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Acadia Pharmaceuticals, Inc. Q4 2008 Earnings Call Transcript

Question-and-Answer Session

Operator

(Operator Instructions). Your first question comes from Charles Duncan with JMP.

Charles Duncan – JMP

I had a quick question for Roger. Can you run through your assumptions in terms of powering for the primary efficacy endpoint? You said 90%, I believe, for each treatment arm. Can you help us understand the magnitude of the effect that you base that on?

Roger Mills

We clearly have powered the study and it provides there is a significant antipsychotic efficacy, and we're obviously using the SAPS scale and basing it for each treatment versus the placebo over a 42-day period, so from baseline to day 42. The primary endpoint is powered. It's a standard level of 90%, and the power calculation is based on a couple of aspects. One is the margin of efficacy that we would expect to see, and we base that on what we saw in the Phase II study, but also it takes into account the variability that was observed in the study, so it's a factor of the two of those in order to be able to be powered around the probability of finding that a difference between the arms does exist, and that would be at 90%.

Charles Duncan – JMP

Can you help me understand a little about the types of patients that you are enrolling in these trials? Are they very similar to the Phase II? That was your aim, but do you anticipate the variability to increase or decrease it? It makes sense to me that with more patients, the variability would actually decrease.

Roger Mills

You covered a couple of points there. The first thing is that in enrolling patients into the study, the criteria used are very similar to those seen in others we used in the Phase II. We would expect to see similar patient population between the Phase III study and the Phase II studies. The aim for a number of things, one obviously we've increased the sample size quite considerably here, but also in the way we manage the patients in terms of oversight of the study, the aim is to actually decrease the variability compared to the Phase II, and therefore we are comfortable with the powering of the study.

Charles Duncan – JMP

Thank you for that added color. Uli, quick question regarding the Phase III data for the first trial versus the second trial. Is it your belief and I understand that's pretty imprecise science, but is it your belief that that data from the first trial may be sufficient to reduce the risk and knock on 103 to perhaps complete partnering discussion?

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