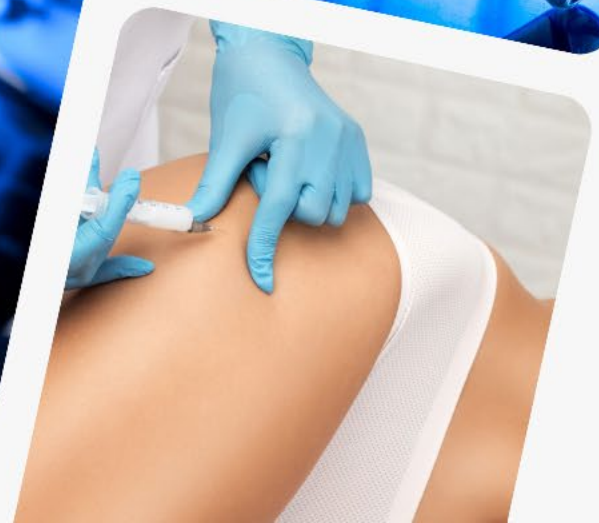
TWSE: 6919

康霈生技
Caliway Biopharmaceuticals

Market Changer Innovation



CBL-514 for Fat Reduction

CBL-0205 Phase 2b Study Results

Vivian Ling, CEO and Chief R&D Officer
2025/03/04

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

Disclaimer

1. This presentation has been prepared by Caliway Biopharmaceuticals Co., Ltd. (Code: 6919) (the “Company”), the content of this presentation is prepared with information available at the time of preparation, and summarizes the past, present, and future of the Company’s operations and activities based on subjective and objective assessments. This presentation contains forward-looking statements and are predictions, projections, and other statements about future events based on current expectations and assumptions. Such forward-looking statements may be affected by uncertainties, known and unknown risks, inferences, regulatory changes, changes in competitive environment, or other factors outside of the Company’s control which may cause actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements in this presentation. Caliway expressly disclaims to the fullest extent permitted by law any obligation or undertaking to provide any additional updates or revisions to any forward-looking statements contained herein to reflect any change in expectations or any change in events, conditions, or circumstances on which any such statements are based.

2. The information provided in this presentation, including forward-looking statements, is based on numerous assumptions and the Company does not guarantee the accuracy or completeness of such information. No representation or warranty, express or implied, is made as to the accuracy, completeness, or reliability of the presentation and the information contained herein, and the information in this presentation does not purport to represent all of the Company’s results of operations, the industry, or future developments.

3. The forward-looking statements in this presentation reflect the Company’s beliefs as of the date of this presentation, the Company undertakes no obligation to timely inform, update, or revise the information in this presentation if circumstances should change. The Company, its affiliates, directors, officers, employees, advisers, connected persons, or any other person disclaim all liability and responsibility for any direct or indirect loss or damage which may be suffered by any person through the use of or reliance on any information contained in this presentation.

4. This presentation and its contents are proprietary to the Company, and no part of the contents or its subject matter may be reproduced, redistributed, disseminated, or otherwise divulged, directly or indirectly, to any other person or published, in whole or in part, for any purpose without the prior written consent of the Company.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b – Protocol Overview

Study design	• Phase 2b • Randomized, **single blind** • **Double Masking** (Participant, Outcomes Assessor)
Treatment	• On **abdomen** • Parallel assignment • 4 groups: 160 subjects in total, 1:1:1:1 - **CBL-514** - **CBL-A1** - **Placebo** - **CBL-A2**
Enrollment Criteria	• **18.5 kg/m^2 <** BMI **<30 kg/m^2** 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 weeks post final treatment**
Locations	• United States: 10 sites • Canada: 5 sites
Recruitment	• Planned to enroll 160 subjects • Actually enrolled 173 subjects - **43 CBL-514 subjects** **43 CBL-A1 subjects** - **44 Placebo subjects** **43 CBL-A2 subjects**
Timeline *(U.S. time)*	• 1st subject dosed: **Dec2023** • Last subject dosed: **May2024** • Last subject last visit: **Oct2024**
ClinicalTrials.gov	NCT06005441

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Results Highlights

Caliway

CBL-514 met primary and major secondary endpoints in the FAS and PP population

Primary Endpoint **54.2%** participants in the CBL-514 group
Lost ≥ 20% subcutaneous fat volume post 4 weeks vs. placebo (0%), p< 0.00001

79.2%

Secondary Endpoint
79.2% of participants in the CBL-514 group achieved ≥1 grade improvement using the CR-AFRS(1) (p< 0.0005) post 4 weeks vs. placebo (29%)

41.7%

Secondary Endpoint
41.7% of participants in the CBL-514 group achieved ≥2 grade Improvement using the CR-AFRS (p < 0.001) post 4 weeks vs. placebo (3.2%)

54.2%

Secondary Endpoint
54.2% of participants in the CBL-514 group Lost ≥ 20% subcutaneous fat volume vs. CBL-A1 (17.4%) and CBL-A2 (7.7%) post 4 weeks. (p<0.02 and p< 0.0005 respectively)

54.2 %

Secondary Endpoint
54.2% of participants in the CBL-514 group lost at least 150 mL subcutaneous fat volume vs. CBL-A1 (13%), CBL-A2 (7.7%), and placebo (0%) post 4 weeks (p<0.005, p< 0.0005 and p<0.00001 respectively)

-24.2%

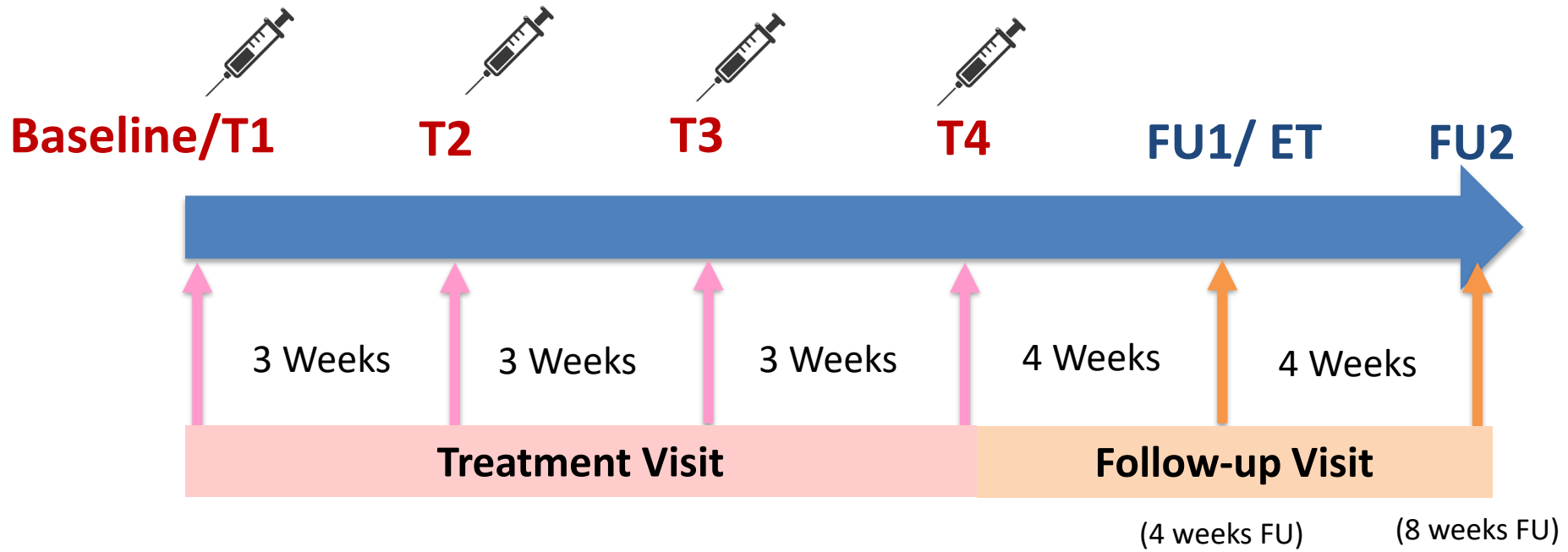
Secondary Endpoint
Compared with the placebo, participants treated with CBL-514 showed an average 24.2 % fat volume reduction post 4 weeks (p<0.00001)

