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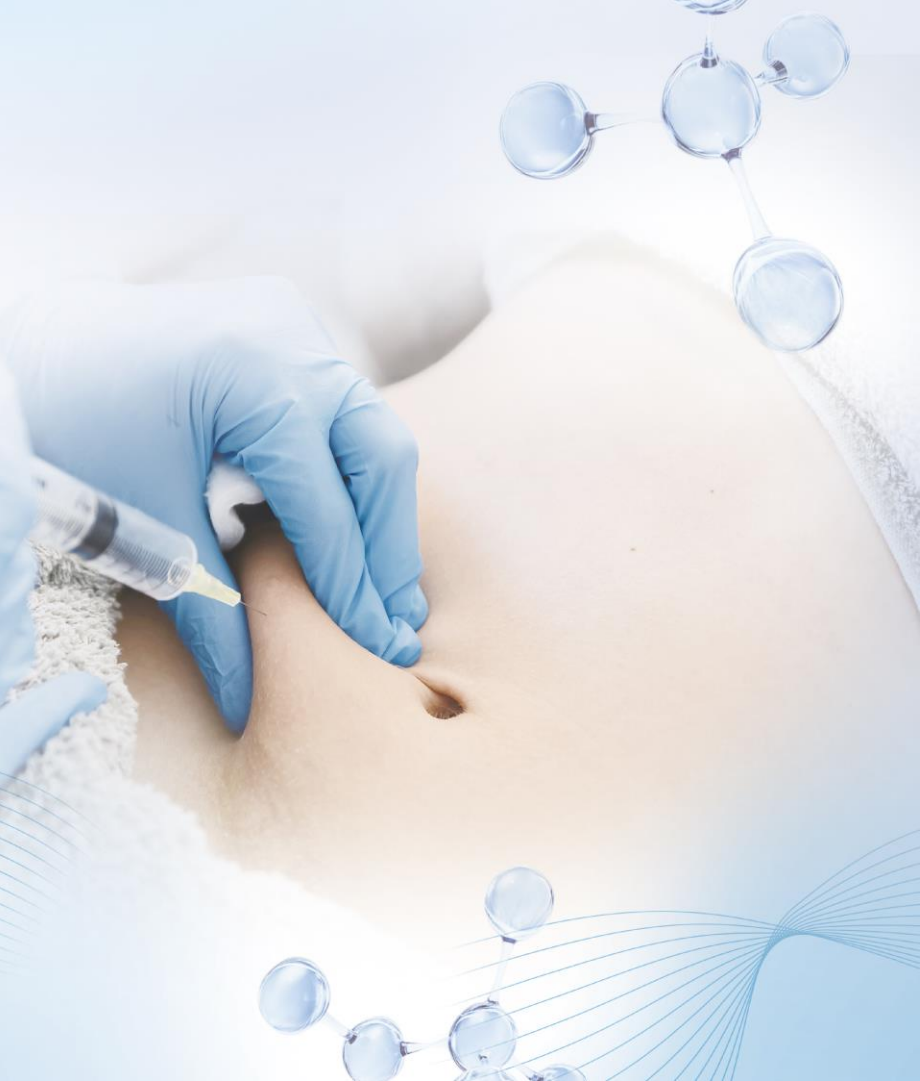
Caliway Biopharmaceuticals



Earnings Call -
CBL-514 Phase 2b Study Results(CBL-0204) for Local Fat Reduction

December 18th, 2024

A Randomized, Placebo-Controlled, Phase 2b Study to Evaluate the Efficacy, Safety and Tolerability of CBL-514 Injection for Reducing Abdominal Subcutaneous Fat

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CBL-0204 Phase 2b Protocol Overview

Study design	• Phase 2b • Randomized • Double Masking (Participant, Outcomes Assessor
Treatment	• On **abdomen** • Parallel assignment • 2 groups: 110 subjects in total, 1:1 - **CBL-514** - **Placebo**
Enrollment Criteria	• BMI **>18.5 and <30 kg/m²** with body weight ≥ 50 kg • **Abdominal fat in Grade 3 or 4** using abdominal fat rating scale (AFRS) • Good skin condition on treatment area • No folding fat or skin on abdomen • No severe abdominal visceral fat • Generally in good health including liver/renal/coagulation/immune function and blood sugar, free from infectious disease and cancer

Visit schedule	• Screening • Treatment - **Up to 4 courses, once every 3 weeks** • Follow-up - **4, 8, 12 weeks post final treatment**
Locations	• United States: 10 sites • Australia: 2 sites
Recruitment	• Planned to enroll 110 subjects • Actually enrolled 107 subjects - **52 CBL-514 subjects** - **55 Placebo subjects**
Timeline *(US time)*	• 1st subject dosed: **Jul2023** • Last subject dosed: **Jan2024** • Last subject last visit: **May2024** • Study results release: **Dec 2024**
ClinicalTrial.gov	NCT05736107

CBL-0204 Phase 2b Endpoints

Efficacy Endpoint - Primary

- Percentage of participants with at least **1-grade improvement** reported by **Investigator** using the CR-AFRS compared with placebo at 12 weeks after the final treatment.

Efficacy Endpoints - Secondary

- Percentage of participants with at least **1-grade improvement** reported by **Investigator** using the CR-AFRS compared with placebo at 4 weeks, and 8 weeks after the final treatment.
- Percentage of participants with at least **2-grade improvement** reported by **Investigator** using the CR-AFRS compared with placebo at 4 weeks, 8 weeks, and 12 weeks after the final treatment.
- Percentage of participants with at least **1-grade improvement** reported by **participant using PR-AFRS compared** with placebo at 4 weeks, 8 weeks, and 12 weeks after the final treatment
- **Number of treatments required** to first occurrence of a **CR-AFRS improvement** reported by **Investigator**.
- Percentage of participant who lose at least **20% of subcutaneous fat volume** compared to baseline measured by MRI compared with placebo at 4 weeks and 12 weeks after the final treatment.
- Percentage of participant who lose at least **20 % of subcutaneous fat thickness** compared to baseline measured by MRI compared with placebo at 4 weeks and 12 weeks after the final treatment.
- **The percentage change in subcutaneous fat thickness** compared to baseline measured by MRI at 4 weeks and 12 weeks after the final treatment.

