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Eli-Lilly- Solanezumab - A Dead or Alive trump card? Does Positive Trend in Mild Alzheimer's Patients Supports an Approval?

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Abstracts

Today, Eli-Lilly announced top line results from most awaited PhIII EXPEDITION trials of Solanezumab. The studies did not meet its primary endpoint both cognitive and functional in mild to moderate Alzheimer's Patients, but demonstrated a statistically significant slowing of cognitive decline in pooled subgroup of mild Alzheimer's disease patients (2/3rd of total study population). The stock price has reacted positively, but we recommend caution, as pooled analysis may not be sufficient for a USFDA approval (in mild patients) and prospectively designed trials would be required. Thus approval timelines may stretch substantially. It should also be noted that EXPEDITION trial allowed approved Alzhemiers medications during the study along with Interventional treatment either with Solanezumab or placebo. The final data which reveals the distribution of add-on approved medications in two treatment arms will be crucial to measure the real efficacy of Solanezumab. Besides with majority of patients (two third) in the trials are with mild Alzheimers, and had the trend of improvement in cognitive function significantly strong in mild patients, we could have as well seen statistically significant efficacy in overall population.

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