Note: clinicaltrials.gov identifier NCT06005441
(1) CR-AFRS : Clinician-Reported Abdominal Fat Rating Scale

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study –Study Design

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



All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

◆ Analysis Population

Group/Analysis population	CBL-514	Placebo	CBL-A1	CBL-A2	Overall
Number of participants in Full Analysis Set Population (FAS)	38	40	41	41	160
Number of participants in Per Protocol Population (PP)	25	31	20	26	102

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.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Efficacy Data of Fat Volume Reduction Measured by MRI

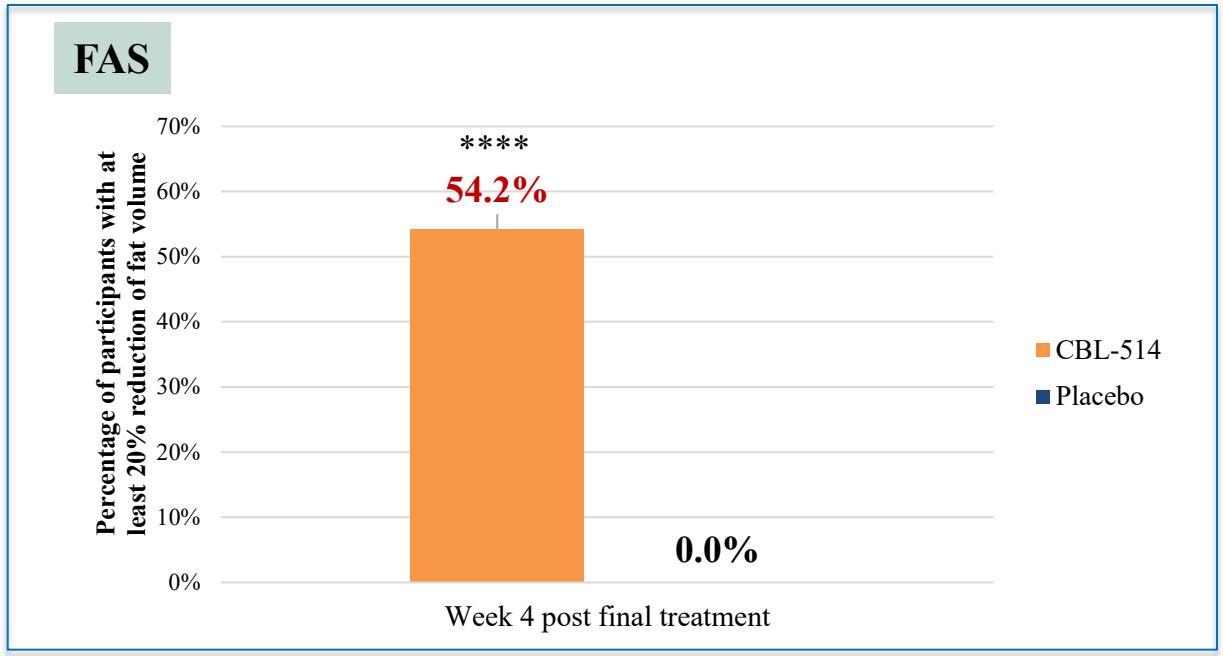
All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

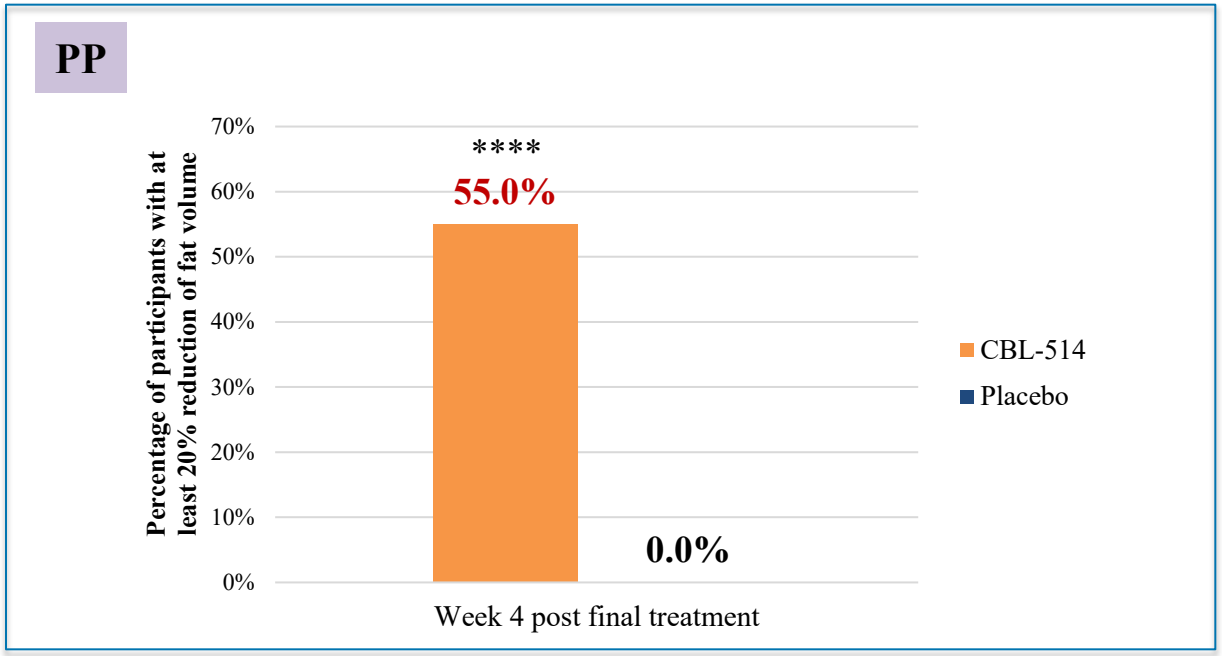
CBL-0205 Phase 2b Study Result

◆ Primary Endpoint:

Percentage of participants with **at least 20% reduction of fat volume** from Baseline to **4 weeks** after the final treatment, as measured by MRI, of CBL-514 compared with Placebo.

54.2 % of participants in the CBL-514 group reduced **at least 20%** fat volume and achieved a statistical significance compared with placebo (p< 0.00001).





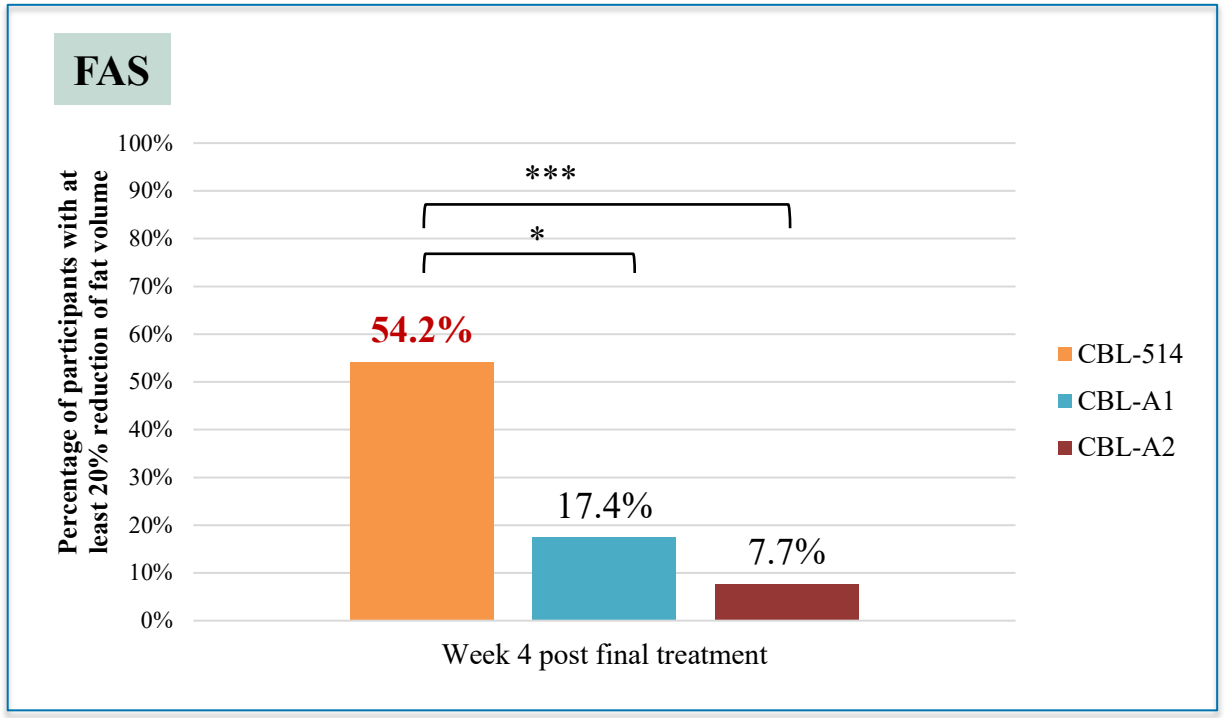
**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by a logistic regression model.*

