

Perhaps one of the biggest surprises of the Christmas period was the earlier-than-expected decision by the FDA to issue Johnson & Johnson and Basilea Pharmaceutica with a complete response letter for antibiotic ceftobiprole (Zevtera). The regulator highlighted concerns over unreliable and unverifiable clinical data submitted by J&J (*Basilea weakened by FDA rejection, January 4, 2010*). Some now believe the two new clinical trials the FDA has requested could delay approval by up to three years. The decision could also increase the acrimony between the two companies. Basilea is currently seeking compensation from J&J, claiming its partner should have done more to get the drug to market.

While the FDA managed to issue a few complete response letters what it did not have time for this year was completing its BLA review of Pfizer's pneumococcal vaccine, Prevnar 13, meaning that the injection missed its PDUFA date of December 30.

The under pressure and under-staffed US regulator also caused Novo Nordisk to announce that it would not be getting any FDA feedback on its diabetes drug Victoza by expected deadline of December 31.

Meanwhile Valeant Pharmaceuticals announced that it had filed an NDA for its epilepsy drug, retigabine. The drug has also been accepted by the European Medicines Agengy, meaning that if both filings come off 2010 could be a very good year for Valeant, which has licensed the drug in the US to GlaxoSmithKline.

Biodel also submitted its new drug application to the FDA for permission to market VIAject, its fast acting insulin treatment for diabetes. If approved it will be Biodel's first marketed product and analysts believe the product could generate royalties of $122m by 2014, if a marketing partner can be found (*Companies still desperate for a partner, June 19, 2009*).

December 29

Having watched its rivals file their NDA's for their obesity drugs, Vivus finally submitted its NDA for Qnexa to the regulator.

December 28

Pharmaxis also received a complete response letter rather than a Christmas card from the regulator for Aridol, its treatment for diagnosing and managing asthma. This time round the regulator drew attention to problems at three of the subcontracted manufacturing and testing facilities the group used and also concerns over post marketing requirements.

December 24

AstraZeneca filed a reply to the FDA's complete response letter on Numax, the follow-on vaccine to its treatment for respiratory syncytial virus, Synagis. FDA sent AstraZeneca its complete response letter in November 2008.

December 23

Pfizer's disappointing festive season started with a complete response letter from the FDA for general anxiety disorder (GAD) drug Lyrica as a monotherapy. What tripped Pfizer was that the data was deemed "insufficient" to support approval, this latest knock back comes after a non-approvable letter in August 2004. But the drug is also being reviewed as an adjunctive therapy for GAD.

Clinical Set Backs

December 29

The lack of Christmas cheer continued for Pfizer as it terminated a phase III trial of figitumumab (CP-751, 871) as a first-line treatment of non-small cell lung cancer after an interim analysis revealed the antibody was unlikely to improve overall survival compared to standard therapy.

December 23

Pfizer was not the only one to call it a day with trials. Arena Therapeutics announced that its partner Merck & Co had decided to end development of MK-1903, a niacin receptor agonist to treat atherosclerosis, after it failed to meet its primary endpoint in phase IIa trials.

Other Events

December 28

Cell Therapeutics was taking no chances about reaping the benefits of its drug for aggressive non-Hodgkin's lymphoma, pixantrone, and put in place a shareholders' rights plan or poison pill to stop any unwelcome advances from companies keen to get their hands on the drug, which has an FDA advisory committee on February 10. The plan, which will come into effect on January 7, is an attempt to prevent anyone from making an unsolicited or hostile bid for Cell Therapeutics.

December 31

Finally, Anesiva announced it will cease operations and seek bankruptcy protection after it failed to complete a merger with Arcion Therapeutics.

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