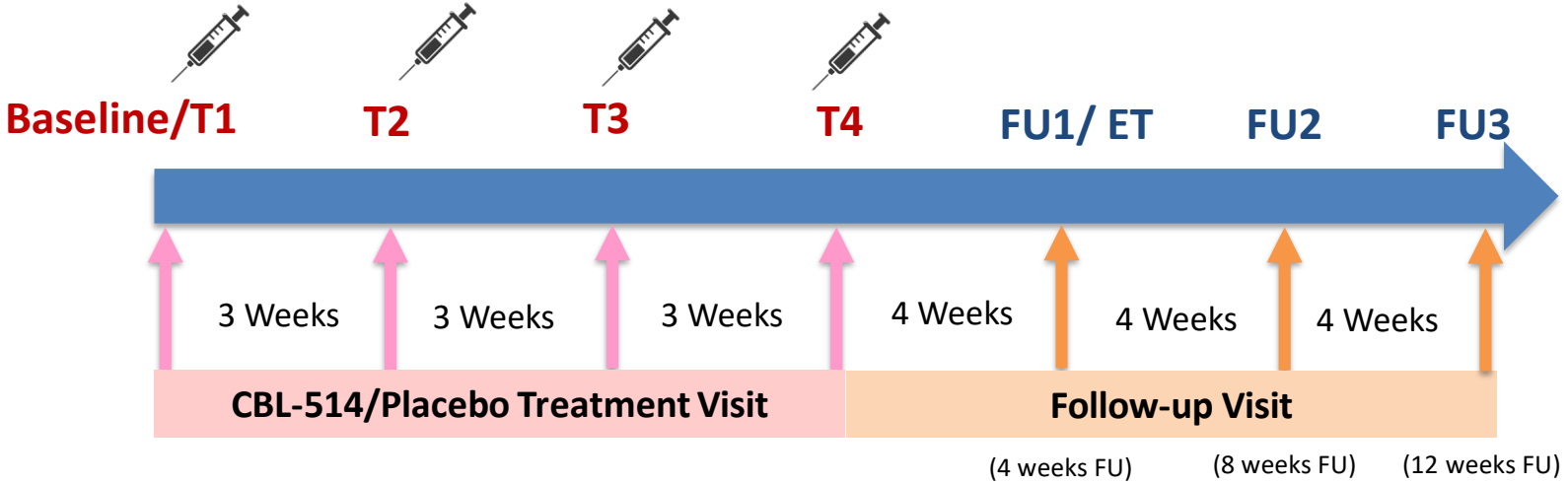
CBL-0204 Phase 2b

Study Results Highlights

- CBL-0204 Phase 2b study results **met all the primary and secondary endpoints**.
- At 12 weeks after the last treatment, **81.8%** of participants treated with CBL-514 compared with placebo (16.7%) achieved an improvement of **1 or more grades** reported by the Investigator using the **CR-AFRS** ($p < 0.0005$).
- At 12 weeks after the last treatment, **81.8%** of participants treated with CBL-514 compared with placebo (17.2%) achieved an improvement of **1 or more grades** reported by participants using the **PR-AFRS** ($p < 0.0002$).
- At 12 weeks after the last treatment, **32%** of participants treated with CBL-514 compared with placebo (0%) achieved an improvement of **2 or more grades** reported by the Investigator using the **CR-AFRS** ($p < 0.002$).
- At 4 weeks after the last treatment, **66.7%** and **61.1%** of participants **treated with CBL-514** lost at least 150mL ($p < 0.00001$) and at least 20% ($p < 0.00005$) of subcutaneous fat volume compared with placebo, respectively, as assessed by MRI.
- **58.82%** of the participants only required one CBL-514 treatment to achieve **at least 1-grade CR-AFRS** improvement.

CBL-0204 Phase 2b Study –Visit Schedule

- **Screening**
- **Treatment**
  - **Up to 4 courses** and **up to 600mg (50 injection)** per course (treatment) , once every 3 weeks,
- **Follow-up**
  - **4** , **8** and **12 weeks** post final treatment



CBL-0204 Phase 2b Study Result

◆ Analysis Population

Population	Safety	Full Analysis Set	Per protocol
Overall	107	100	53
CBL-514 group	52	49	23
Placebo group	55	51	30

Full Analysis Set Population:

The full analysis set (FAS) population will be all eligible participants who are randomized to receive at least one course of IP and contribute qualified baseline efficacy data and at least one post-dose efficacy data point.

According to ICH E9 Statistical Principles for Clinical Trials, **the analysis results of FAS and the Intention-to-Treat (ITT) are the same.**

CBL-0204 Efficacy Data of AFRS Improvement

CBL-0204 Phase 2b Study Result

Primary Endpoints:

Percentage of participants with **at least 1-grade improvement** reported by Investigator using the Clinician-Reported Abdominal Fat Rating Scale **(CR-AFRS)** compared with placebo at **12 weeks** after the final treatment.

81.8% of participants treated with CBL-514 compared with placebo (16.7%) achieved an improvement of **1 or more grades** reported by the Investigator using the **CR-AFRS** (p< 0.0005) at W12.