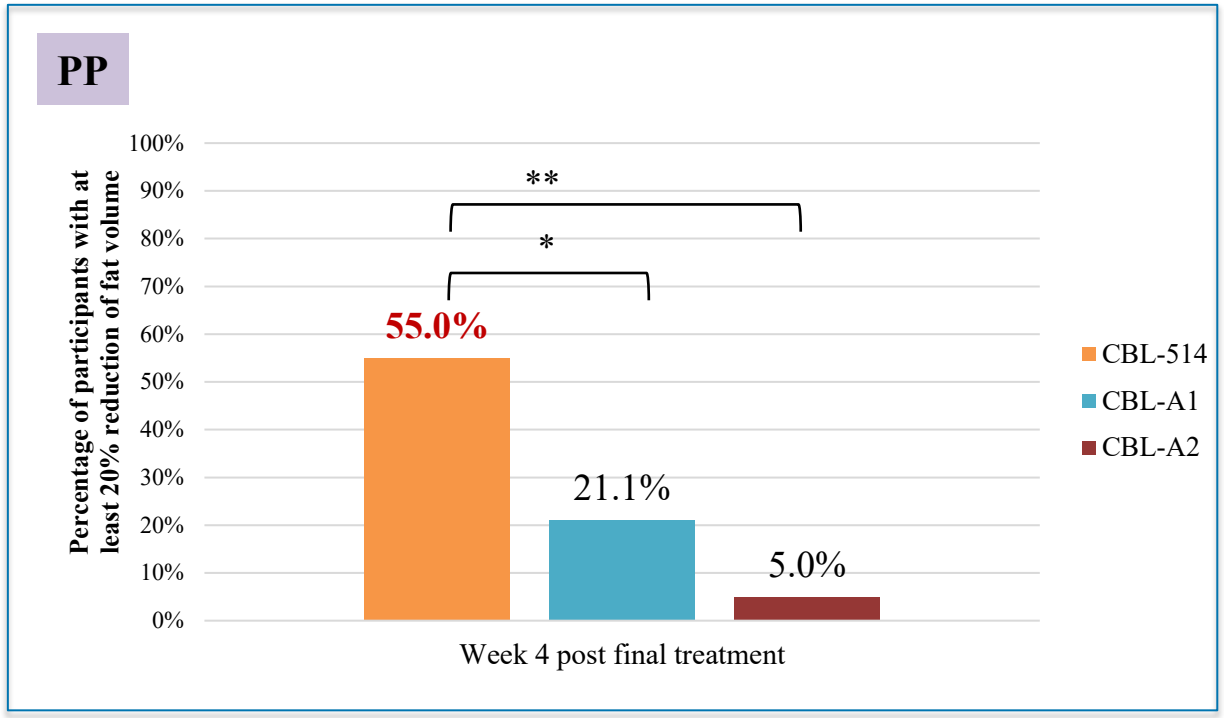
All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

◆ Secondary Endpoint(s):

Percentage of participants with **at least 20% reduction of fat volume** from Baseline to 4 weeks after the final treatment, as measured by MRI, of CBL-514 compared with CBL-A1 and CBL-A2.





**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by a logistic regression model.*

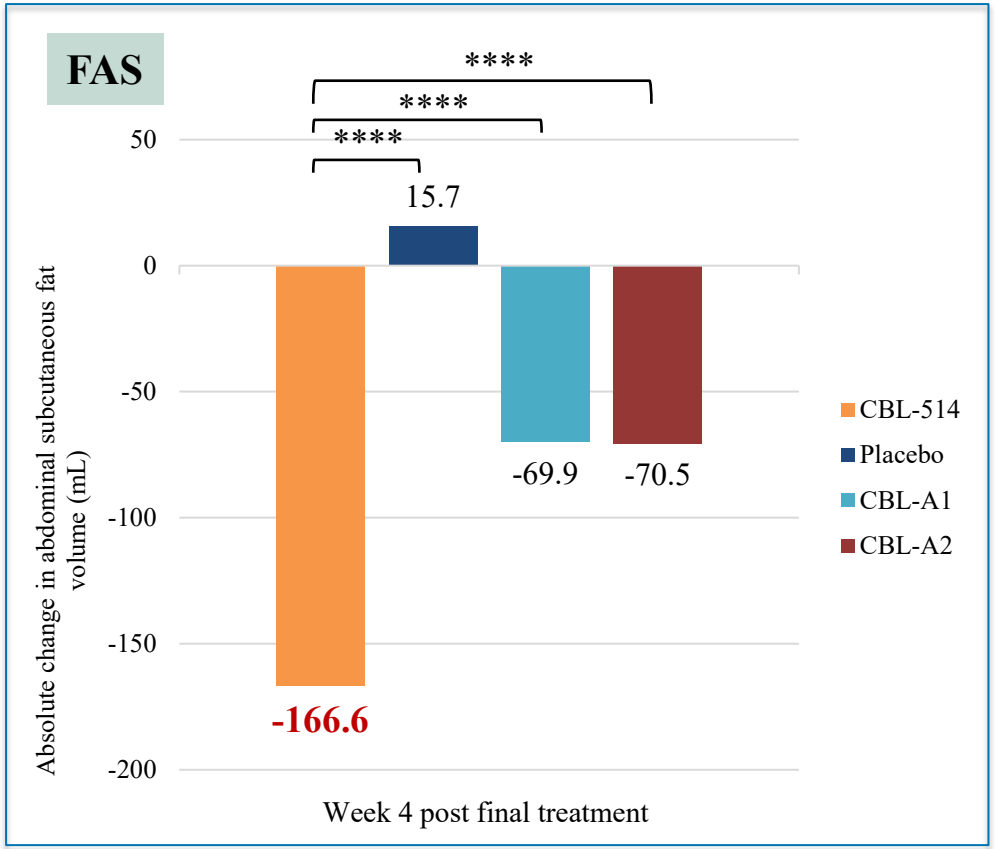
More participants treated with **CBL-514 (54.2%) lost at least 20% of subcutaneous fat volume** in the treated area and achieved statistical significance compared with CBL-A1 (17.4%) and CBL-A2 (7.7%), p<0.02 and p< 0.0005 respectively.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

◆ Secondary Endpoint(s):

Absolute change in abdominal subcutaneous fat volume from Baseline to 4 weeks and 8 weeks after the final treatment, as measured by MRI, of CBL-514 compared with CBL-A1, CBL-A2, and Placebo.



