A Phase 3, Open-label, Multi-center Trial to Evaluate the Long-term Safety and Efficacy of Repeat Treatments of DaxibotulinumtoxinA for Injection in Adults With Isolated Cervical Dystonia

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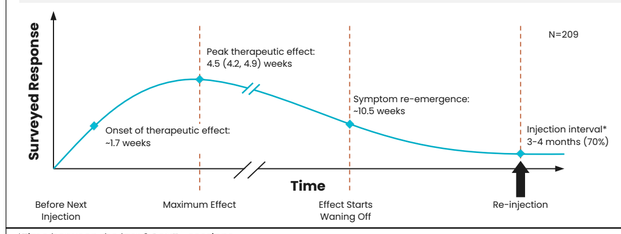
Introduction

Cervical Dystonia and Botulinum Toxin Treatment

- Cervical dystonia (CD), or spasmodic torticollis, is a chronic condition characterized by involuntary contractions of neck muscles, often associated with discomfort or pain[1]
- Botulinum toxin injections are first-line treatment for CD, with ~85% of patients receiving injections[2]
- Patients treated with currently approved botulinum toxin products typically receive re-treatment every 12-14 weeks[3-5]
- 88% of patients report the reappearance of pre-existing symptoms between botulinum toxin injections[6]
- 71% of patients would like longer-lasting benefits[6]

Patient Experiences With Botulinum Toxins Suggest Symptoms Re-emerge Before Being Re-treated[6]

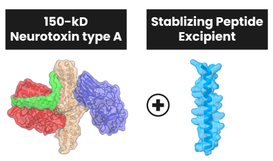
Respondents were asked: On average, how many days or weeks after your BoNTA injections do you experience: (1) The first effect of the treatment on your CD; and (2) The maximum effects of the treatment on your CD (in days or weeks). In general, how long after your BoNTA injections do your pre-existing symptoms begin to reappear?



*Time between the last 2 BoNTA sessions.
BoNTA, botulinum toxin type A; CD, cervical dystonia.

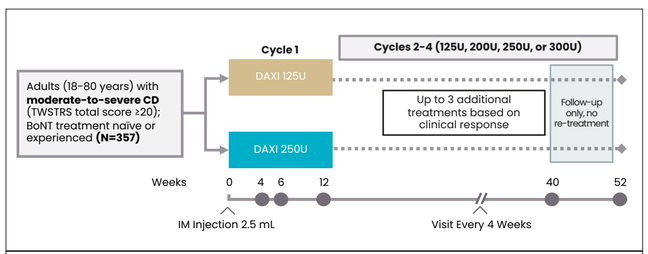
DaxibotulinumtoxinA-lanm for Injection (DAXI)

- DAXI is a long-acting formulation of botulinum toxin type A in development for the treatment of CD, as well as other indications, including glabellar lines and upper limb spasticity
- DAXI is composed of a purified 150-kD botulinum toxin formulated with a stabilizing peptide excipient that binds electrostatically to negatively charged surfaces on the neurotoxin[7]
- In vitro data suggest that the peptide increases affinity of the botulinum toxin for cell membranes[8]
- In a Phase 2, open-label, dose-escalation study of DAXI in patients with moderate-to-severe CD, DAXI demonstrated efficacy and extended duration of effect in adults with CD[9]
- In the Phase 3, randomized, controlled, single-dose study, ASPEN-1, DAXI demonstrated efficacy and extended duration of effect in adults with CD[10]
  - Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) total scores were significantly improved at Weeks 4 and 6 vs placebo ($p<0.0001$, 125U vs placebo; $p=0.0006$, 250U vs placebo)
  - Median duration of effect was 24 weeks for the 125U dose and 20 weeks for the 250U dose
- ASPEN-OLS is a Phase 3 open-label study to evaluate the long-term safety and efficacy of up to 4 repeat treatments of DAXI
- DAXI has not yet been approved for CD



