DaxibotulinumtoxinA for Injection **ASPEN**[1]

Phase 3 Study for the Treatment of Cervical Dystonia

DaxibotulinumtoxinA for Injection is an investigational agent that is not yet approved by the FDA.

ASPEN[1]

Is a randomized, double-blind, placebo-controlled clinical trial for evaluating the efficacy of **DaxibotulinumtoxinA for Injection** for the treatment of **cervical dystonia**.

The study results suggest that DaxibotulinumtoxinA for Injection has the potential to **REDUCE FREQUENCY OF CERVICAL DYSTONIA** treatments by up to **50% ANNUALLY.**

CERVICAL DYSTONIA is a painful and disabling chronic condition in which the neck muscles contract involuntarily, causing **abnormal movements** and **awkward posture** of the head and neck.[1]

BOTULINUM TOXIN (BoNT) injections are the current standard of care.[2]

ASPEN[1] STUDY SITES

United States, Canada, and Europe

60 study sites

WITH MODERATE TO SEVERE CERVICAL DYSTONIA

Toxin naive and experienced

301 SUBJECTS

3:3:1 randomization

Treated with:

125 U or | 250 U or | PLACEBO

ASPEN[1] MEASURE OF EFFICACY

Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)

TWSTRS was used to assess each patient's severity, pain and disability caused by cervical dystonia over time.

OVERALL IMPACT OF CERVICAL DYSTONIA

on the patients' daily life is **MEASURED BY SEVERITY, PAIN, AND DISABILITY** and is commonly used in the evaluation and treatment of cervical dystonia.

Patients were followed for up to **36 WEEKS.**

DAY: 0
Baseline

WEEK: 4 & 6
Average of weeks 4 and 6

WEEK: 36

PRIMARY ENDPOINT

The average of the change from baseline at weeks 4 and 6 in TWSTRS Total Score.

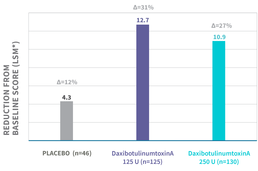
SECONDARY ENDPOINT

Duration of Effect, as defined as time from treatment to loss of 80% of the peak treatment effect achieved at weeks 4 and 6.

STUDY RESULTS →

ASPEN[1]

Met primary and all secondary endpoints with **HIGH STATISTICAL SIGNIFICANCE** at both doses.



p<0.0001 (**125 U** vs. Placebo)
p=0.0006 (**250 U** vs. Placebo)
p=0.1902 (**250 U** vs. **125 U**)

* LSM=Least Square Means.
Δ Change from Baseline

MEDIAN DURATION OF RESPONSE of **24 WEEKS** with 125 U dose of **DaxibotulinumtoxinA for Injection.**

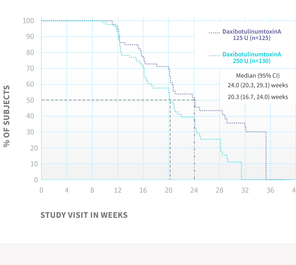
NO UNEXPECTED ADVERSE EVENTS WERE OBSERVED

COMMON ADVERSE EVENTS

Dysphagia (difficulty swallowing) and muscle weakness, are common adverse events of special interest for cervical dystonia treatment with botulinum toxin. Occurrence was low for dysphagia, 1.6% and 3.9%, and for muscular weakness, 4.7% and 2.3%, in the 125 U and 250 U dose groups, respectively.

SECONDARY ENDPOINT

Median time to loss of ≥ 80% of peak treatment effect



For more information contact Medical Affairs at *medicalaffairs@revance.com*

revance

REFERENCES

1. Dystonia Medical Research Foundation. Web Site. https://dystonia-foundation.org/what-is-dystonia/types-dystonia/cervical-dystonia/. Accessed 8/11/20
2. Simpson Metal, Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache Neurology, May 10, 2016.