

Unknown

From: Aked Dominic DM
Sent: Thursday, October 26, 2000 9:30 PM
To: Rak Ihor IW
Cc: O'Brien Shawn SP; Shadwell Pamela PG; Holdsworth Debbie D; Jones Martin AM - PHMS
Subject: RE: Data for weight neutral slide

Hi Ihor

Many thanks for this important feedback.

I agree we need to be able to tell a convincing story to our internal and external customers. I'm sure we can do this.

- Re US PI: From what I can see any mention of weight gain in the US PI relates to short-term studies. We may be able to make a clear distinction between this clinical situation and long-term treatment (that is, acutely psychotic relapse versus long-term maintenance). Presumably the latter is what is important clinically given that patients receive long-term treatment.

A promotional claim 'Seroquel is weight neutral during long-term treatment' should help to make this distinction.

- There may be a rationale to explain why acutely psychotic patients may gain weight in the short term, following effective therapy. The relief of negative symptoms, apathy etc, disorganised thinking, may result in return to normal activities like having regular meals.

There are useful indicators in the patient satisfaction study to support the view that effective long term therapy with Seroquel helps to normalise eating.

Benefits noticed in last 6 mo by patients on Seroquel

55% patients prepare and cook meals

64% go shopping for food/personal items

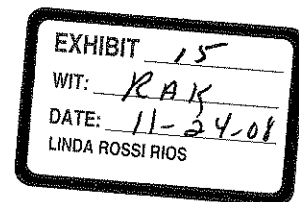
73% eat more normally

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One additional comment (where there's a ying there's a yang): if we look at incidence of patients gaining >7% baseline weight, we should also consider looking at patients losing >7% baseline weight, or what would be considered a clinically significant weight loss.

Kind regards

Dom

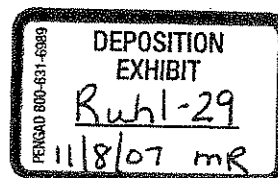


From: Rak Ihor IW
Sent: 25 October 2000 02:16
To: 'Rob Kite'; Holdsworth Debbie D; Jones Martin AM - PHMS
Cc: Shadwell Pamela PG; Ashworth Phillip P; Aked Dominic DM; Gavin Jim JP; O'Brien Shawn SP
Subject: RE: Data for weight neutral slide

All

I had the pleasure of presenting 5 weight slides (from the International Speaker's Training meeting) to the US SEROQUEL Product Team.

The titles of the 5 slides were: SEROQUEL-minimal effect on weight long term; SEROQUEL- neutral effect on weight at all doses; 3 slides-- Long-term SEROQUEL monotherapy has neutral effect on weight (1 with confidence intervals, another n=112 of 53 weeks exposure and longer shifts in BMI category, and another shifts in BMI category in obese/severely obese patients).



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