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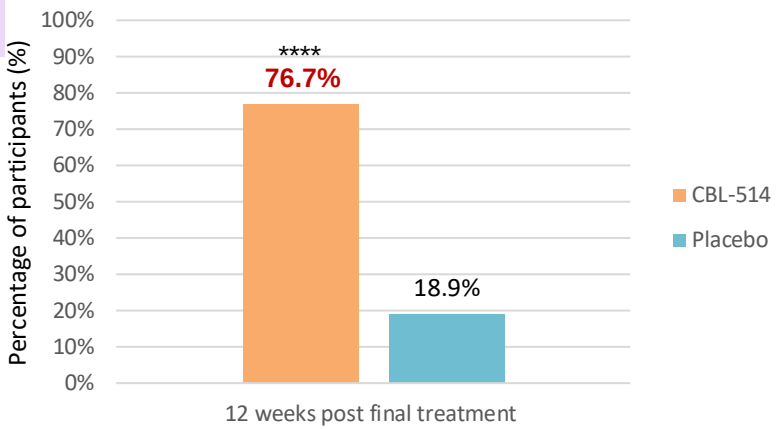

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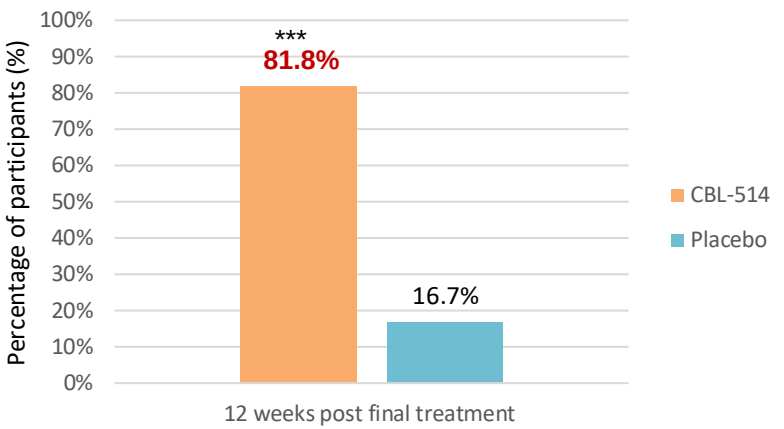

Percentage of participants with at least 1-grade improvement reported by Investigator using CR-AFRS	CBL-514	Placebo	*p value*
12 weeks post final treatment	76.7% (23/30)	18.9% (7/37)	<0.00005

Percentage of participants with at least 1-grade improvement reported by Investigator using CR-AFRS	CBL-514	Placebo	*p value*
12 weeks post final treatment	81.8% (18/22)	16.7% (5/30)	<0.0005

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by logistic regression model.*

CBL-0204 Phase 2b Study Result

Secondary Endpoints:

Percentage of participants with **at least 1-grade improvement** reported by Investigator using **CR-AFRS** compared with placebo at **4 weeks, and 8 weeks** after the final treatment.

Compared with the placebo, more participants treated with CBL-514 improved **1 or more grades** reported by the Investigator using the CR-AFRS at W4 and W8.

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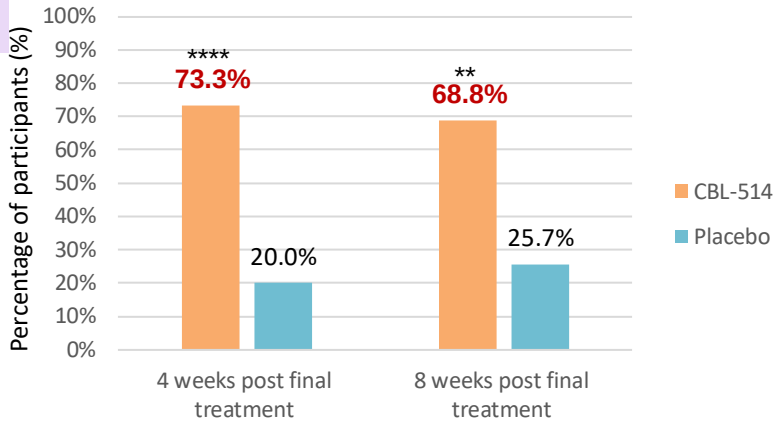

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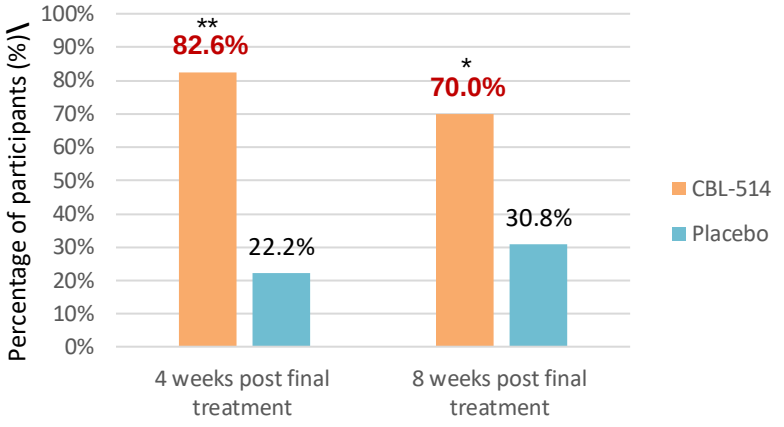

Percentage of participants with at least 1-grade improvement reported by Investigator using CR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	73.3% (33/45)	20.0% (8/40)	0.00001
8 weeks post final treatment	68.8% (22/32)	25.7% (9/35)	<0.002

Percentage of participants with at least 1-grade improvement reported by Investigator using CR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	82.6% (19/23)	22.2% (6/27)	<0.002
8 weeks post final treatment	70.0% (14/20)	30.8% (8/26)	<0.02

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by logistic regression model.*

CBL-0204 Phase 2b Study Result

Secondary Endpoints:

Percentage of participants with **at least 2-grade improvement** reported by Investigator using **CR-AFRS** compared with placebo at **4 weeks, 8 weeks, and 12 weeks** after the final treatment.

