**On the Impossible:**

Why Anavex Life Sciences’ blarcamesine will fail approval and the stock will trade at book value

Liam Render

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**Executive Summary**

In this work I will prove that

(high AE, biomarkers not significant, OLE data, no separation (even some worsening) from placebo until 48 weeks)

Conditionals:

1: It didn’t matter that they failed significance in dose-dependent groups in both the ITT and the nominal WT (better) group after Bonferroni correction and failing co-primary ADCS-ADL and they are able to substitute for CDR-SB, and the FDA will consider or even approve based on the combined doses vs placebo. Probability: at most 25%

2: The tipping point analysis which showed a plausible difference is robust enough for the FDA to consider the results of the pooled doses trustworthy and the non-disclosure of the SAP or reasons why the data was changed many times from presentation to presentation isn’t indicative of how trustworthy the results are. Probability: at most 10%

Condition 3: The rejection of pridopidine with similar results and the same mechanism of action in the EMA

https://www.neurology.org/doi/10.1212/WNL.0000000000212224

Total probability at most: 2.5%

The many failures of other sigma-1 agonists in related neurological diseases aren’t indicative of the success in pipeline drugs have a chance of success with the same mechanism and indication of previous drugs that have failed with terrible p values (p=0.81). Probability at most 10% pipeline worth nothing

**Introduction**

Med

**References**

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odd SIGMAR1 research:

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<https://pubmed.ncbi.nlm.nih.gov/37166702/>

<https://www.nature.com/articles/s41467-022-28946-w>

failed SIGMAR1 drugs:

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<https://www.ahajournals.org/doi/10.1161/STROKEAHA.114.005835>

<https://movementdisorders.onlinelibrary.wiley.com/doi/10.1002/mds.28064>

<https://bpspubs.onlinelibrary.wiley.com/doi/10.1111/bcp.14952>

<https://pubmed.ncbi.nlm.nih.gov/31282954/>

Anavex Clinical Trials:

NCT03790709

NCT04314934 OLE

NCT04304482 Rett Syndrome Failed PE