ASPEN-OLS Methods and Study Design

- ASPEN-OLS was conducted across 65 sites in the USA, Canada, the UK, and the EU
- Subjects were rolled over from the 36-week, double-blind, placebo-controlled, single-dose study, ASPEN-1 (n=271), or were enrolled de novo (n=86)
- Subjects received up to 4 DAXI treatment cycles in ASPEN-OLS:
  - Cycle 1: DAXI 125U or 250U was selected by the investigator according to predefined clinical criteria, including the subject's CD severity and botulinum toxin treatment history
  - Cycles 2-4: The investigator could administer the same dose as in Cycle 1 or increase or decrease the subject's dose by 1 dose step per cycle based on clinical judgment of the subject's response in the prior cycle



BoNT, botulinum toxin; CD, cervical dystonia; DAXI, DaxibotulinumtoxinA-lanm for injection; IM, intramuscular; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

Results

Subject Exposure

	ASPEN-OLS (N=358)*
DAXI treatment in ASPEN-OLS	
Total number of DAXI treatments	985
Treatments by cycle	N (%)
Cycle 1	357 (99.7)
Cycle 2	329 (91.9)
Cycle 3	234 (65.4)
Cycle 4	65 (18.2)

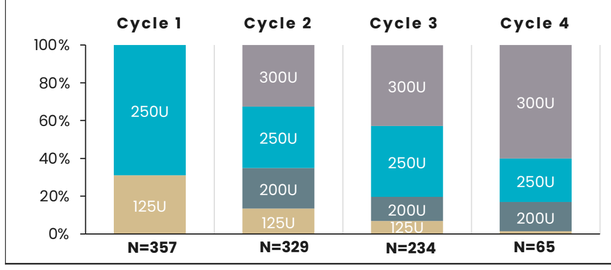
*One additional enrolled subject was ineligible and did not receive study treatment; the subject was excluded from the efficacy and safety analyses.
DAXI, DaxibotulinumtoxinA-lanm for injection.

Demographics and Baseline Characteristics

	ASPEN-OLS (N=357)
Sex, female, n (%)	238 (66.7)
Age, years	
Mean (SD)	57.6 (11.9)
Range	19-80
Race, n (%)	
White	342 (95.8)
Black/African American	6 (1.7)
Other*	9 (2.5)
Baseline TWSTRS total score	
Mean (SD)	43.3 (10.1)
Range	17-75
CD duration, years, mean (SD)	10.4 (9.1)
Prior BoNT for CD, n (%)	291 (81.5)

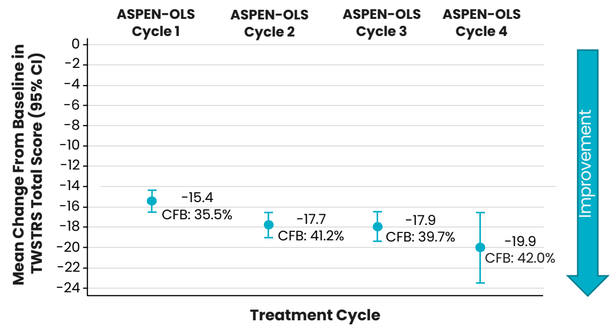
*Other includes Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and other.
BoNT, botulinum toxin; CD, cervical dystonia; SD, standard deviation; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

Dose Progression With Repeat Treatment



- Investigators chose the Cycle 1 dose (125U or 250U) based on prior botulinum toxin dose and disease severity
- Subsequent doses could increase or decrease based on clinical judgment
- Doses administered:
  - Cycle 1:
    - 31% of subjects received 125U
    - 69% of subjects received 250U
  - Cycles 2-4:
    - 77% of subjects received a dose of 250U or higher
    - Only 13% of subjects remained on 125U for all treatments
- The average final dose across all subjects was 243.4U

Change From Baseline in TWSTRS Total Score Averaged Over Weeks 4 and 6



CI, confidence interval; CFB, change from baseline; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

- Efficacy was substantial and increased with successive treatments

Duration of Effect

Duration	Cycle 1 DAXI 125U	Cycle 1 DAXI 250U	Cycle 1 Total	Cycle 2 DAXI 125U	Cycle 2 DAXI 200U	Cycle 2 DAXI 250U	Cycle 2 DAXI 300U	Cycle 2 Total
Time (weeks) to reach target TWSTRS score*	21.3	19.9	20.1	26.0	21.0	20.1	20.1	20.1