Compared with the placebo, more participants treated with CBL-514 improved **2 or more grades** reported by the Investigator using the CR-AFRS at W4, W8, and W12.

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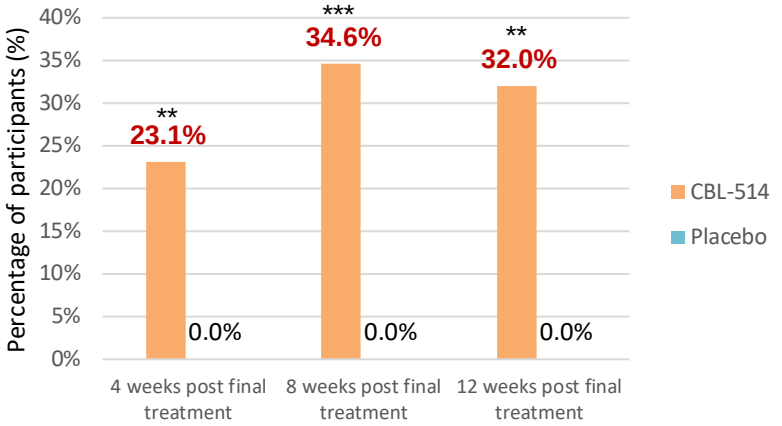

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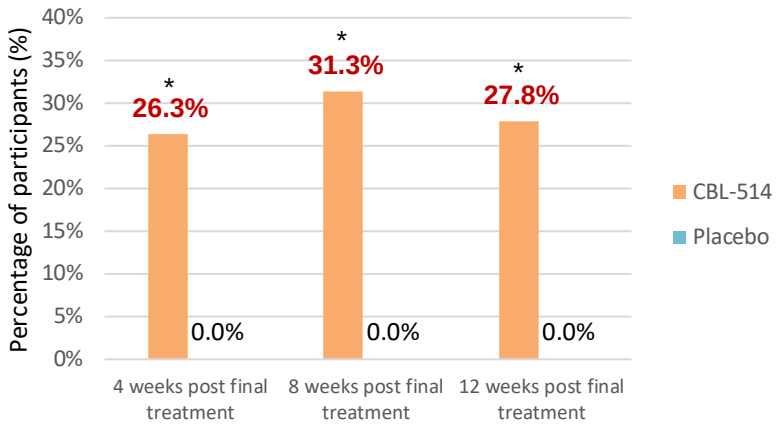

Percentage of participants with at least 2-grade improvement reported by Investigator using CR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	23.1% (9/39)	0.0% (0/33)	<0.005
8 weeks post final treatment	34.6% (9/26)	0.0% (0/27)	<0.001
12 weeks post final treatment	32.0% (8/25)	0.0% (0/28)	<0.002

Percentage of participants with at least 2-grade improvement reported by Investigator using CR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	26.3% (5/19)	0.0% (0/21)	<0.02
8 weeks post final treatment	31.3% (5/16)	0.0% (0/19)	<0.02
12 weeks post final treatment	27.8% (5/18)	0.0% (0/23)	<0.02

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by Fisher's exact test.*

CBL-0204 Phase 2b Study Result

Secondary Endpoints:

Percentage of participants with **at least 1-grade improvement** reported by participant using the Patient-Reported Abdominal Fat Rating Scale (**PR-AFRS**) compared with placebo at 4 weeks, 8 weeks and 12 weeks after the final treatment.

Compared with the placebo, more participants treated with CBL-514 improved **1 or more grades** reported by the participant using the PR-AFRS at W4, W8, and W12.

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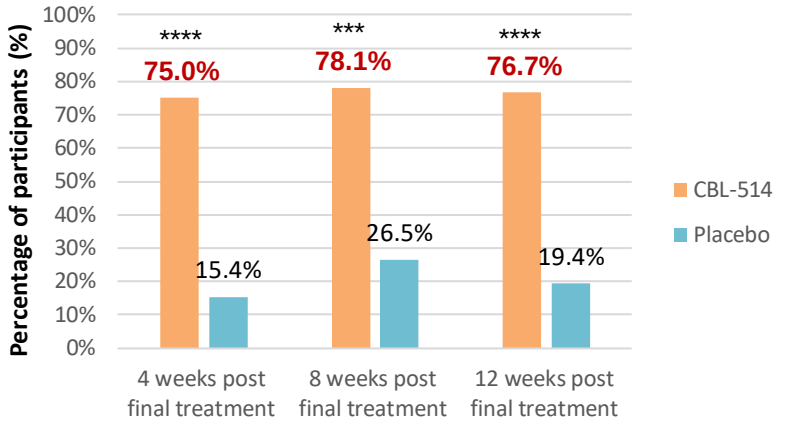

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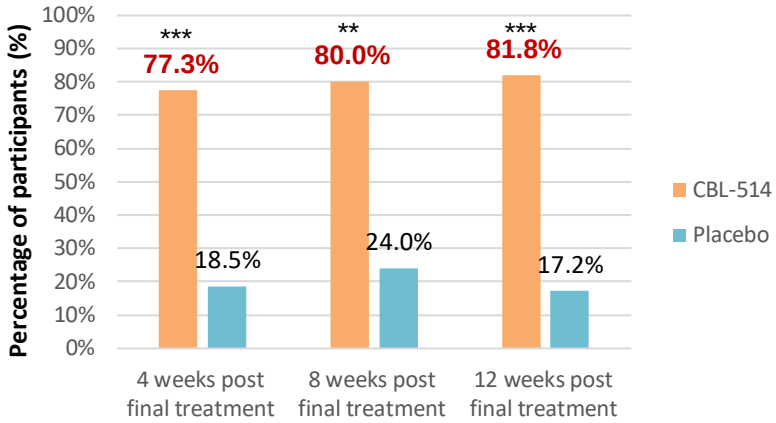

