FOR IMMEDIATE RELEASE

Aviva Bio Launches to Transform Hormone-Based Medicine—Starting with Women

Concord, MA – [May 6, 2025] – Aviva Biopharm Inc., a clinical-stage biotech company, launches this month with a mission to rewrite the future of hormone-based medicine. With its lead asset, AVA-291 (d3-Testosterone), Aviva Bio is targeting a long-overlooked need in healthcare: an FDA-approved testosterone therapy for women.

While testosterone plays a vital role in women's health, there are currently no FDA-approved or dose-appropriate testosterone treatments for women, despite more than 30 formulations approved for men. AVA-291 (d3-T) is a first-in-class, non-aromatizing androgen developed specifically for postmenopausal women experiencing symptoms such as low libido, muscle loss, and fatigue.

> *"We are creating the first efficacious testosterone for women that doesn't convert to estrogen – a key safety challenge that has blocked innovation for decades,"* said Judith Boice, PhD, CEO of Aviva Bio *"This molecule has the potential to redefine care for millions of women."*

A New Standard in Women's Health

Aviva Bio's innovation, d3-T, has completed preclinical assessment and demonstrated a compelling safety and efficacy profile in early studies. Unlike existing testosterone formulations, d3-T is engineered to resist aromatization, the biochemical process that converts testosterone into estradiol (E2), a form of estrogen associated with increased breast cancer risk in postmenopausal women.

d3-T achieves this through precision molecular design: select hydrogen atoms are replaced with deuterium, a naturally-occurring alternative form of hydrogen, that maintains therapeutic function while altering metabolic behavior.

> *"Aviva's approach is innovative, intuitive, and uses the foundation of a known hormone, with targeted molecular changes focused on improving safety,"* said Robert Dudley, PhD, a testosterone expert and former CEO of Clarus Therapeutics who will serve as a Scientific Advisor to Aviva Bio.

Positioned for Breakthrough

By 2030, 65 million U.S. women will be in one of the three stages of menopause, and millions already suffer from untreated symptoms due to the lack of safe, effective hormone therapies. d3-T not only addresses this unmet need but also holds promise for broader indications—including muscle loss and libido changes associated with GLP-1 agonist use.

World-Class Executives and Experts

Aviva Bio is led by an accomplished Executive Team with extensive pharmaceutical and healthcare industry expertise and a proven track record in drug commercialization, biotech start-ups, and women's health. Members of the Executive Team include: Judith Boice, PhD, CEO; Brad Sippy, Chief Technology Officer; Jessica Halem, Head of Business Development; and Mary M. Sherman, PhD, DMPK-Bioanalytical.

They are supported by a growing Scientific Advisory Board featuring leaders in clinical research and healthcare innovation including: Robert Dudley, PhD, former CEO of Clarus Therapeutics and Barbara Levy, MD, FACOG, FACS, MSCP, Clinical Professor, Obstetrics and Gynecology, The George Washington University School of Medicine and Health Sciences, CMO of Visana Health, and Former VP for Health Policy, the American College of Obstetricians and Gynecologists.

What's Next

Aviva Bio will present new research on d3-T at **ENDO 2025**, the world's leading endocrinology conference, in San Francisco this July.

About Aviva Bio

Aviva Bio is a clinical-stage biotechnology company unlocking the full potential of hormone-based medicine. Through novel drug design and a focus on unmet needs in women's health, Aviva Bio is developing first-in-class therapeutics to improve lives. Its lead program, AVA-291 (d3-Testosterone), is on track to become the **first FDA-approved testosterone therapy designed for women**.

About AVA-291 (d3-Testosterone)

AVA-291 or d3-Testosterone (d3-T) is a structurally identical, deuterium-substituted isotopologue of testosterone (T) designed to resist aromatization to estradiol (E2). Conversion of T into E2 is linked with potential safety (breast cancer) and tolerability (gynecomastia) concerns associated with T therapy. In *in vitro* studies, d3-T has demonstrated a similar hepatic metabolic profile and similar androgen receptor affinity as T, but unlike T it is highly resistant to aromatization to E2. d3-T may be a useful alternative to T in clinical situations where the aromatization of T limits its therapeutic potential, such as hormone replacement therapy in postmenopausal women, addressing muscle wasting in patients on GLP-1 therapy, the treatment of ER+ breast cancer, or in men on T therapy who develop gynecomastia.

To learn more, visit:

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