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12 December 2013

Dear Professor Jureidini

Thank you for your letter dated 10 December 2013. I apologise for any misunderstanding – I was awaiting confirmation of your general agreement before progressing development of a data sharing agreement to cover the CRFs.

I understand from your letter that you agree in principle to access the anonymised data and CRFs via our secure web-based access system subject to agreeing details of a data sharing agreement. Thank you for your comments on the agreement template that is available on our website. We will consider these and send you an agreement for your review and signature. We will also provide you with an estimated date when the anonymised datasets and CRFs will be available.

With regard to the other question you raise, as is standard procedure with clinical management of individual patients who participate in clinical trials, the follow-up of patients is the responsibility of the investigator and the treating physician. GSK has no contact with participants in clinical trials and we are confident of investigators and physicians' commitment to ensuring appropriate care of their patients following our clinical trials. For the 329 study the protocol states that Investigators should follow-up subjects with adverse experiences until the event has subsided (disappeared) or until the condition has stabilised.

As I stated in my previous letter, could you please send me further details on the discrepancies in the adverse event tables you referred to in your letter of 29 October. This is of concern to me and something I would like to investigate further. As you are no doubt aware, this study was part of re-analyses conducted by FDA[i] and GSK[ii] which identified increased risk of suicidality in paediatrics given serotonin re-uptake inhibitors. The GSK study analysed paroxetine studies in children and adolescents (including 329) using an expert panel to blindly review and categorise adverse events as suicidal or non-suicidal which showed that adolescents treated with this medicine had an increased risk of suicidality.

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I'd be more than happy to talk this through on the phone. I look forward to hearing from you.

Yours sincerely

James Shannon
Chief Medical Officer

[1] Hammad TA, Laughren T, Racoosin J. Suicidality in Pediatric Patients Treated with Antidepressant Drugs. Arch Gen Psychiatry 2006; 63:332-339

[2] Apter A, Lipschitz A, Fong R et al Evaluation of Suicidal Thoughts and Behaviors in Children and Adolescents Taking Paroxetine Journal of Child and Adolescent Psychopharmacology 2006; 16: 77-90