



CBL-514 — SCIENTIFIC RESEARCH PROFILE

Injectable Lipolytic Agent | DYRK1B Inhibitor | First-in-Class Small Molecule

Searchable via: LCH493814

| COA Reference | Batch / Lot No. | Searchable via |
|---------------|-----------------|----------------|
| LCH493814 | 000493 | LCH493814 |

1. COMPOUND IDENTITY & CLASSIFICATION

CBL-514 is a first-in-class small-molecule injectable drug candidate developed by Caliway Biopharmaceuticals Co., Ltd. (Taiwan; TWSE: 6919). Classified as a non-peptide small molecule with a bile-acid-related pharmacophore, designed to induce selective adipocyte apoptosis via DYRK1B kinase inhibition upon subcutaneous injection. Exact chemical structure, MW, and CAS are proprietary under 32 active patents (Synapse Database, Oct. 2023).

| | |
|-----------------|---|
| COA Reference | LCH493814 |
| Batch / Lot No. | 000493 |
| INN / Code | CBL-514 (investigational code; INN not yet assigned) |
| Chemical Class | Small molecule; bile acid-derived pharmacophore (non-peptide) |
| Mol. Formula | Not publicly disclosed (proprietary — Caliway Biopharmaceuticals) |
| Mol. Weight | Not publicly disclosed (proprietary) |
| CAS Registry | Not registered in open chemical databases as of August 2025 |
| PubChem CID | Not available in public domain |
| Formulation | 5 mg/mL aqueous solution; 20 mL glass vial (100 mg/vial); subcutaneous injection |
| Appearance | White to off-white lyophilized powder; clear aqueous solution upon reconstitution |
| Storage | Lyophilized: RT up to 3 weeks; reconstituted: 2–8°C 2–7 days; long-term: ≤–18°C |

2. MECHANISM OF ACTION

Primary target: DYRK1B (Dual-specificity tyrosine phosphorylation-regulated kinase 1B) — serine/threonine kinase that promotes cell survival in quiescent adipocytes. CBL-514 inhibits DYRK1B, triggering the intrinsic apoptosis pathway specifically in adipose tissue.

| | |
|-------------|--|
| Step 1 | Subcutaneous injection into target adipose depot |
| Step 2 | CBL-514 inhibits DYRK1B (adipocyte cell survival kinase) |
| Step 3 | Upregulation of Caspase-3 + increased Bax/Bcl-2 ratio |
| Step 4 | Dose-dependent programmed adipocyte apoptosis (not necrosis/cytolysis) |
| Step 5 | Selective reduction of subcutaneous fat volume in treatment area |
| Selectivity | No systemic effects on CNS, cardiovascular, or respiratory systems |





Key differentiation from Deoxycholic Acid (Kybella/ATX-101): Unlike DCA, which destroys adipocytes via non-selective cytolysis (membrane disruption), CBL-514 induces selective programmed apoptosis — hypothesized to result in reduced inflammatory burden and superior local tolerability, supported by the absence of systemic adverse events in Phase 2 clinical data.

3. CLINICAL DEVELOPMENT PROGRAM

| STUDY | DESIGN | STATUS | KEY OUTCOMES |
|------------------------------|---|-----------------------------|---|
| CBL-0201 Ph2a NCT04575467 | Abdominal fat; SAD 320–800 mg; US + Australia | Completed | All primary & secondary endpoints met; no systemic AEs |
| CBL-0202 Ph2 Stage 2 | Subcutaneous fat; placebo-ctrl; 99 subjects | Completed | >300 mL fat reduction avg; superior to liposuction; all endpoints met |
| CBL-0201DD NCT05387733 | Dercum's disease lipomas; open-label | Completed | 64.5% clearance or >50% reduction; pain –4.7 VAS; no systemic AEs |
| CBL-0201EFP | Cellulite (EFP); 23 subjects | Completed (results pending) | Enrollment complete; efficacy data expected post-Q2 2024 |
| CBL-0204 Ph2b | Abdominal fat; 100 subjects; FDA IND approved | Ongoing | Initiated May 2023; AFRS ≥1 grade improvement primary endpoint |
| + Tirzepatide | Weight management combo; IND Q4 2025 | Pre-IND | Phase 2 IND to FDA planned; weight loss maintenance indication |

4. ANALYTICAL CHARACTERIZATION STATUS

| PARAMETER | DATA AVAILABLE | VERIFICATION STATUS |
|-------------------|---|--|
| Appearance | White lyophilized powder; clear aqueous solution | CONFIRMED (clinical docs) |
| Purity (HPLC) | ≥ 99.0% specification declared | CONFIRMED (IND filing) |
| Identity (MS) | Small molecule; exact MW/formula proprietary | PARTIAL — structure undisclosed |
| Identity (NMR) | No published characterization | <i>Not publicly disclosed</i> |
| Melting Point | Not disclosed | <i>Not publicly disclosed</i> |
| Specific Rotation | Not disclosed | <i>Not publicly disclosed</i> |
| Solubility | 5 mg/mL aqueous; subcutaneous injectable | CONFIRMED (clinical docs) |
| Mol. Formula | Proprietary — not in public databases | <i>Not publicly disclosed</i> |
| CAS Number | Not registered in open chemical databases | <i>Not publicly disclosed</i> |
| Mechanism Target | DYRK1B inhibition — peer-reviewed | CONFIRMED (PMC9384315) |
| Clinical Safety | No systemic AEs on CNS/CV/respiratory | CONFIRMED (Phase 2 data) |
| Clinical Efficacy | >300 mL fat reduction; multiple Phase 2 endpoints met | CONFIRMED (Phase 2 data) |

5. REFERENCES & DATA SOURCES

[1] Goodman GJ et al. Efficacy of a Novel Injection Lipolysis to Induce Targeted Adipocyte Apoptosis. *Aesthetic Surgery Journal*, 2022. PMC9384315.





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[2] [ClinicalTrials.gov NCT04575467](https://clinicaltrials.gov/ct2/show/study/NCT04575467) — CBL-514 Subcutaneous Fat Reduction, Phase 2. Caliway Biopharmaceuticals Australia.

[3] [ClinicalTrials.gov NCT05387733](https://clinicaltrials.gov/ct2/show/study/NCT05387733) — CBL-514 in Dercum's Disease, Phase 2.

[4] Caliway Press Release, Sept. 13, 2023: CBL-514 Phase 2 Dercum's Disease Topline Results.

[5] Caliway Press Release, Oct. 2, 2023: CBL-0202 Phase 2 — Superior efficacy vs. liposuction; >300 mL reduction.

[6] Caliway Press Release, May 31, 2023: Initiation of CBL-0204 Phase 2b Study.

[7] Synapse Database, Oct. 2023: CBL-514 — 32 patents; DYRK1B + BAX dual target profile.

[8] [ClinicalTrials.gov Protocol: CBL-0202 \(NCT04575467\)](https://clinicaltrials.gov/ct2/show/study/NCT04575467) — Caliway Biopharmaceuticals Australia Pty Ltd.

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