



Biotech Daily

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Botanix Falls 48% As Cannabinoid BTX1503 Misses Acne Endpoint

Botanix says its 368-patient, phase II trial of synthetic cannabinoid BTX1503 for acne did not meet its primary endpoint for reduction of inflammatory lesions at 12 weeks.

Botanix said the randomized, double blind, controlled trial enrolled patients with moderate to severe acne at 35 sites in Australia and the US to evaluate the safety and efficacy of BTX 1503, reductions in inflammatory and non-inflammatory lesions and investigator's global assessment (IGA) score improvements.

The company said the five treatment groups included five percent BTX1503 once daily, five percent BTX1503 twice daily, 2.5 percent BTX1503 once daily and combined vehicle, once or twice daily.

Botanix said top-line data showed that inflammatory lesions were reduced in all dose groups, including the combined vehicle control group.

The company said that the highest efficacy result was for the five percent BTX1503 once daily group, which had a reduction of 11.8 inflammatory lesions or an average 40.54 percent reduction, but the combined vehicle group had a reduction of 11.3 lesions or 40.15 percent, and the difference was not statistically significant.

Botanix did not provide a "p" value for the level of significance between the two groups.

Botanix said that all dose groups reduced the number of non-inflammatory lesions and the 17.3 lesion reduction (34.99%) by the five percent BTX1503 once daily group was statistically significant compared to the 8.3 lesion reduction (19.08%) for the combined vehicle group (p = 0.006).

Botanix said the results were affected by an unusually high vehicle response, limited to the US clinical sites, with Australian results at week 12 showing statistical significance for the five percent BTX1503 twice daily group and all three treatment groups for non-inflammatory lesion reductions.

The company said the combined vehicle showed 7.7 reductions for inflammatory lesions and 4.6 reductions for non-inflammatory lesions in Australia compared to 11.3 and 8.3 for the whole trial.

Botanix said the IGA scores were similar across all treatment groups, ranging from an improvement of 13.2 percent for the 2.5 percent BTX1503 once daily group to 14.1 percent for combined vehicle, 15.2 percent for the five percent BTX1503 once daily and 16.3 percent for the five percent BTX1503 twice daily group.

The company said BTX 1503 was well-tolerated and adverse events were low across all treatment groups, with upper respiratory tract infections.

Botanix said it was planning an end-of-phase II meeting with the US Food and Drug Administration and was preparing for a phase III trial of BTX1503.

Botanix fell 11.5 cents or 47.9 percent to 12.5 cents with 138.8 million shares traded.