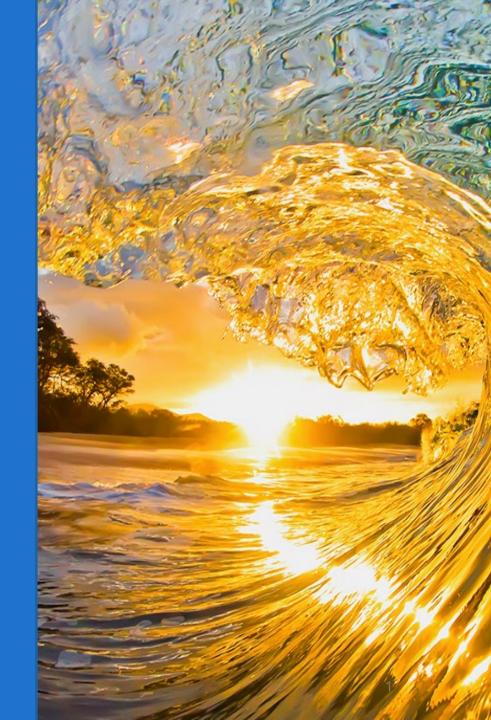
## FDA Presentation – AOD-9604

Presented by:

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## AOD 9604

• Synthetic, orally active lipolytic peptide fragment of hGH

 AOD 9604 appears to enhance lipolysis in mice by upregulating beta-3 adrenergic receptors

Increases fat oxidation

### AOD 9604

 How is AOD 9604 generally used by the medical community? Adjunct for weight management support

 4 preclinical animal and 2 human clinical trials of significance



- Reported safe in human studies
  - Human GRAS status in USA as dietary supplement

Ng FM, et al. Metabolic studies of a synthetic lipolytic domain (AOD9604) of human growth hormone. Horm Res. 2000;53(6):274-8.

# AOD 9604 Human Safety Study

#### SAFETY AND TOLERATIBILITY STUDY – IV and PO

- 2013 meta-analysis = six randomized, double-blind, placebo-controlled trials n= 900 adult subjects
- Reported no effect on serum IGF-1 levels
- AOD 9604 has no negative effect on carbohydrate metabolism (in contrast to hGH) – oral carb test
- No anti-AOD 9604 antibodies detected in any of the patients selected for antibody assay
- Authors concluded that AOD 9604 displays a very good safety and tolerability profile indistinguishable from placebo, with none of the adverse effects associated with full-length hGH treatment

Stier H, et al. Safety and tolerability of the hexadecapeptide AOD9604 in humans. J Endocrinol Metab. 2013;3(1-2):7-15.

#### AOD 9604 Level of Evidence

|   | Level of Evidence | Description  |
|---|-------------------|--|
|   | Level 1           | FDA Approved Drug studies  |
|   | Level 2           | Evidence obtained from systematic review and/or meta-analyses of |
|   |                   | studies including RCTs and other human studies                   |
| X | Level 3           | Evidence obtained from <u>a</u> RCT                              |
|   | Level 4           | Evidence obtained from a study without randomization             |
|   | Level 5           | Evidence obtained from case reports                              |
| X | Level 6           | Evidence obtained from in vitro human studies                    |
| X | Level 7           | Evidence obtained from laboratory animal studies                 |
| X | Level 8           | Evidence obtained from Opinions or Reviews                       |

6 RCT using AOD 9604 for weight management support reported

## **AOD 9604 Dispensing Data**

Community Pharmacy dispensing data

- 158,989 doses of AOD 9604 dispensed, including:
  - Injection
  - Troche
  - Cream
  - Capsules