Jackie Westaway-1

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13:04

To: Barry Brand, Bonnie Rossello, Lionel D Houle, Jackie C Owens, Pascale Richetta, Beatrix Steffen, Luis DE LORENZO, Ken DiPangrazio, Roland Kaan, Eddy R Beke, Frank D Auton, B Srinivasan, Christophe Weber

cc: Julie Wilson-1, Sarah Daniels-1, Jill Andrews-1, Margaret M Black, Keiron T Sparrowhawk, Graham Griffiths-1, Susanne Borrett-1, Fiona Barnard-1, Paul Jenner-1, Jane M Nicholass, Anne J Bell

Subject: Seroxat/Paxil in Adolescent Depression

Please find attached to this memo a position piece, prepared by Julie Wilson of CMAT, summarising the results of the clinical studies in Adolescent Depression.

As you will know, the results of the studies were disappointing in that we did not reach statistical significance on the primary end points and thus the data do not support a label claim for the treatment of Adolescent Depression. The possibility of obtaining a safety statement from this data was considered but rejected. The best which could have been achieved was a statement that, although safety data was reassuring, efficacy had not been demonstrated. Consultation of the Marketing Teams via Regulatory confirmed that this would be unacceptable commercially and the decision to take no regulatory action was recently endorsed by the TAT.

As you will see from the position piece the positive trends in efficacy which were seen in Study 329 are being published as a poster at ECNP this year and a full manuscript is in development. Published references will therefore be available for the study. There are no plans to publish data from Study 377.

This report has been prepared for internal use only, Data on File summaries will be prepared and issued once the final reports from the studies have been approved. This position piece will also be available on The Seroxat/Paxil resource database

Best wishes

Jackie Westaway

Produced By GSK In In Re Paxil, C.P.Ct.PA (On-Drug)