	CBL-514 vs Placebo		
	LS Mean difference (mL)	95% CI	*p-value*
Week 4 post final treatment	**-182.3**	[-224.6, -140.0]	< 0.00001

	CBL-514 vs CBL-A1		
	LS Mean difference (mL)	95% CI	*p-value*
Week 4 post final treatment	**-96.8**	[-140.9, -52.6]	< 0.00005

	CBL-514 vs CBL-A2		
	LS Mean difference (mL)	95% CI	*p-value*
Week 4 post final treatment	**-96.1**	[-138.8, -53.4]	< 0.00005

**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by ANCOVA model.*

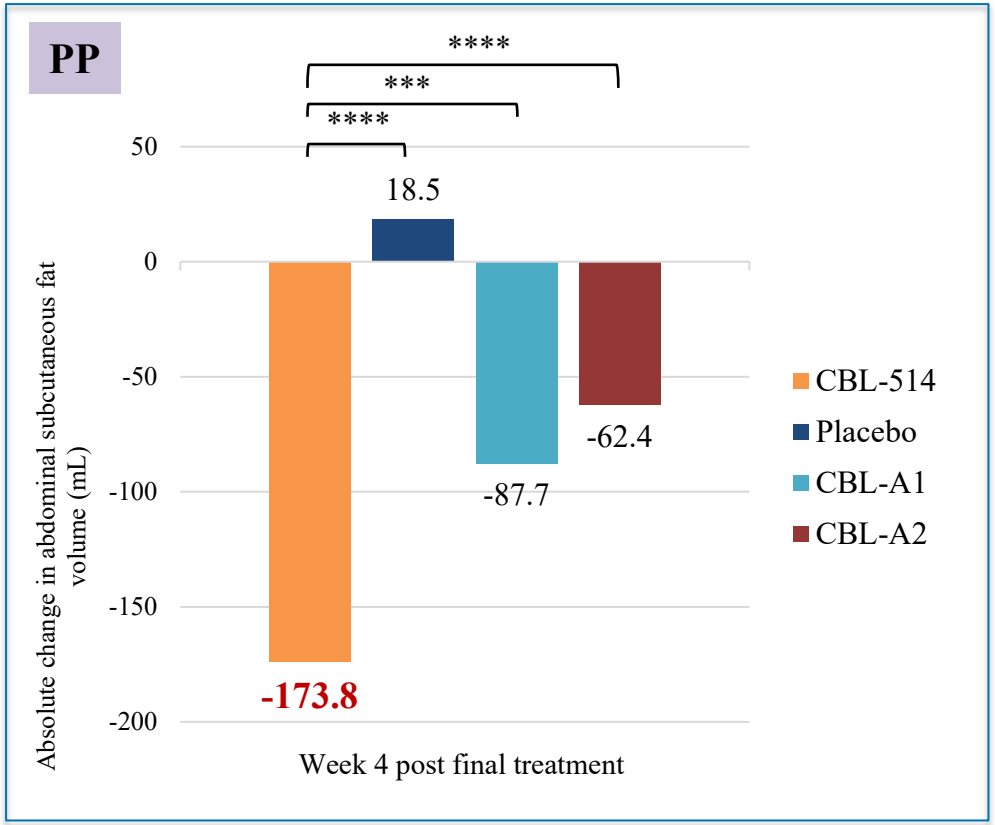
Compared with CBL-A1, CBL-A2, and placebo, a higher abdominal subcutaneous fat volume reduction in the CBL-514 group achieved statistical significance.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

◆ Secondary Endpoint(s):

Absolute change in abdominal subcutaneous fat volume from Baseline to 4 weeks and 8 weeks after the final treatment, as measured by MRI, of CBL-514 compared with CBL-A1, CBL-A2, and Placebo.



	CBL-514 vs Placebo		
	LS Mean difference (mL)	95% CI	*p-value*
Week 4 post final treatment	**-192.2**	[-237.7, -146.8]	< 0.00001

	CBL-514 vs CBL-A1		
	LS Mean difference (mL)	95% CI	*p-value*
Week 4 post final treatment	-86.1	[-134.6, -37.6]	< 0.001

	CBL-514 vs CBL-A2		
	LS Mean difference (mL)	95% CI	*p-value*
Week 4 post final treatment	-111.4	[-159.1, -63.6]	< 0.00002

**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by ANCOVA model.*

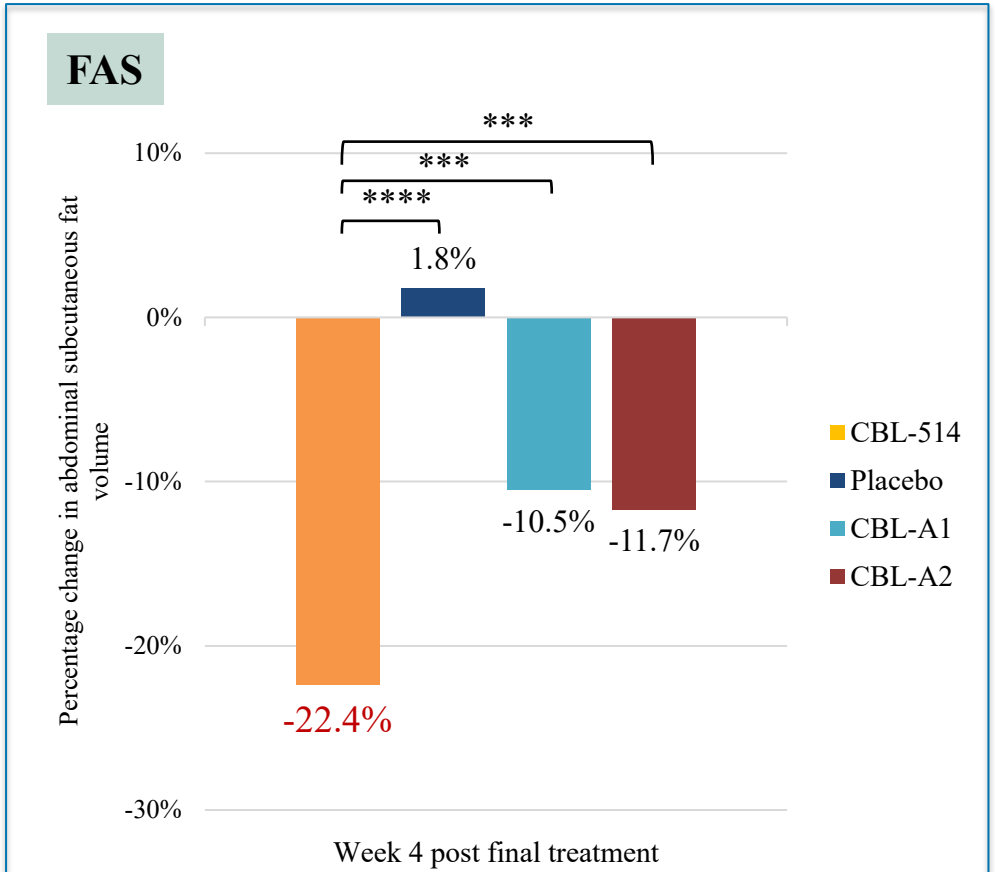
Compared with CBL-A1, CBL-A2, and placebo, a higher abdominal subcutaneous fat volume reduction in the CBL-514 group achieved statistical significance.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

◆ Secondary Endpoint(s):

Percentage change in abdominal subcutaneous fat volume from Baseline to 4 weeks and 8 weeks after the final treatment, as measured by MRI, of CBL-514 compared with CBL-A1, CBL-A2, and Placebo.



	CBL-514 vs Placebo		
	LS Mean difference (%)	95% CI	*p-value*
Week 4 post final treatment	**-24.2**	[-29.9, -18.5]	< 0.00001

	CBL-514 vs CBL-A1		
	LS Mean difference (%)	95% CI	*p-value*
Week 4 post final treatment	-11.9	[-17.8, -5.9]	< 0.0002

	CBL-514 vs CBL-A2		
	LS Mean difference (%)	95% CI	*p-value*
Week 4 post final treatment	-10.7	[-16.5, -5.0]	< 0.0005