*Time to reach target TWSTRS score (time from treatment to loss of ≥80% of peak treatment effect) in weeks.
DAXI, DaxibotulinumtoxinA-lanm for injection; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

- No consistent pattern was observed between doses
- Subjects could not be re-treated past Week 40, due to a 52-week limit on study participation
- Cycles 3 and 4 were artificially truncated due to total study duration and are not included in these analyses; durations presented are Kaplan-Meier median estimates in weeks

TEAEs by Treatment Cycle

	Cycle 1 (n=357)	Cycle 2 (n=329)	Cycle 3 (n=234)	Cycle 4 (n=65)	Rate Per Treatment (N=985 Treatments)
Subjects with TEAEs, %					
Any TEAEs	48.2	40.7	41.9	33.8	85.3
Any treatment-related TEAEs	21.0	17.0	19.7	13.8	28.2
Serious TEAEs*	0.6	1.8	3.4	1.5	1.9
Any AESI based on investigator assessment	9.5	10.9	13.2	9.2	14.3
TEAEs leading to death	0	0.3	0	0	0.1
TEAEs leading to study discontinuation	0.3	0	0.9	0	0.3
Subjects with treatment-related TEAEs, %					
Any treatment-related TEAEs	21.0	17.0	19.7	13.8	28.2
Dysphagia	3.9	4.3	4.7	3.1	4.2
Muscular weakness	4.2	4.6	6.4	3.1	4.9
Injection site pain	4.2	2.1	0.9	3.1	2.7
Injection site erythema	2.2	1.8	3.0	1.5	2.2
Neck pain	1.4	1.2	1.3	0	1.2

*No serious TEAEs were treatment related.
Note: Musculoskeletal pain: Cycle 1, 2 subjects and 2 events; Cycle 2, 0 events; Cycles 3 and 4, 1 subject and 1 event.
AESI, adverse event of special interest; TEAE, treatment-emergent adverse event.

Summary of Safety

- ASPEN-OLS confirmed the safety profile of DAXI established in the ASPEN-1 pivotal study,[10] with no new tolerability or safety concerns reported and stable or decreasing rates of adverse events (AEs) with repeat dosing
- Higher doses of DAXI were well tolerated and not associated with increased risk of AEs
  - Overall incidence rate and rates of the most common preferred terms were generally stable across the 4 cycles
- Treatment-related AEs occurred in 34.2% of subjects overall, which was consistent with ASPEN-1 (26.7%)
  - The incidence of treatment-related AEs generally decreased with repeat treatment, from 21.0% in Cycle 1 to 13.8% in Cycle 4
  - The most frequently reported side effects related to the effects of the toxin itself were dysphagia and muscular weakness, which were observed in ASPEN-OLS at rates comparable with rates reported for other botulinum toxin type A treatments (dysphagia 10-25% and muscular weakness 2-8%[3-5,11])
- No treatment-related serious AEs were observed

Summary of Efficacy

- ASPEN-OLS confirmed the efficacy and safety results observed in ASPEN-1 and demonstrated continued improvement of CD signs and symptoms with repeat dosing of DAXI
- Improvement in TWSTRS total score from baseline was observed in all treatment cycles
  - In general, the degree of improvement numerically increased across treatment cycles
- Doses were adjusted based on clinical judgment
  - With subsequent cycles, patients tended to receive higher doses, resulting in an average final dose of 243U
  - Only 13% of patients remained on 125U for all treatments
- Median duration of effect, defined by time to loss of ≥80% of peak treatment effect, ranged from 19.9 to 26.0 weeks across treatment Cycles 1 and 2 and DAXI doses, which is consistent with the duration observed in ASPEN-1 of 24.0 weeks for DAXI 125U and 20.3 weeks for DAXI 250U[11]

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S. Paus: Employee at GFO Clinics Troisdorf, Troisdorf, Germany; has served on scientific advisory boards for BIAL, Ipsen, and Merz; and has received honoraria for speaking engagements from AbbVie, Acadia, Allergan, Bayer Healthcare, Ipsen, and Merz.

