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Wilmington, DE 19850-5437

Memorandum

DATE: 20-March-2004
TO: Jack Schwartz
FROM: Ellis Wilson
Clinical Project Director, Neuroscience
AstraZeneca
RE: Special Award for BOLDER Team

I am writing to request awards, at special levels, for the members of the BOLDER team who worked so hard to deliver this groundbreaking study for AstraZeneca.

Specifically, I am requesting three tiers of recognition:

\$5,000 - Robin McCoy, CTM

\$3,000 - Margaret Minkwitz, Statistics

\$3,000 Jeris Minor, DM

\$500 - Remaining Team Members (~10)

The BOLDER team was charged with executing and delivering the first Seroquel study in bipolar depression. A careful viability exercise was carried out, confirming the difficulty of recruiting in this arena and underscoring the risk associated with placebo response. This high performance team focused attention on optimally recruiting this study through careful planning via the risk management program, which became a model for the entire Seroquel program. This focus on planning and execution resulted in delivering the study some 8 months early. This strategy, developed before a single patient was recruited, proved to be critical as the team sustained an extraordinary level of productivity from study start to final closeout. The industry literature reveals that 80% of clinical studies do not recruit on time; to complete this study 8 months early is truly a remarkable achievement.

Creativity and 'outside-the-box' thinking are often part of the equation when projects set new standards, and this is another element of the BOLDER accomplishment. In the study design stages, the BOLDER team identified a niche CRO with specific expertise in this difficult arena. Although this vendor was not on the 'approved list' the team developed a business case and successfully lobbied with the Outsourcing Group for a waiver. This CRO's performance was stellar, and was a significant factor in the study's success.

Delivering a study well ahead of schedule is only valuable to AZ and to our patients if the study quality is high. In depression studies, a high placebo response is common and often causes failed studies when the active compound fails to separate from the placebo arm. The BOLDER team implemented a number of quality strategies – some novel, some old-fashioned hard work – and these strategies were very successful in managing the placebo response rate and ensuring that we delivered a high quality study 8 months early.

Communication is always a key in outperforming projects. The BOLDER team made site and physician investigator communications a priority. This was nowhere better evidenced than in the customized approach to site advertising. AZ CTM lead Robin McCoy partnered with each investigative site to support advertising specifically tailored for that site and market. ROI for this initiative was very high, as was clinical site satisfaction. This strategy contributed significantly to the study's high performance, while confirming AZ's commitment to long term, mutually satisfying relationships with researchers.

In conclusion, in executing the BOLDER study, this team has blown through one original set of target milestone dates and two revised sets of dates. Those original dates were set based on carefully documented industry standards and depression experts outside AZ site the BOLDER study as the most efficiently executed depression study ever. Even more importantly, the BOLDER study provides dramatic evidence of Seroquel's efficacy in a devastating disease state where there is a large unmet patient need. This contribution to the AZ business and to bipolar depression patients everywhere merits special recognition.