**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by ANCOVA model.*

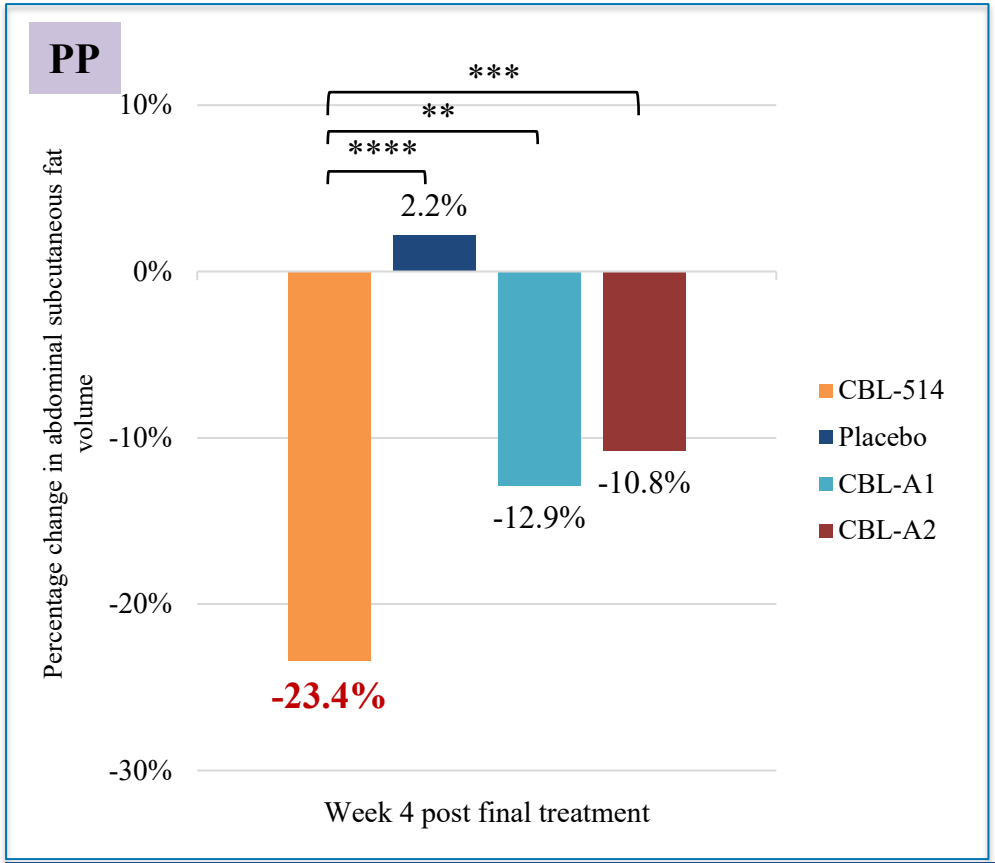
Compared with CBL-A1, CBL-A2, and placebo, a higher percentage reduction in abdominal subcutaneous fat volume in the CBL-514 group achieved statistical significance.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

◆ Secondary Endpoint(s):

Percentage change in abdominal subcutaneous fat volume from Baseline to 4 weeks and 8 weeks after the final treatment, as measured by MRI, of CBL-514 compared with CBL-A1, CBL-A2, and Placebo.



	CBL-514 vs Placebo		
	LS Mean difference (%)	95% CI	*p-value*
Week 4 post final treatment	**-25.5**	[-31.6, -19.5]	< 0.00001

	CBL-514 vs CBL-A1		
	LS Mean difference (%)	95% CI	*p-value*
Week 4 post final treatment	-10.5	[-16.9, -4.0]	< 0.002

	CBL-514 vs CBL-A2		
	LS Mean difference (%)	95% CI	*p-value*
Week 4 post final treatment	-12.6	[-18.9, -6.2]	< 0.0002

**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by ANCOVA model.*

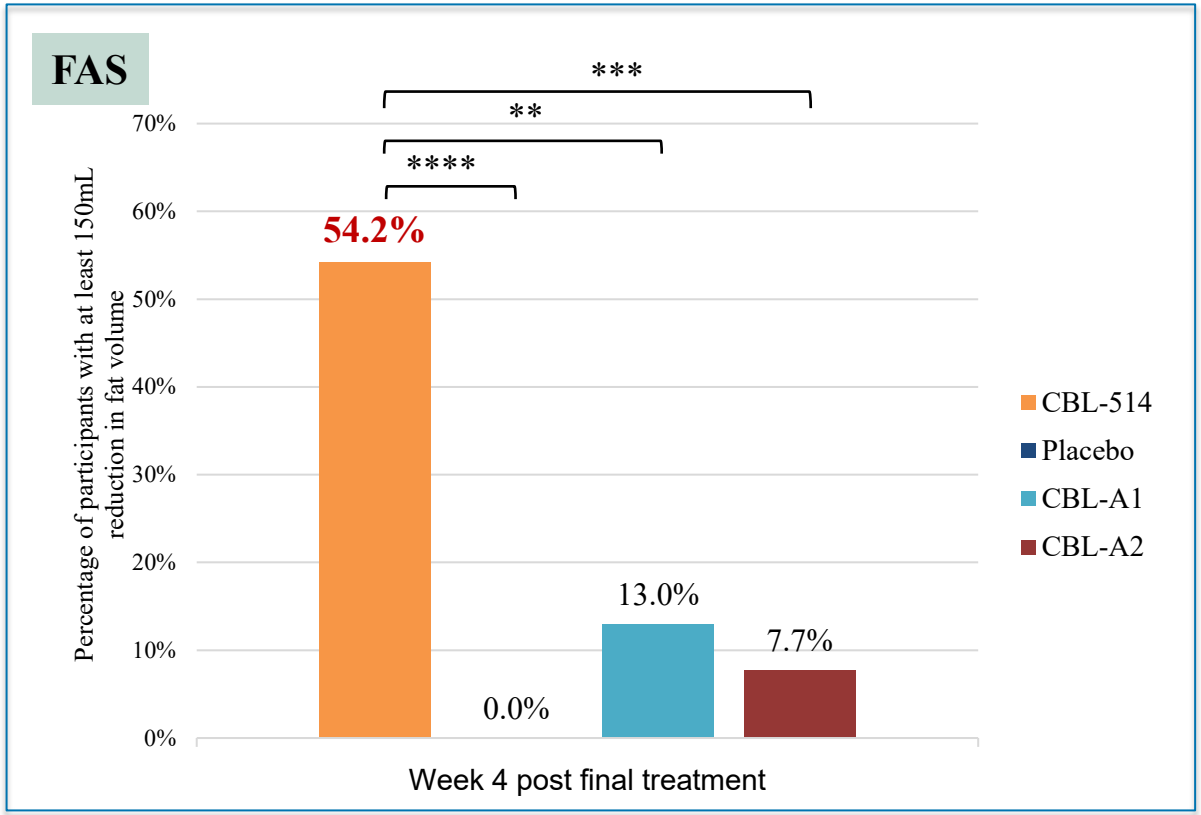
Compared with CBL-A1, CBL-A2, and placebo, a higher percentage reduction in abdominal subcutaneous fat volume in the CBL-514 group achieved statistical significance

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

◆ Secondary Endpoint(s):

Percentage of participants with **at least 150mL reduction in abdominal subcutaneous fat volume** from Baseline to 4 weeks and 8 weeks after the final treatment, as measured by MRI, of CBL-514 compared with CBL-A1,CBL-A2, and Placebo.



p value	CBL-514 vs Placebo	< 0.00001
	CBL-514 vs CBL-A1	< 0.005
	CBL-514 vs CBL-A2	< 0.0005