Percentage of participants with at least 1-grade improvement reported by participant using PR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	75.0% (33/44)	15.4% (6/39)	<0.00001
8 weeks post final treatment	78.1% (25/32)	26.5% (9/34)	<0.0005
12 weeks post final treatment	76.7% (23/30)	19.4% (7/36)	<0.00005

Percentage of participants with at least 1-grade improvement reported by participant using PR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	77.3% (17/22)	18.5% (5/27)	<0.001
8 weeks post final treatment	80.0% (16/20)	24.0% (6/25)	<0.002
12 weeks post final treatment	81.8% (18/22)	17.2% (5/29)	<0.0002

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by logistic regression model.*

CBL-0204 Phase 2b Study Result

◆ Internal Analysis (Not Endpoint)

Percentage of participants with **at least 2-grade improvement** reported by participant using the Patient-Reported Abdominal Fat Rating Scale (**PR-AFRS**) compared with placebo at 4 weeks, 8 weeks and 12 weeks after the final treatment.

Compared with the placebo, more participants treated with CBL-514 improved **2 or more grades** reported by the participant using the PR-AFRS at W4, W8, and W12.

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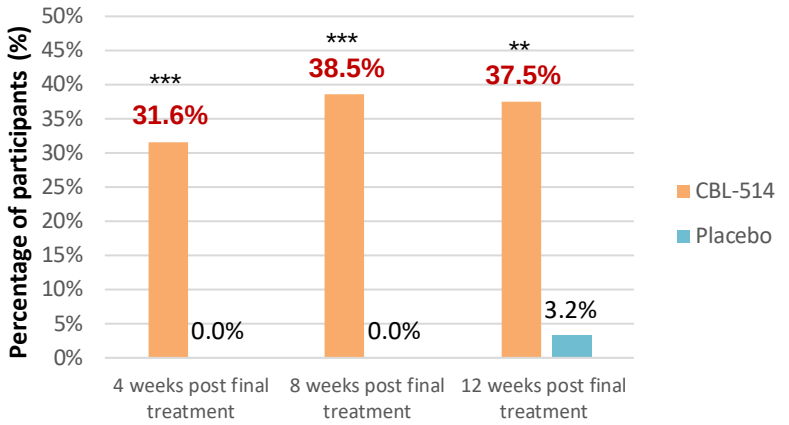

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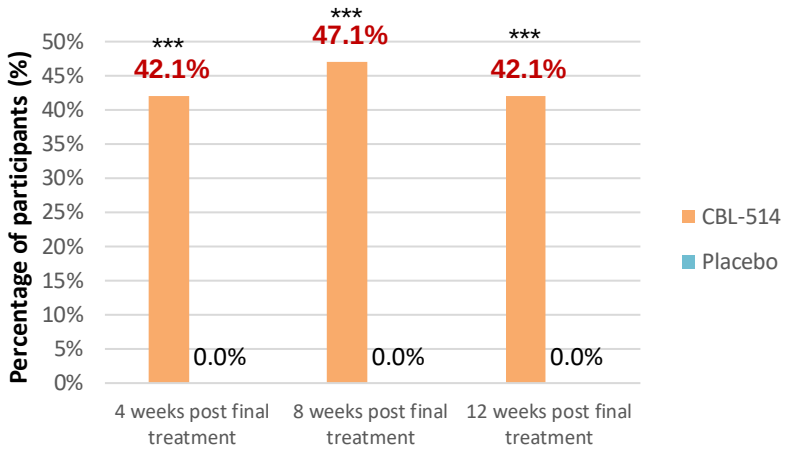

Percentage of participants with at least 2-grade improvement reported by participant using PR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	31.6% (12/38)	0.0% (0/34)	<0.0005
8 weeks post final treatment	38.5% (10/26)	0.0% (0/28)	<0.0005
12 weeks post final treatment	37.5% (9/24)	3.2% (1/31)	<0.002

Percentage of participants with at least 2-grade improvement reported by participant using PR-AFRS	CBL-514	Placebo	*p value*
4 weeks post final treatment	42.1% (8/19)	0.0% (0/22)	<0.001
8 weeks post final treatment	47.1% (8/17)	0.0% (0/20)	<0.001
12 weeks post final treatment	42.1% (8/19)	0.0% (0/24)	<0.001

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by Chi-Square test.*

CBL-0204 Phase 2b Study Result

◆ Secondary Endpoints:

Number of treatments required to first occurrence of a CR-AFRS improvement reported by Investigator in CBL-514 group.

58.82% of the participants only required one CBL-514 treatment to achieve at least 1-grade CR-AFRS improvement.

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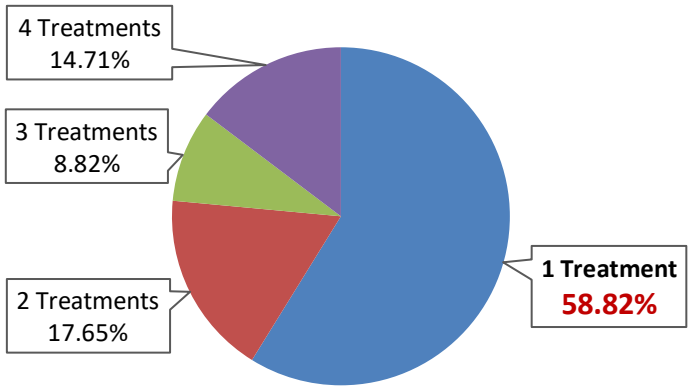