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T.M. Gross and **D. Vitarella:** Employees and stockholders of Revance Therapeutics, Inc.

R.G. Rubio and **J.P. Kesslak:** Employees of Revance Therapeutics, Inc. at the time of the study.

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Efficacy of DaxibotulinumtoxinA for Injection Over Successive Treatments in Adults With Isolated Cervical Dystonia in the Phase 3 ASPEN-1 and ASPEN-OLS Trials

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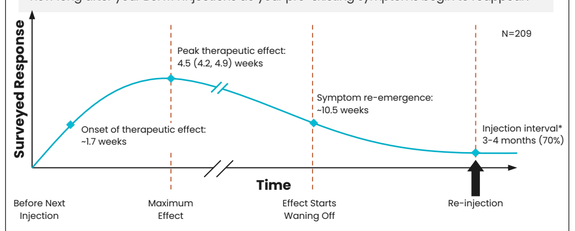

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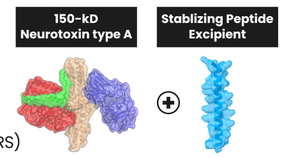
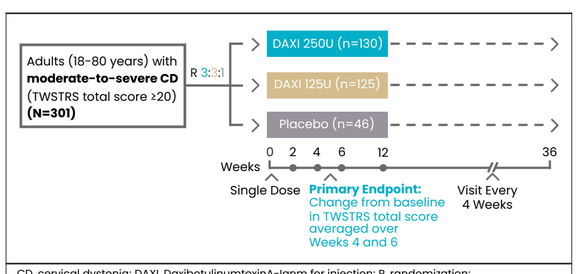


- ASPEN-OLS is a Phase 3 open-label study to evaluate the long-term safety and efficacy of up to 4 repeat treatments of DAXI
- DAXI has not yet been approved for CD

ASPEN-1 Study Design

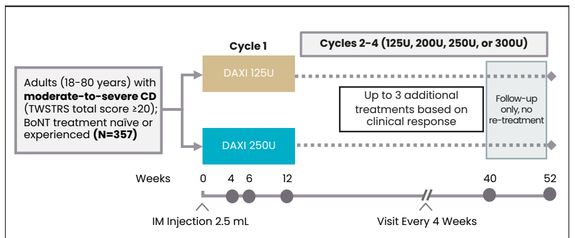
- ASPEN-1 was a Phase 3, single-dose, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of 2 doses of DAXI for the treatment of CD over 36 weeks across 60 sites in the USA, Canada, the UK, and the EU



CD, cervical dystonia; DAXI, DaxibotulinumtoxinA-lanm for injection; R, randomization; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

ASPEN-OLS Methods and Study Design

- ASPEN-OLS was conducted across 65 sites in the USA, Canada, the UK, and the EU
- Subjects were rolled over from the 36-week, double-blind, placebo-controlled, single-dose study, ASPEN-1 (n=271), or were enrolled de novo (n=86)
- Subjects received up to 4 DAXI treatment cycles in ASPEN-OLS:
  - Cycle 1: DAXI 125U or 250U was selected by the investigator according to predefined clinical criteria, including the subject's CD severity and botulinum toxin treatment history
  - Cycles 2-4: the investigator could administer the same dose as in Cycle 1 or increase or decrease the subject's dose by 1 dose step per cycle based on clinical judgment of the subject's response in the prior cycle



BoNT, botulinum toxin; CD, cervical dystonia; DAXI, DaxibotulinumtoxinA-lanm for injection; IM, intramuscular; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

Results

Subject Exposure

	ASPEN-OLS (N=358)*
DAXI treatment in ASPEN-OLS	
Total number of DAXI treatments	985
Number of DAXI treatments in ASPEN-1	255
Number of subjects across both studies	382
Treatments by cycle	N (%)
Cycle 1	357 (99.7)
Cycle 2	329 (91.9)
Cycle 3	234 (65.4)
Cycle 4	65 (18.2)

*One additional enrolled subject was ineligible and did not receive study treatment; the subject was excluded from the efficacy and safety analyses.
DAXI, DaxibotulinumtoxinA-lanm for injection.