**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by logistic regression model.*

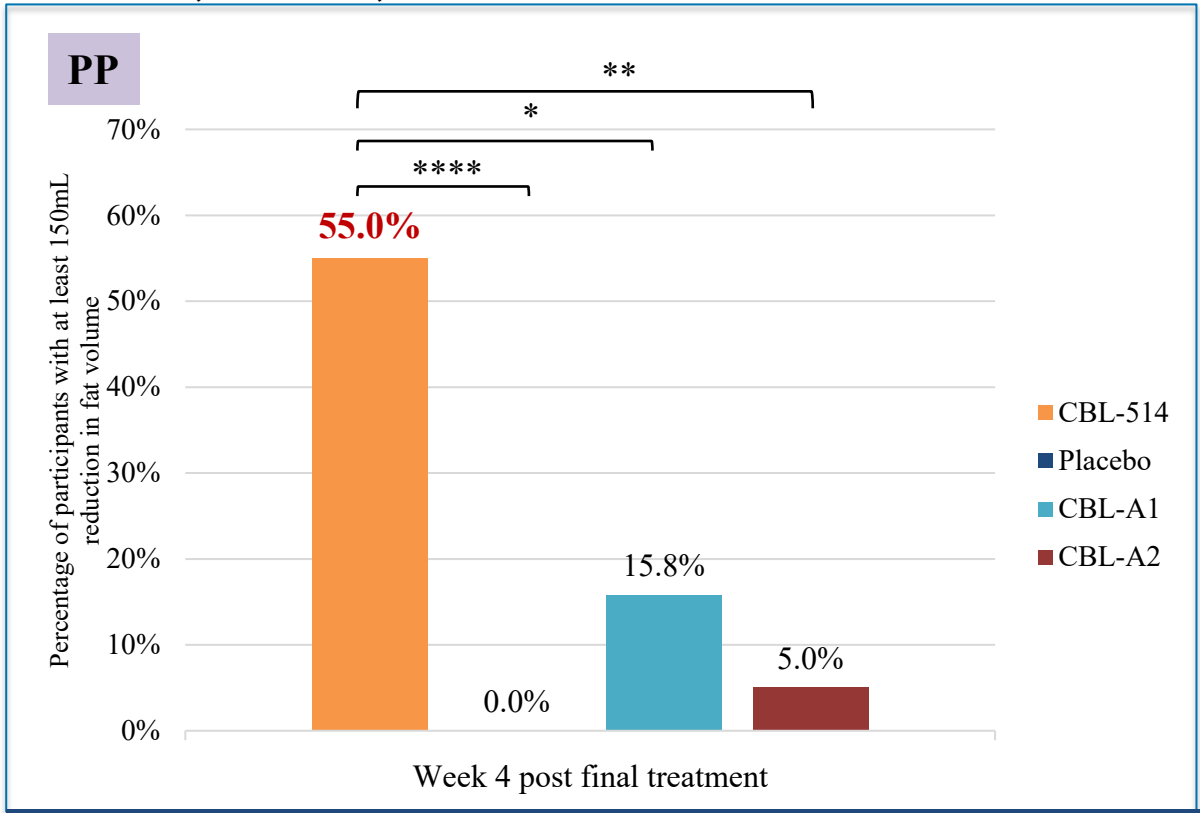
More participants treated with **CBL-514 (54.2%) lost at least 150mL reduction in abdominal subcutaneous fat volume** in the treated area and achieved statistical significance compared with CBL-A1 (13.0%) , CBL-A2 (7.7%) and Placebo (0%), p<0.005, p< 0.0005 and p< 0.00001 respectively.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

Secondary Endpoint(s):

Percentage of participants with **at least 150mL reduction in abdominal subcutaneous fat volume** from Baseline to 4 weeks and 8 weeks after the final treatment, as measured by MRI, of CBL-514 compared with CBL-A1,CBL-A2, and Placebo.



p value	CBL-514 vs Placebo	0.00002
	CBL-514 vs CBL-A1	< 0.02
	CBL-514 vs CBL-A2	< 0.002

**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by logistic regression model.*

More participants treated with **CBL-514 (55.0%) lost at least 150mL reduction in abdominal subcutaneous fat volume** in the treated area and achieved statistical significance compared with CBL-A1 (15.8%), CBL-A2 (5.0%) and Placebo (0%), p<0.02, p< 0.002 and p= 0.00002 respectively.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Efficacy Data of AFRS Improvement

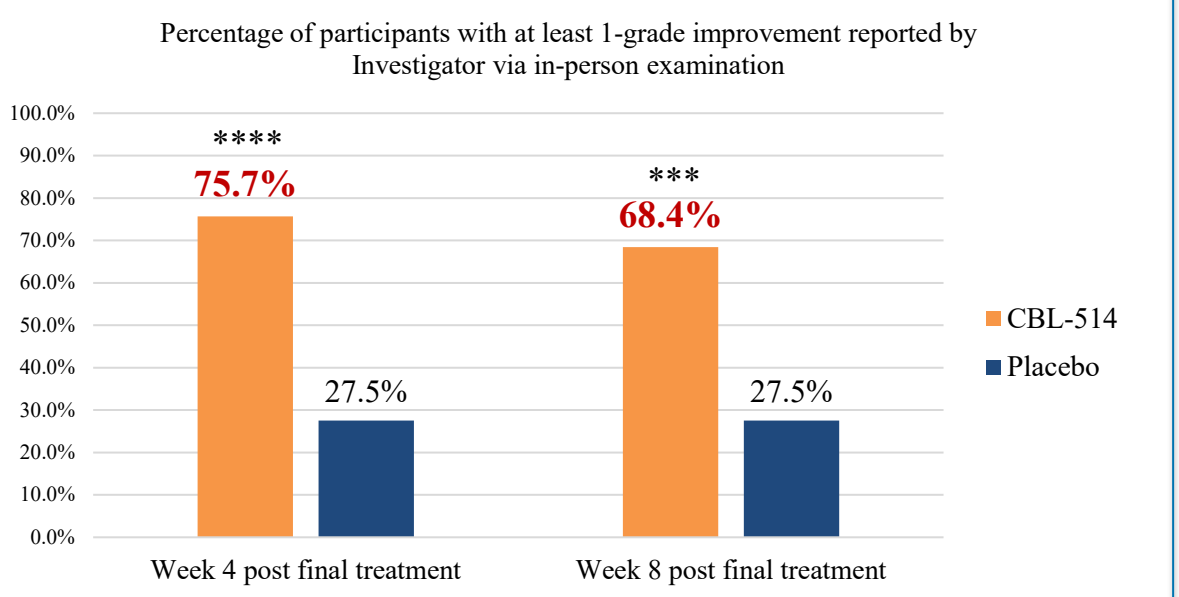
All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

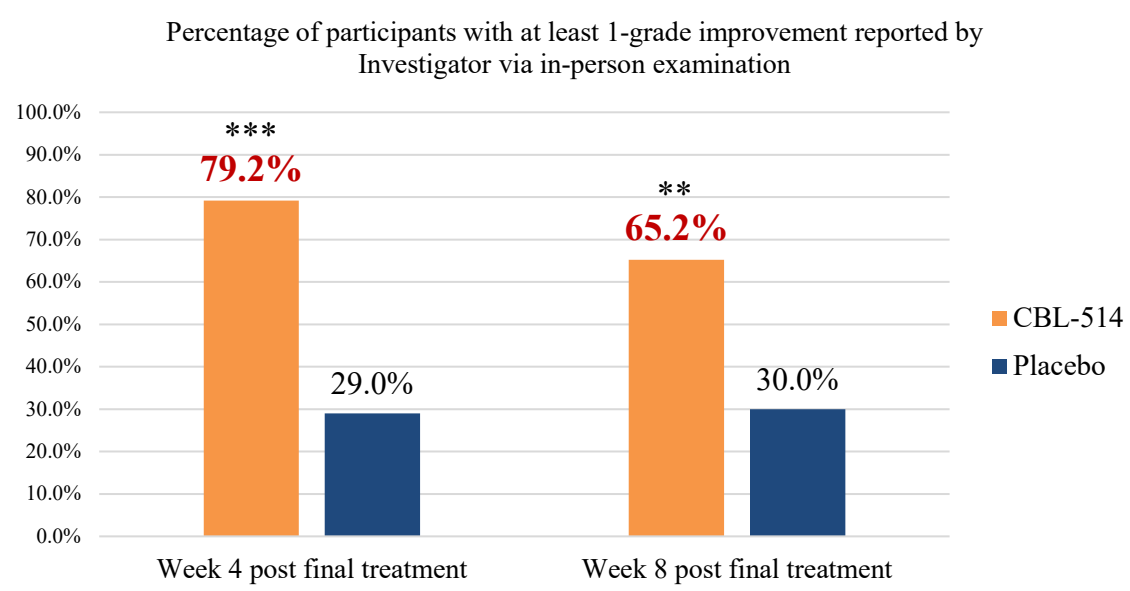
◆ Secondary Endpoints:

Percentage of participants with at least 1-grade improvement reported by the Investigator using the Clinician-Reported Abdominal Fat Rating Scale (CR-AFRS) via examining the participants in-person at 4 weeks and 8 weeks after the final treatment, for CBL-514 compared with placebo

FAS-Imputed



PP



*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; ****$p < 0.0001$. Statistical significance determined by logistic regression model.*

Compared with placebo (29.0%), **79.2%** of participants treated with CBL-514 achieved an improvement of **1 or more grades** reported by the Investigator using the **CR-AFRS** post 4 weeks ($p < 0.0005$).