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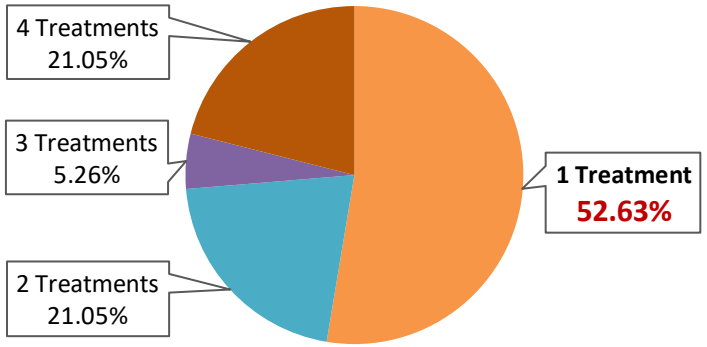

Total Number of Participants with CR-AFRS improvement in CBL-514 group	34	
1 Treatment to first occurrence of a CR-AFRS improvement	20	58.82%
2 Treatments to first occurrence of a CR-AFRS improvement	6	17.65%
3 Treatments to first occurrence of a CR-AFRS improvement	3	8.82%
4 Treatments to first occurrence of a CR-AFRS improvement	5	14.71%

Total Number of Participants with CR-AFRS improvement in CBL-514 group	19	
1 Treatment to first occurrence of a CR-AFRS improvement	10	52.63%
2 Treatments to first occurrence of a CR-AFRS improvement	4	21.05%
3 Treatments to first occurrence of a CR-AFRS improvement	1	5.26%
4 Treatments to first occurrence of a CR-AFRS improvement	4	21.05%

CBL-0204 Efficacy Data of Fat Thickness Reduction Measured by MRI

CBL-0204 Phase 2b Study Result

Secondary Endpoints:

Percentage of participant who **lose at least 20% of subcutaneous fat thickness** compared to baseline measured by MRI compared with placebo at 4 weeks and 12 weeks after the final treatment.

77.8 % of participants in the CBL-514 group reduced **over 20%** fat thickness and achieved a statistically significant difference compared with placebo (p< 0.00001).

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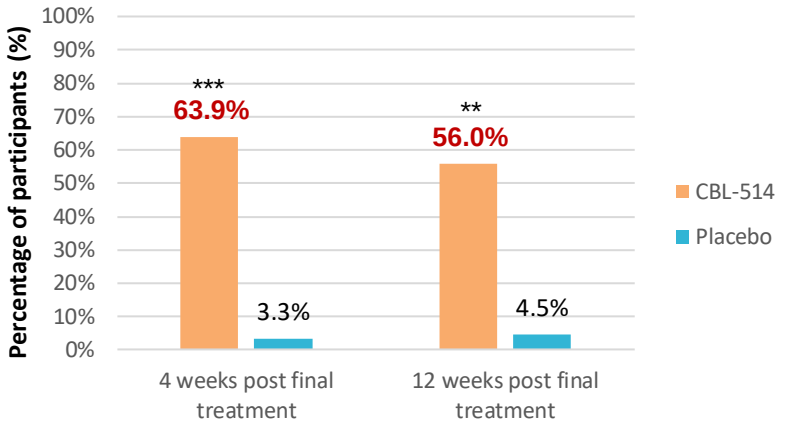

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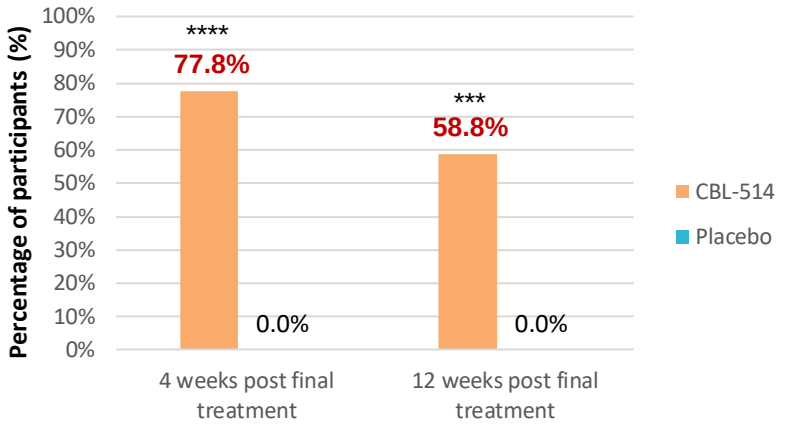

Percentage of participant who lose at least 20% of subcutaneous fat thickness	CBL-514	Placebo	*p value*
4 weeks post final treatment	63.9% (23/36)	3.3% (1/30)	<0.0002
12 weeks post final treatment	56.0% (14/25)	4.5% (1/22)	<0.005

Percentage of participant who lose at least 20% of subcutaneous fat thickness	CBL-514	Placebo	*p value*
4 weeks post final treatment	77.8% (14/18)	0.0% (0/21)	<0.00001
12 weeks post final treatment	58.8% (10/17)	0.0% (0/17)	<0.0005

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by Fisher's exact test and logistic regression model.*

CBL-0204 Phase 2b Study Result

◆ Secondary Endpoints:

The **percentage change in subcutaneous fat thickness** compared to baseline measured by MRI at 4 weeks and 12 weeks after the final treatment.

Compared with the placebo, participants in the CBL-514 group showed an average loss of **31.4% fat thickness** and a statistically significant difference was achieved (p< 0.00001).

