Ken Inglis
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04/15/2001 08:41 AM

To: parshall_timothy_f@lilly.com
cc:
Subject: Fw: Allison Data Global Press Release - Draft 1 (ICSR)

ZY 2230 1648

FYI - did cc this to you but for some reason it would not go through

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> From: Ken Inglis <ken.inglis@village.uunet.be>
> To: smith_andrea_k@lilly.com
> Cc: penny_read@uk.cohnwolfe.com
> Subject: Allison Data Global Press Release - Draft 1 (ICSR)
> Date: 15 April 2001 15:38
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>
>
> Dear Andrea
>
> Here is the release announcing the Allison data to be presented at ICSR. I
> have endeavoured to stay close to the data and hope I have been successful
> in interpreting it correctly.
>
> Couple of points, Patrizia wanted me to refer to glucose changes or
> glycemic changes rather than diabetes or hyperglycemia in the release,
> which I have tried to do when reporting directly on the data (in a number
> of cases I've referred to glucose elevations rather than changes as this is
> what is referred to in the "Olanzapine - Blood Glucose Changes" the summary
> document you emailed to me as part of the briefing materials for this
> release). However, when trying to explain the significance of the data to
> the wider world (ie the medical press) I have introduced the terms diabetes
> and hyperglycemia. Mainly because case reports/review articles attacking
> olanzapine on this issue, talk about olanzapine creating an increased risk
> of hyperglycemia or diabetes, not glycemic change (hence my interest in
> finding out what the four important glycemic thresholds referred to in the
> data mean in clinical practice). Your own global market research found
> that many psychs believe Zyprexa is the most likely antipsychotic to cause
> diabetes - we should clearly refute this using consistent terminology.
>
> Secondly, Patrizia recommended we did not mention placebo data (due to its
> limitations) - however in a poster you sent over of the Allison data one of
> the conclusion points states "Further, the relative hazards of experiencing
> a diabetic event associated with glucose thresholds to or above 126, 140,
> 160 or 200 mg/dl were not significantly different between olanzapine and
> haloperidol, PLACEBO, or risperidone." I'm a bit confused as to why
> placebo is included in the poster but not thought suitable for the press
> release? Or have I completely got the wrong end of the stick? We should
> remember that the competition is happy to claim a link between olanzapine
> and hyperglycemia/diabetes based on relatively few flimsy case reports.
>
> I realise timing is tight on this release - would it be possible to skip EU
> approval in this case (ie for a straightforward data release for the
> medical press)? - after all the release still has to go through each
> affiliate's local approval before being sent to the press. It would be
> great if we could get this out to affiliates on the 23 April (to give them
> a week to translate, adapt and approve). If we can send this release out
> to all affiliates with just global, we would need final global approval by
> the 23rd. If we have to involve the EU approval system we would need final
> global approval by Wednesday 18 April.
>

> Thanks for your help with this. I hope you had a great Easter and I look
> forward to speaking to you on Tuesday (UK has a bank holiday on Monday).
>
> Best wishes
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>
> Penny Read
> PS I'm sending this from my parents' machine in Belgium so when replying
> pse send this to my C&W address (in the cc) - thanks
>
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