

## Historic First: FDA Grants Meeting for Gender Affirming Development Program

- First ever proposed Phase III program for gender-affirming care
- Proposed indication is as a feminizing agent in the management of gender incongruence

Newton, MA, October 17, 2023 –

The Research Institute for Gender Therapeutics (RIGT), Inc. a non-profit pharmaceutical organization and 501(c)(3) public charity focused on seeking FDA approval of treatments for gender incongruence, is excited to announce a meeting has been granted by the U.S. Food and Drug Administration (FDA) for RIGT’s proposed estradiol development program for gender-affirming care. The goal of this development program is a stand-alone form of estradiol with a singular indication for people with gender incongruence. A historic first, the Phase III controlled study would be the most advanced study ever conducted for gender-affirming care.

This is an important step in RIGT’s larger mission to research, develop, and seek FDA approval for therapeutic options for gender incongruence. Gender incongruence, sometimes called gender dysphoria, is when the gender identity of a person does not align with the gender assigned at birth. Gender incongruence is recognized by every major U.S. medical association and the World Health Organization as a serious medical condition, and untreated gender incongruence is associated with mental health concerns such as depression, psychological distress, and suicidal ideation and attempts.<sup>1</sup>

Hormone therapy for the treatment of gender incongruence typically includes estrogen as a feminizing agent and testosterone as a masculinizing agent. These medications, though long approved as safe and effective by the FDA for other indications, are currently used off-label for gender incongruence. Off-label use is common in medicine: approximately 20 percent of medication use for adults, and up to 50-75 percent in pediatric populations, is off-label.<sup>2, 3</sup> After demonstrated effectiveness in clinical use for off-label indications, some medications may be submitted to the FDA for additional approval of these indications.

“Important work has been done previously to establish hormone medications as safe and effective for gender affirming care. We are seeking formal FDA approval to support these life-saving treatments and protect healthcare access for the underserved gender diverse population” said Bradford C. Sippy, Founding Director and President of RIGT.

“The importance of RIGT’s proposed program with estradiol to enhance medical care and access for the gender diverse community cannot be overstated. This is the exact type of study the field needs at the exact right time.” said Zil Goldstein, FNP-BC, Associate Director of Medicine, Transgender and Gender Non-Binary Health, Callen-Lorde Community Health Center.

### About Estradiol

Estradiol is the most potent and principal intracellular human estrogen. It is a primary recommended treatment as a feminizing agent in the management of gender incongruence.<sup>4, 5</sup>

A robust body of evidence compiled over more than four decades indicates that treatment for gender incongruence is associated with improved mental and physical health for transgender people.<sup>6,7</sup>

The use of estradiol in gender affirming care is supported by all major US medical associations, including the Endocrine Society and the American Medical Association.<sup>8</sup>

### **About Gender Incongruence**

Gender incongruence is defined as a condition in which the gender identity of a person does not align with the gender assigned at birth.

RIGT is adopting the ICD-11 definition of gender incongruence as an update to the previous term gender dysphoria, which is no longer defined as a psychiatric condition in ICD-11.<sup>9</sup>

### **About The Research Institute for Gender Therapeutics**

The Research Institute for Gender Therapeutics (RIGT) is a registered 501c3 public charity that was founded to address the significant unmet medical and social needs of gender diverse individuals. The clinical treatment of gender diverse individuals is often stigmatized, under-researched, and there are no treatments specifically approved by the FDA to treat gender incongruence. RIGT was established to address these issues and has recruited a team of world-renowned experts in gender care and drug development to guide our organization and help support a world where the treatment of gender diverse individuals is broadly accessible and accepted as standard medical practice.

For more information, please visit [www.rigt.org](http://www.rigt.org).

### **References**

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## **Contacts**

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