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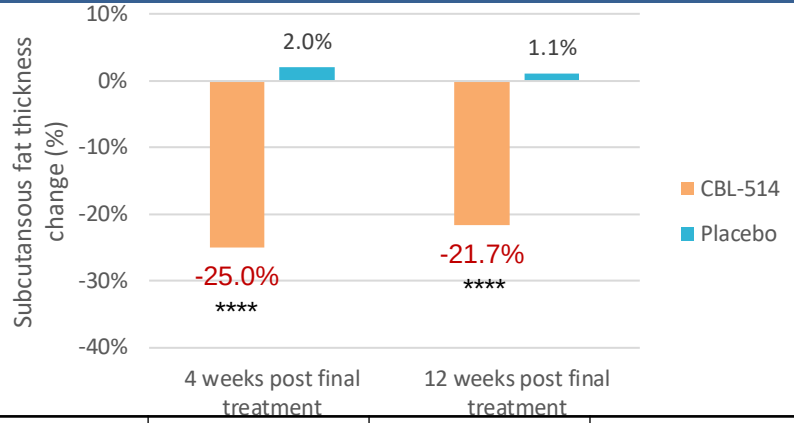

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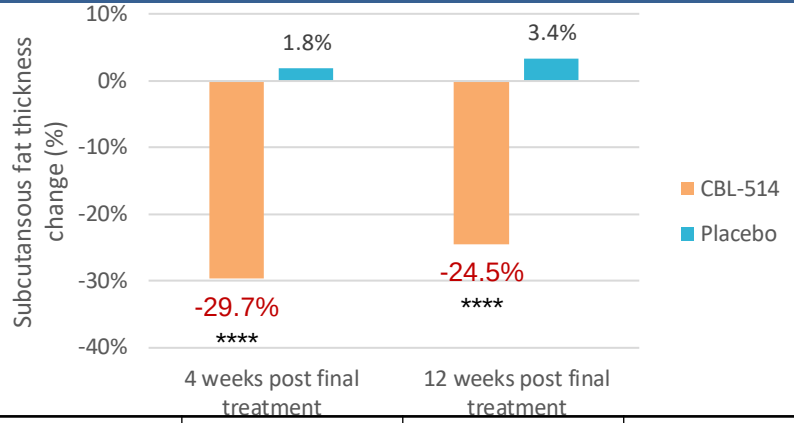

	CBL-514		Placebo		CBL-514 vs Placebo	
	% Change from Baseline		% Change from Baseline		LS Mean (%)	*p value*
	n	LS Mean (%)	n	LS Mean (%)		
4 weeks post final treatment	36	-25.0%	30	2.0%	**-27.1%**	<0.00001
12 weeks post final treatment	25	-21.7%	22	1.1%	**-22.8%**	<0.00001

	CBL-514		Placebo		CBL-514 vs Placebo	
	% Change from Baseline		% Change from Baseline		LS Mean (%)	*p value*
	n	LS Mean (%)	n	LS Mean (%)		
4 weeks post final treatment	18	-29.7%	21	1.8%	**-31.4%**	<0.00001
12 weeks post final treatment	17	-24.5%	17	3.4%	**-27.8%**	<0.00001

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by ANCOVA model.*

CBL-0204 Efficacy Data of Fat Volume Reduction Measured by MRI

CBL-0204 Phase 2b Study Result

Secondary Endpoints:

Percentage of participant who **lose at least 20% of subcutaneous fat volume** compared to baseline measured by MRI compared with placebo at 4 weeks and 12 weeks after the final treatment.

61.1 % of participants in the CBL-514 group reduced **over 20%** fat volume and achieved a statistically significant difference compared with placebo (p= 0.00002).

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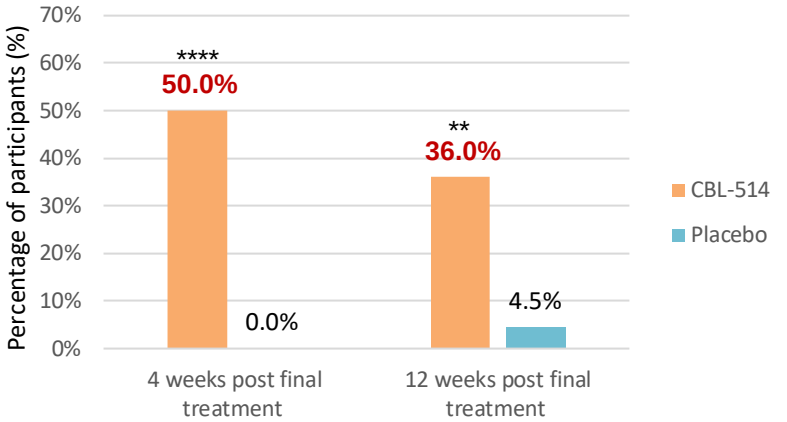

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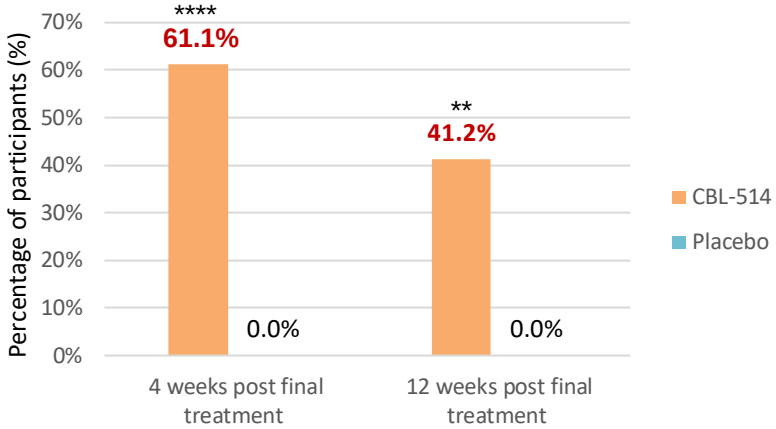

Percentage of participant who lose at least 20% of subcutaneous fat volume	CBL-514	Placebo	*p value*
4 weeks post final treatment	50.0% (18/36)	0.0% (0/30)	<0.00001
12 weeks post final treatment	36.0% (9/25)	4.5% (1/22)	<0.02

Percentage of participant who lose at least 20% of subcutaneous fat volume	CBL-514	Placebo	*p value*
4 weeks post final treatment	61.1% (11/18)	0.0% (0/21)	<0.00005
12 weeks post final treatment	41.2% (7/17)	0.0% (0/17)	<0.01

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by Fisher's exact test and logistic regression model.*

CBL-0204 Phase 2b Study Result

◆ Exploratory Endpoints:

The **percentage change in subcutaneous fat volume** compared to baseline measured by MRI at 4 weeks and 12 weeks after the final treatment.

