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## Summarized Technical Data Sheet – CBL-514 – Please Read Carefully

### Identification

**Name:** CBL-514

**Class:** Injectable small molecule for localized subcutaneous fat reduction

**Investigational Indication:** Non-surgical reduction of localized subcutaneous fat.

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### Mechanism of Action

CBL-514 works by promoting the selective apoptosis (programmed cell death) of adipocytes, resulting in the gradual reduction of the treated adipose tissue.

Preclinical studies indicate that the compound:

- Inhibits the cell survival kinase DYRK1B;
  - Increases the expression of pro-apoptotic mediators, including caspase-3 and Bax/Bcl-2;
  - Induces dose-dependent apoptosis in adipocytes;
  - Promotes lipolysis and localized fat reduction without causing significant tissue necrosis.
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### Evaluated Dose



## Target dose:

**2 mg/cm<sup>2</sup>**

This was the dose that demonstrated the best efficacy outcomes in Phase II clinical studies.

## Practical Equivalent

Using a concentration of **5 mg/mL**:

- **2 mg/cm<sup>2</sup> = 0.4 mL/cm<sup>2</sup>**

## Examples

### Treated Area Total Dose

50 cm<sup>2</sup>      100 mg (20 mL)

100 cm<sup>2</sup>     200 mg (40 mL)

150 cm<sup>2</sup>     300 mg (60 mL)

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## Efficacy Results

At the 2 mg/cm<sup>2</sup> dose, clinical studies reported:

- An average reduction of approximately 25% in abdominal fat volume;
- A significant reduction in subcutaneous fat thickness measured by ultrasound;
- Superior efficacy compared with the 1.2 mg/cm<sup>2</sup> and 1.6 mg/cm<sup>2</sup> dose groups.

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Safety Profile (Phase IIa and Phase II Studies)

## Most Common Adverse Events

Primarily related to the injection site:

- Local pain;
- Edema;
- Erythema;
- Ecchymosis (bruising);
- Pruritus (itching);
- Local induration.

## Severity

- Approximately **80%** of adverse events were classified as **mild**;
- Approximately **19%** were **moderate**;
- No serious treatment-related adverse events were reported;
- No deaths or life-threatening events were attributed to CBL-514.

## Laboratory Findings

A small number of participants experienced:

- Transient elevation of total cholesterol;
- Transient elevation of triglycerides.

## Relevant Findings

Clinical studies reported no evidence of:

- Skin necrosis;
  - Ulceration;
  - Nerve injury;
  - Clinically significant systemic adverse effects.
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## ✓ Reconstitution of One Lyophilized Vial with One Diluent Vial

- The exact volume of diluent is critical. Consult your physician to establish an appropriate protocol based on your individual circumstances.
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## ✓ Administration into the Subcutaneous Fat Layer

- CBL-514 has been developed for administration into subcutaneous adipose tissue.
- Therefore, injecting into the fat layer is consistent with its proposed mechanism of action.

### ✓ Multiple Injection Sites

- In treatments targeting localized fat deposits, it is common practice to distribute the product across multiple injection sites to achieve uniform coverage of the treatment area.
- In published clinical studies, CBL-514 was investigated for administration into areas containing localized subcutaneous fat, particularly the abdominal region. The selection of the treatment area, injection technique, and materials used should follow the Standard Operating Procedures (SOPs) established for the respective clinical study.



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### ✓ **Gentle Massage After Administration**

- Some treatment protocols include gentle massage after administration to facilitate local dispersion of the product.

