Other US regulatory news

Celgene Corporation has received an approvable letter from the US FDA for **thalidomide** [Thalomid] for the treatment of newly diagnosed multiple myeloma.[1] The agency has requested revised product labelling with updated safety information, and additional patient information before it finalises its review.

The FDA has granted priority review status to the supplemental Biologics License Application filed by Biogen Idec and Elan Corporation for **natalizumab** [Tysabri] for the treatment of multiple sclerosis.[2]

The supplemental New Drug Application filed by Cubist Pharmaceuticals for its **daptomycin** injection [Cubicin] has also been granted priority review status by the FDA.[3] The application is for the treatment of patients with bacteraemia with known or suspected endocarditis caused by *Staphylococcus aureus*.

GlaxoSmithKline and Vertex Pharmaceuticals have received approval from the FDA to update the labelling and prescribing information for **fosamprenavir** [Lexiva], an HIV protease inhibitor.[4] The new information includes clinical data showing that blood levels of fosamprenavir are not lowered when it is coadministered with esomeprazole.

The FDA has requested that the product labelling for GlaxoSmithKline's **salmeterol/fluticasone propionate** [Advair Diskus] and **salmeterol** [Serevent Diskus], as well as Schering-Plough's **formoterol** [Foradil Aerolizer], be updated with new warnings.[5] The warnings point out that these asthma medications may increase the risk of severe asthma episodes and consequent death, and recommend against first-line use of the treatments.

1. Celgene Corporation. Celgene Receives Approvable Letter From FDA for THALOMID(R) in Treatment of Newly Diagnosed Multiple Myeloma. Media Release : 15 Nov 2005. Available from: URL: http://www.celgene.com.
2. Biogen Idec, et al. Biogen Idec and Elan Announce FDA Acceptance of Supplemental Biologics License Application and Priority Review Designation for TYSABRI(R) in Multiple Sclerosis. Media Release : 17 Nov 2005. Available from: URL: http://www.biogenidec.com.
3. Cubist Pharmaceuticals Inc. FDA Accepts CUBICIN(R) sNDA and Grants Priority Review. Media Release : 21 Nov 2005. Available from: URL: http://www.cubist.com.
4. GlaxoSmirthKline, et al. FDA Approves Updated Labeling for LEXIVA. Media Release : 19 Nov 2005. Available from: URL: http://www.vrtx.com.
5. FDA Public Health Advisory. FDA Public Health Advisory - Serevent Diskus (salmeterol xinafoate inhalation powder), Advair Diskus (fluticasone propionate & salmeterol inhalation powder), Foradil Aerolizer (formoterol fumarate inhalation powder). Media Release : 18 Nov 2005. Available from: URL: http://www.fda.gov.

800999719