Compared with the placebo, participants in the CBL-514 group showed an average loss of over **25% fat volume**, and a statistically significant difference was achieved (p< 0.00001).

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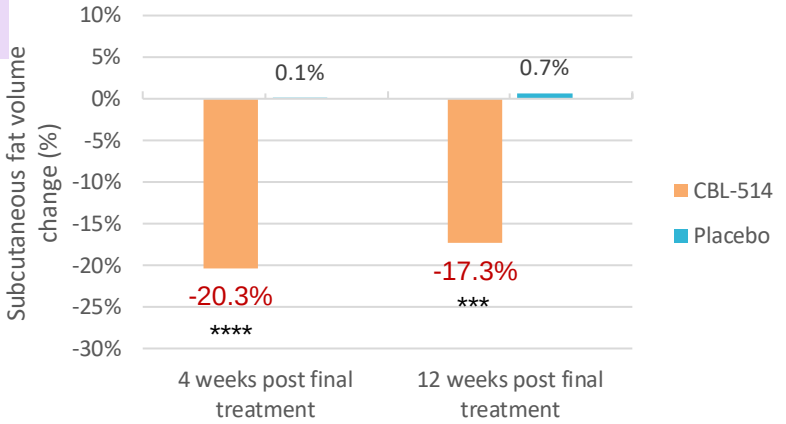

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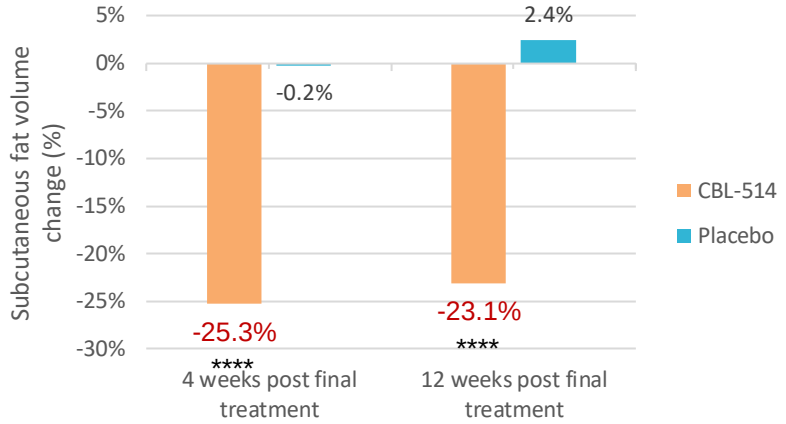

	CBL-514		Placebo		CBL-514 vs Placebo	
	% Change from Baseline		% Change from Baseline		LS Mean (%)	*p value*
	n	LS Mean (%)	n	LS Mean (%)		
4 weeks post final treatment	36	-20.3%	30	0.1%	**-20.5%**	<0.00001
12 weeks post final treatment	25	-17.3%	22	0.7%	**-18.0%**	<0.001

	CBL-514		Placebo		CBL-514 vs Placebo	
	% Change from Baseline		% Change from Baseline		LS Mean (%)	*p value*
	n	LS Mean (%)	n	LS Mean (%)		
4 weeks post final treatment	18	-25.3%	21	-0.2%	**-25.0%**	<0.00001
12 weeks post final treatment	17	-23.1%	17	2.4%	**-25.5%**	<0.00005

**A p-value was calculated to compare treatment with placebo. p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by ANCOVA model.*

CBL-0204 Phase 2b Study -Safety Result

- **Safety Endpoint:**

Safety as assessed by recording of TEAEs, laboratory assessments, vital signs, ECGs, physical examinations, and ISRs compared with placebo.

The overall safety and tolerability of participants who completed up to 4 courses of CBL-514 were favorable. **Most of the adverse events were mild to moderate injection site reactions (ISR).**

Overall, there were no clinically significant changes related to the study drug in the laboratory tests, vital signs, electrocardiograms, and physical examination after treatment.

CBL-514 Pivotal Phase 3 Future Timeline

CBL-514 Pivotal Phase 3 Future Timeline

Caliway

2025

2026

Q1

EOP2

FDA EOP2 Meeting Request

- CBL-0301 LPI
- CBL-0302 Recruiting

Recruiting 0302

Q2

0301 IND

- FDA EOP2 Meeting Document
- Pivotal Phase 3 CBL-0301 IND

- CBL-0302 LPI

0302 LPI

Q3

0302 IND

- Pivotal Phase 3/ CBL 0301 Recruiting
- Pivotal Phase 3 CBL-0302 IND

- CBL-0301 Study Complete (LPO)

0301 Completed

Q4

Recruiting 0301 0302

Pivotal Phase 3/ CBL-0301 Recruiting CBL-0302 Recruiting

- CBL-0301 Study Result Released
- CBL-0302 Study Complete (LPO)

0301 Topline

Market Changer Innovation

Caliway (TWSE-6919)

Taiwan Leading Pharmaceuticals For Revolutionary Aesthetic Medicine