DAXXIFY® (daxibotulinumtoxinA-lanm injection) | ASPEN 1

Phase 3 Study for the Treatment of Cervical Dystonia

DAXXIFY® is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adults.[1]

ASPEN 1 a randomized, double-blind, placebo-controlled clinical trial for evaluating the safety and efficacy of **DAXXIFY®** for the treatment of **cervical dystonia.**[2]

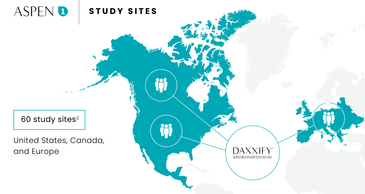
The study results suggest that **DAXXIFY® showed impressive duration,** demonstrating the opportunity for **durable symptom control injection to injection.**[2*]

Median duration of effect, defined as time from treatment until loss of ≥80% of the peak effect (change from baseline in TWSTRS total score averaged across weeks 4 and 6), was 24 weeks with DAXXIFY® 125U and 20.3 weeks with DAXXIFY® 250U. In patients that requested retreatment prior to the loss of ≥ 80% of peak effect, median efficacy remaining was 45% to 54% in ASPEN 1. Median time to retreatment was between 15 and 17 weeks in ASPEN 1 and cycles 1 and 2 in the ASPEN OLS.[2]

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.[4,5]

BOTULINUM TOXIN (BoNT) injections are the current standard of care.[6]

ASPEN 1 STUDY SITES



60 study sites[2]

United States, Canada, and Europe

301 SUBJECTS[2]

with moderate to severe cervical dystonia
Included both toxin naive and experienced

3:3:1 RANDOMIZATION[2]

125U | *250U* | *PLACEBO*

ASPEN 1 MEASURE OF EFFICACY[2]

Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS)

TWSTRS measures the overall impact of cervical dystonia on the patient's daily life **in terms of severity, pain, and disability over time** and is commonly used in the evaluation and treatment of cervical dystonia.[7]

Patients were followed for up to **36 Weeks**[2]

DAY: 0
Baseline

WEEK: 4 & 6
Average of weeks 4 and 6

WEEK: 36

PRIMARY ENDPOINT[2]
The average of the change from baseline at weeks 4 and 6 in TWSTRS total score.

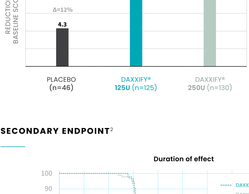
SECONDARY ENDPOINT[2]
Duration of effect, defined as time from treatment to loss of 80% of the peak treatment effect achieved at weeks 4 and 6.

Study Results

DAXXIFY® met primary and secondary endpoints with high statistical significance at both doses.[2]

PRIMARY ENDPOINT[2]

Change from baseline in TWSTRS total score at weeks 4 and 6

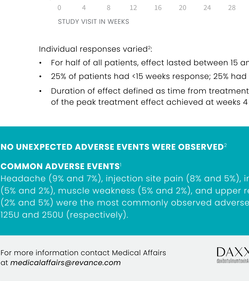


p=0.0001 (125U vs Placebo)
p=0.0006 (250U vs Placebo)

* LSM=Least Square Means
& Change from Baseline

SECONDARY ENDPOINT[2]

Duration of effect



Individual responses varied[2]:

- For half of all patients, effect lasted between 15 and 28 weeks
- 25% of patients had <15 weeks response; 25% had >28 weeks
- Duration of effect defined as time from treatment to loss of 80% of the peak treatment effect achieved at weeks 4 and 6

NO UNEXPECTED ADVERSE EVENTS WERE OBSERVED[2]

COMMON ADVERSE EVENTS[2]
Headache (9% and 7%), injection site pain (8% and 5%), injection site erythema (5% and 2%), muscle weakness (5% and 2%), and upper respiratory tract infection (2% and 5%) were the most commonly observed adverse events for DAXXIFY® 125U and 250U (respectively).

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

DAXXIFY® (daxibotulinumtoxinA-lanm injection) | REVANCE THERAPEUTICS

REFERENCES

1. DAXXIFY® Prescribing Information. Revance Therapeutics, Inc; 2023.
2. Data on File. ASPEN CSR. Newark, CA: Revance Therapeutics, Inc; 2018.
3. Data on File. ASPEN OLS CSR. Newark, CA: Revance Therapeutics, Inc; 2018.
4. Dystonia Medical Research Foundation. Cervical Dystonia. Dystonia Medical Research Foundation website. https://dystonia-foundation.org/what-is-dystonia/types-dystonia/cervical-dystonia/. Updated 2023. Accessed May 31, 2023.
5. Vu JP, Lee HY, Chen Q, et al. Head tremor and pain in cervical dystonia. J Neurol. 2021;268(5):1949-1950.
6. Simpson DM, Hallett M, Ashman EJ, et al. Practice guideline update summary: Botulinum neurotoxin for the treatment of blepharospasm, cervical dystonia, adult spasticity, and headache: Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2016;86(19):1818-1826.
7. Jost WH, Vetter H, Stenner A, Reichel G. Rating scales for cervical dystonia: a critical evaluation of tools for outcome assessment of botulinum toxin therapy. J Neural Transm (Vienna). 2013;120(3):487-496.

INDICATION
DAXXIFY® (daxibotulinumtoxinA-lanm) injection is an acetylcholine release inhibitor and neuromuscular blocking agent indicated for the treatment of cervical dystonia in adults.

WARNING: DISTANT SPREAD OF TOXIN EFFECT
The effects of DAXXIFY® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. DAXXIFY® is not approved for the treatment of spasticity or any conditions other than cervical dystonia and glabellar lines.

IMPORTANT SAFETY INFORMATION

Contraindications
DAXXIFY® contraindications include hypersensitivity to any botulinum toxin preparation or any of the components in the formulation and infection at the injection site(s).

Warnings and Precautions
Please refer to Boxed Warning for Distant Spread of Toxin Effect.

The potency units of DAXXIFY® are not interchangeable with preparations of other botulinum toxin products. Recommended dose and frequency of administration should not be exceeded. Patients should seek immediate medical attention if respiratory, speech or swallowing difficulties occur. Use caution when administering to patients with pre-existing cardiovascular disease. Concomitant neuromuscular disorders may exacerbate clinical effects of treatment.

Adverse Reactions
The most commonly observed adverse reactions (≥5%) were headache (9%), injection site pain (8%), injection site erythema (5%), muscular weakness (5%), and upper respiratory tract infection (5%).

Drug Interactions
Co-administration of DAXXIFY® and aminoglycoside antibiotics, anticholinergic agents or any other agents interfering with neuromuscular transmission or muscle relaxants should only be performed with caution as the effect of DAXXIFY® may be potentiated. The effect of administering different botulinum neurotoxins during course of treatment with DAXXIFY® is unknown.

Use in Specific Populations
DAXXIFY® is not recommended for use in children or pregnant women.

Please see DAXXIFY® full Prescribing Information, including Boxed Warning and Medication Guide.

To report side effects associated with DAXXIFY®, please visit safety.revance.com or call 1-877-373-8669. You may also report side effects to the FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

DAXI-0047215