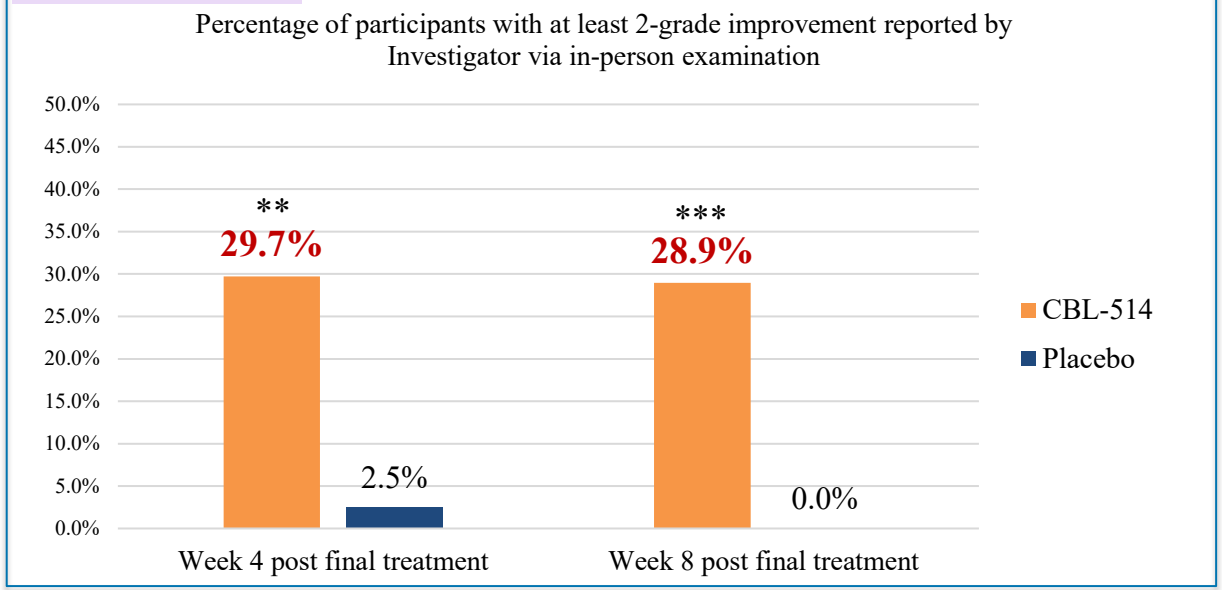
All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

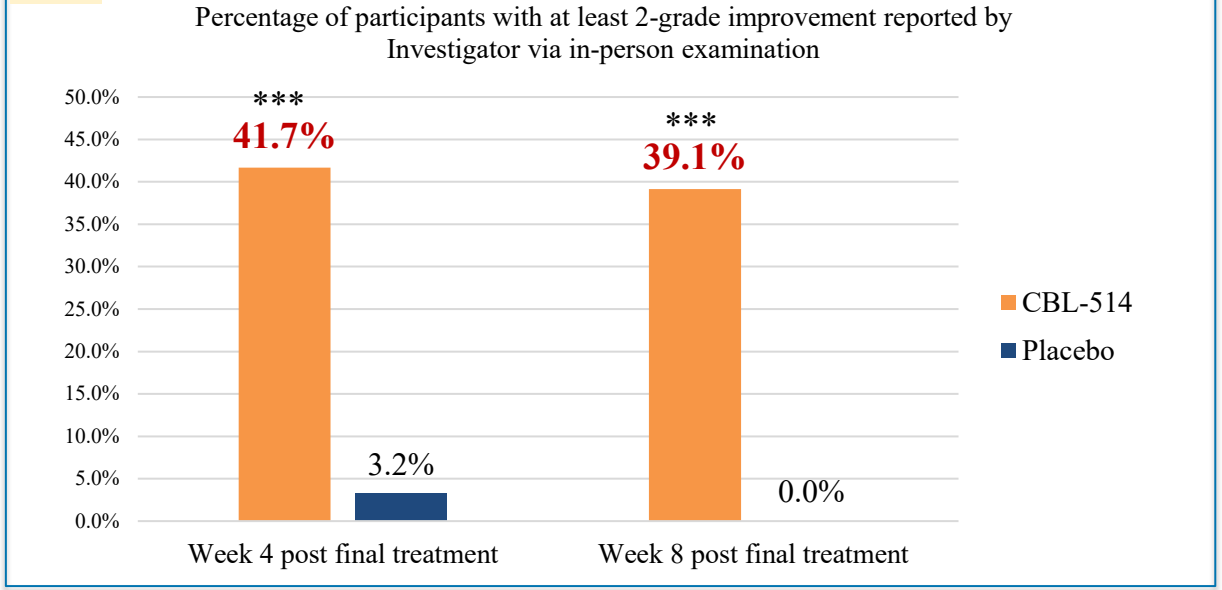
◆ Secondary Endpoints:

Percentage of participants with at least 2-grade improvement reported by the Investigator using the Clinician-Reported Abdominal Fat Rating Scale (CR-AFRS) via examining the participants in-person at 4 weeks and 8 weeks after the final treatment, for CBL-514 compared with placebo

FAS-Imputed



PP



**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by logistic regression model.*

Compared with the placebo (3.2%) , **41.7%** participants treated with CBL-514 improved **2 or more grades** reported by the Investigator using the **CR-AFRS** post 4 weeks (p< 0.001).

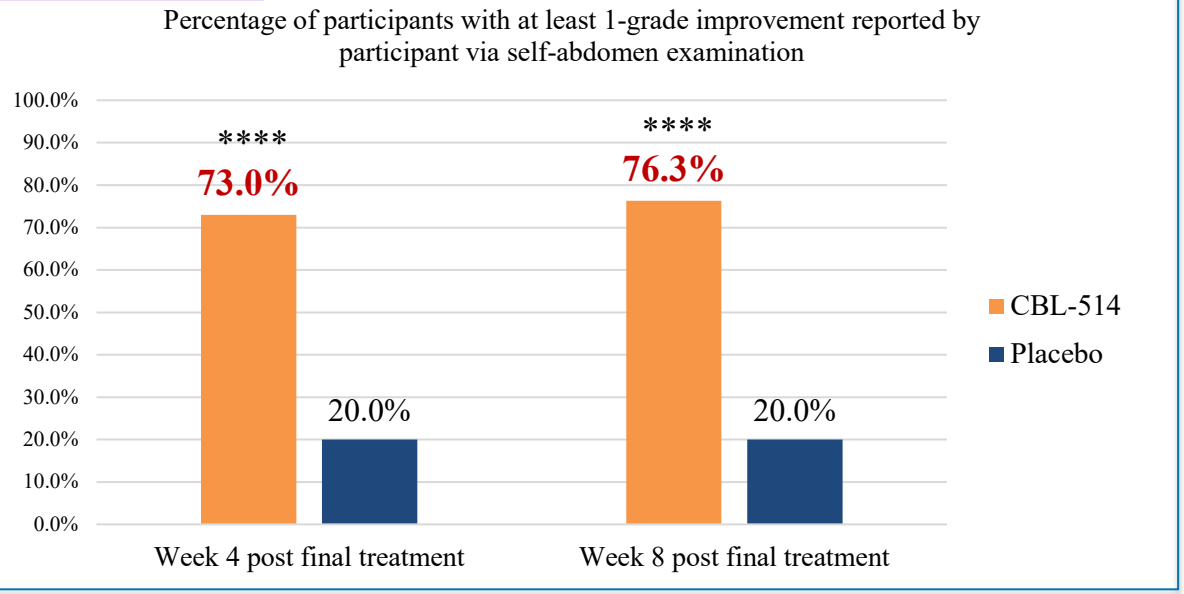
All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