Demographics and Baseline Characteristics

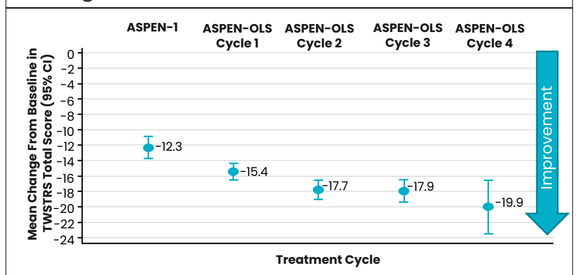
	ASPEN-1 (N=301)	ASPEN-OLS (N=357)
Sex, female, n (%)	195 (64.8)	238 (66.7)
Age, years		
Mean (SD)	57.7 (12.0)	57.6 (11.9)
Range	18-80	19-80
Race, n (%)		
White	287 (95.3)	342 (95.8)
Black/African American	6 (2.0)	6 (1.7)
Other*	8 (2.7)	9 (2.5)
Baseline TWSTRS total score		
Mean (SD)	43.3 (9.3)	43.3 (10.1)
Range	20.3-72.0	17-75
CD duration, years, mean (SD)	10.8 (9.2)	10.4 (9.1)
Prior BoNT for CD, n (%)	254 (84.4)	291 (81.5)

*Other includes Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and other.
BoNT, botulinum toxin; CD, cervical dystonia; SD, standard deviation; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

Dose Escalation for ASPEN-1 and ASPEN-OLS

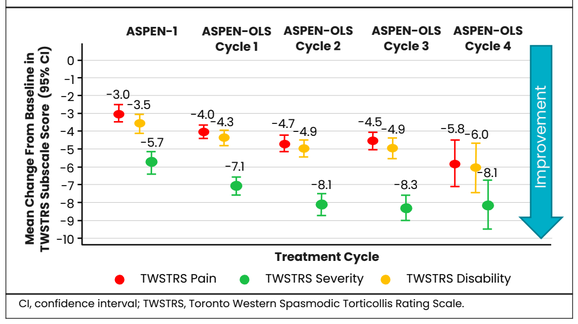
- ASPEN-1
  - Randomized treatment assignment
  - Approximately equal subjects were dosed with 125U and 250U
    - 130 subjects were dosed with 250U and 125 subjects were dosed with 125U
- ASPEN-OLS
  - Investigators chose the Cycle 1 dose (125U or 250U) based on prior toxin dose and disease severity
  - Subsequent doses could increase or decrease based on clinical judgment
  - Doses administered:
    - Cycle 1:
      - 31% of subjects received 125U
      - 69% of subjects received 250U
    - Cycles 2-4:
      - 77% of subjects received a dose of 250U or higher
      - Only 13% of subjects remained on 125U for all treatments
  - The average final dose across all subjects was 243.4U

Change From Baseline in TWSTRS Total Score Averaged Over Weeks 4 and 6



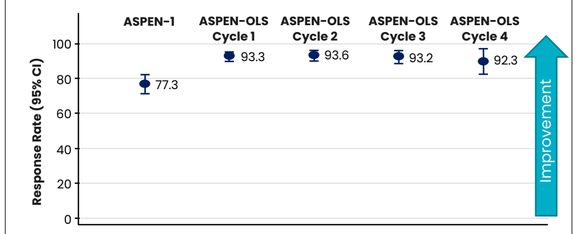
CI, confidence interval; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

Change From Baseline in TWSTRS Subscale Scores Averaged Over Weeks 4 and 6



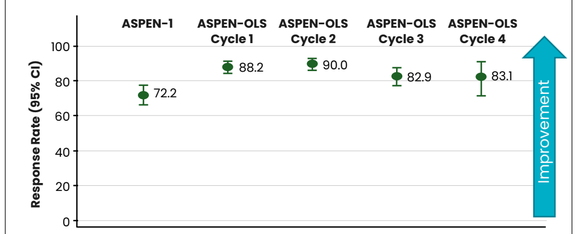
CI, confidence interval; TWSTRS, Toronto Western Spasmodic Torticollis Rating Scale.

