Innovations
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Modified Recombinant Follicle Stimulating Hormone

Product

New therapeutic

Indication

Osteopenia/Osteoporosis

Value Propositions

- More potent stimulator of estradiol
- Preserves bone strength and prevents fat accumulation in post-menopausal women

Market

- $10.7 billion—Global osteoporosis market (4.3% CAGR 2018-2026)

Intellectual Property

- PCT pending*
- Available for licensing

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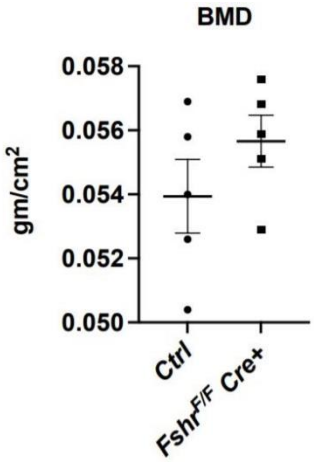
Background on CU5155H

During menopause, levels of estrogen, the key regulator of bone metabolism, significantly drop. As a result, menopause and the accompanying loss of ovarian estrogens are associated with declines in bone mineral density (BMD). It is estimated that 1 in 4 women over the age of 65 have significant osteoporosis, or severe reductions in BMD.

One hormone critically involved in ovarian estrogen production and bone health is follicle stimulation hormone (FSH). Drug companies have developed formulations of FSH to address ovarian induction and estrogen production in aged women, but these formulations have not shown success at increasing or sustaining BMD. Current drugs targeted again osteoporosis have undesirable side effects. Therefore, there is presently a need for improved products and methods of treatment and prevention of bone density loss.

Technical Innovation

Dr. T. Rajendra Kumar at the University of Colorado has discovered that during young and normal reproductive cycles, women produce mostly hypo-glycosylated FSH, whereas older women produce predominantly fully-glycosylated FSH. His data further indicate that hypo-glycosylated FSH is more biologically active, and binds FSH receptors on ovarian cells or cell lines more effectively than fully-glycosylated FSH. To take advantage of this discovery, Dr. Kumar has developed a new recombinant FSH (rFSH) which mimics the FSH glycoform which is found in younger women. Preliminary studies in vivo have had promising results, and shown that knocking out FSH receptors on bone osteoclasts, the cells responsible for bone resorption, increases overall bone mineral density compared to control (Figure 1). Published studies indicate the new rFSH more potently produces estrogen.



This new therapeutic is additionally advantageous to commercially available FSH in that it uses the pituitary cell expression system which is closer to the native pituitary gonadotropes, instead of the Chinese Hamster Ovary cell expression system currently employed to produce rFSH. There is tremendous potential for this rFSH to enhance estrogen production and decrease the risk of bone loss in post-menopausal women.

Figure: Bone mineral density in control mice vs. osteoclast FSH receptor knockout

***PCT pending: PCT/US2020/059382— "Modified Follicle-Stimulating Hormone and Methods of Using the Same"—Filed November 6th, 2020.*