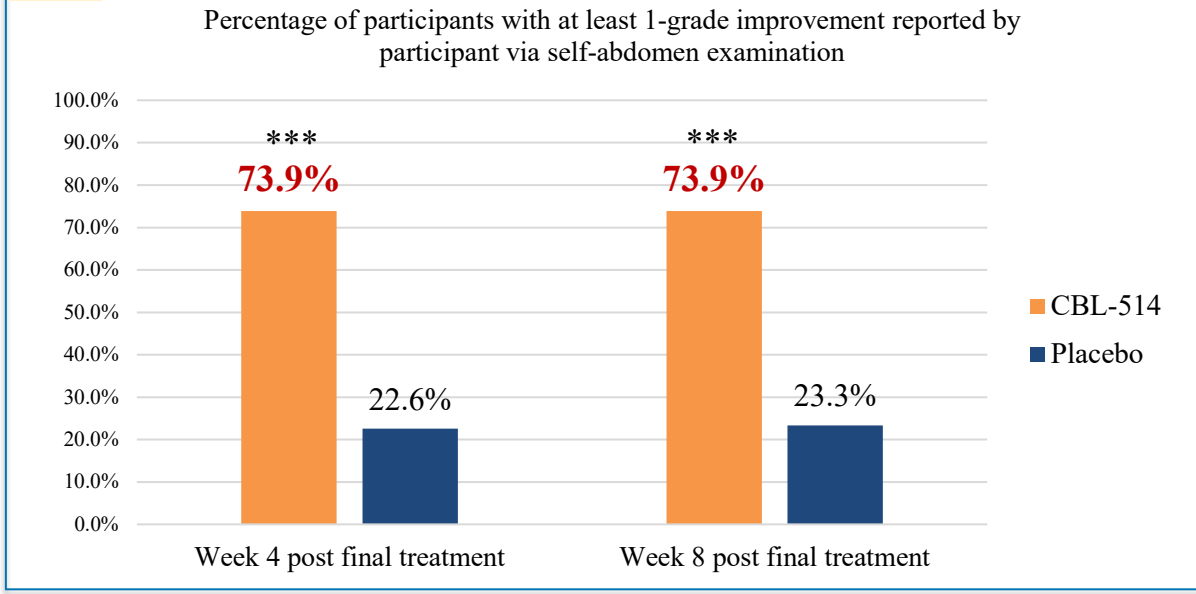
Secondary Endpoints:

Percentage of participants with at least 1-grade improvement reported by the participant using the Patient-Reported Abdominal Fat Rating Scale (PR-AFRS) via examining self-abdomen in the mirror at 4 weeks and 8 weeks after the final treatment, for CBL-514 compared with placebo

FAS-Imputed



PP



**p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001. Statistical significance determined by logistic regression model.*

More participants treated with CBL-514 compared with placebo achieved an improvement of **1 or more grades** reported by the participant using the **PR-AFRS**.

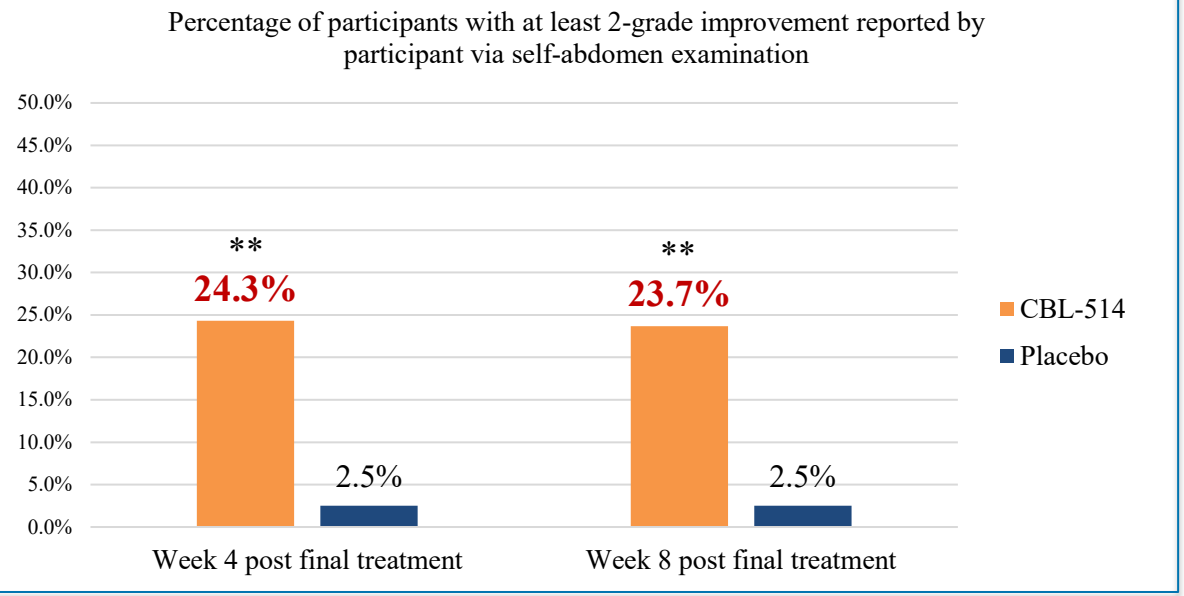
All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 Phase 2b Study Result

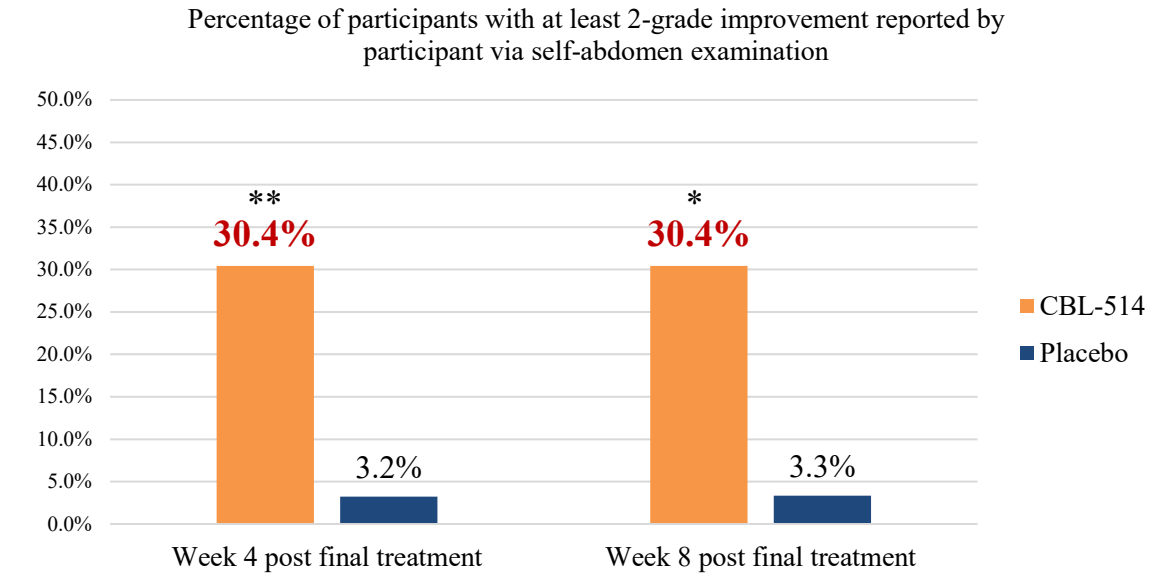
◆ Secondary Endpoints:

Percentage of participants with at least 2-grade improvement reported by the participant using the Patient-Reported Abdominal Fat Rating Scale (PR-AFRS) via examining self-abdomen in the mirror at 4 weeks and 8 weeks after the final treatment, for CBL-514 compared with placebo

FAS-Imputed



PP



*$p < 0.05$; **$p < 0.01$; ***$p < 0.001$; ****$p < 0.0001$. Statistical significance determined by logistic regression model.*

More participants treated with CBL-514 compared with placebo achieved an improvement of **2 or more grades** reported by the participant using the **PR-AFRS**.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-0205 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.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-514 Pivotal Phase 3 Clinical Study Plan for Fat Reduction

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

CBL-514 Clinical Study Plan for Fat Reduction in 2025-2027

Milestone		2025				2026				2027	
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2
CBL-0205 Phase 2b study results announced		✓									
CBL-0301 Pivotal Phase 3	IND submission		✓								
	Subject recruitment			✓							
	Subject recruitment complete					✓					
	Study results release								✓		
CBL-0302 Pivotal Phase 3	IND submission			✓							
	Subject recruitment				✓						
	Subject recruitment complete						✓				
	Study results release									✓	

Note: The CBL-0301 and CBL-0302 study design will be the same; the actual time for subject recruitment will be determined based on the actual situation.

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.

To Bring Market Changing Innovation

Caliway

TWSE：6919

Contact: IR@caliway.com.tw

All rights reserved. Do Not disclose, copy, distribute or disseminated with explicit permission.