Responder at Week 4 or 6 in CGIC



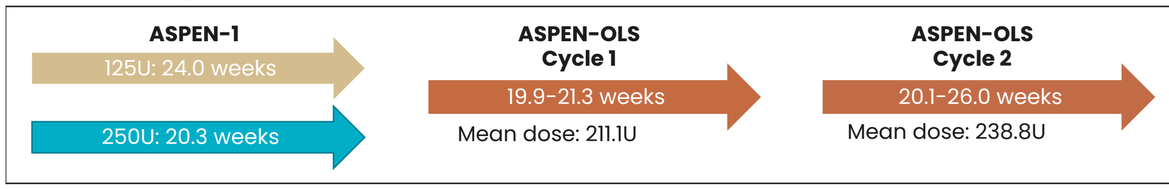
Note: Responder is defined as a response of a little better (+1), moderately better (+2), or very much better (+3) at Week 4 or 6. Missing responses for subjects still on study at Week 4 are considered as about the same (0).
CGIC, Clinical Global Impression of Change; CI, confidence interval.

Responder at Week 4 or 6 in PGIC



Note: Responder is defined as a response of a little better (+1), moderately better (+2), or very much better (+3) at Week 4 or 6. Missing responses for subjects still on study at Week 4 are considered as about the same (0).
CI, confidence interval; PGIC, Patient Global Impression of Change.

Duration of Response in ASPEN-1 and ASPEN-OLS



- The median duration of effect across doses, defined as time to loss of ≥80% of peak treatment effect, ranged from 19.9 to 26.0 weeks in the evaluable cycles and was consistent with ASPEN-1[10]
- No consistent pattern was observed between doses
- Subjects could not be re-treated past Week 40 due to the 52-week limit on study participation
- Cycles 3 and 4 are not applicable because they are artificially truncated due to total study duration; durations presented are Kaplan-Meier median estimates in weeks

TEAEs by DAXI Cycle

	ASPEN-1	ASPEN-OLS				
	ASPEN-1 (n=255)	Cycle 1 (n=357)	Cycle 2 (n=329)	Cycle 3 (n=234)	Cycle 4 (n=65)	Rate Per Treatment (N=985 Treatments)
Subjects with treatment-related TEAEs, %						
Any treatment-related TEAEs	26.7	21.0	17.0	19.7	13.8	28.2
Dysphagia	2.7	3.9	4.3	4.7	3.1	4.2
Muscular weakness	3.5	4.2	4.6	6.4	3.1	4.9
Injection site pain	6.7	4.2	2.1	0.9	3.1	2.7
Injection site erythema	3.5	2.2	1.8	3.0	1.5	2.2
Neck pain	3.5	1.4	1.2	1.3	0	1.2

Note: Musculoskeletal pain: Cycle 1, 2 subjects and 2 events; Cycle 2, 0 events; Cycles 3 and 4, 1 subject and 1 event.
DAXI, DaxibotulinumtoxinA-lanm for injection; TEAE, treatment-emergent adverse event.

Summary of Efficacy and Safety

- ASPEN-OLS confirmed the efficacy and safety results observed in ASPEN-1 and demonstrated continued improvement of CD signs and symptoms with repeat dosing of DAXI
  - With subsequent cycles, patients tended to receive higher doses, resulting in an average final dose of 243U; only 13% of patients remained on 125U for all treatments
- Improvement in TWSTRS total score from baseline was observed in all treatment cycles
  - In general, the degree of improvement numerically increased across from ASPEN-1 to Cycle 4 of ASPEN-OLS
  - Similar trends for increasing change from baseline over successive cycles were seen for TWSTRS subscales of pain, disability, and severity
- CGIC and PGIC responder rates at Week 4 or 6 also increased from ASPEN-1 to Cycle 4 of ASPEN-OLS
- ASPEN-OLS confirmed the safety profile of DAXI established in the ASPEN-1 pivotal study with no new tolerability or safety concerns reported and stable or decreasing rates of adverse events across 4 treatment cycles
  - Higher doses of DAXI were well tolerated and not associated with increased risk of AEs

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