



## **TheraVida Initiates Phase 2 Trial of THVD-201 for Overactive Bladder and Urinary Incontinence**

### **Multi-national Study to be Conducted by Novotech in Australia, New Zealand, and South Korea**

MOUNTAIN VIEW, California, and SYDNEY, Australia, May 16, 2011 /PRNewswire-iReach/ -- TheraVida, Inc., a clinical stage biopharmaceutical company developing novel combination drug products, announced the start of a Phase 2 clinical trial of its lead product candidate THVD-201 for the treatment of overactive bladder (OAB) and urge urinary incontinence (UUI). Novotech, a leading Asia Pacific contract research organization, has been selected to manage the study for TheraVida.

This Phase 2 clinical trial is designed to examine the safety, side effect profile, tolerability and efficacy of THVD-201, as compared to placebo control and standard anti-muscarinic therapy Detrol<sup>®</sup> (tolterodine tartrate) by Pfizer, Inc. The study is targeted to enroll 120 female patients with OAB and UUI at 9 sites in Australia, 5 sites in New Zealand, and 3 sites in the South Korea. A previous Phase 1 study of THVD-201 demonstrated improvements in salivary output and related dry mouth side effects in healthy volunteers receiving THVD-201, as compared to Detrol<sup>®</sup> (tolterodine tartrate).

“TheraVida is very pleased to be advancing our novel combination drug product THVD-201 into Phase 2 clinical trials for overactive bladder and urinary incontinence, in this multi-national study with Novotech,” said Roger Flugel, Ph.D., Chairman and Chief Executive Officer of TheraVida. Alek Safarian, Founder and CEO of Novotech, commented, “The Novotech team is enthusiastic about working together with TheraVida in the Asia Pacific region on the human clinical trials of THVD-201, an exciting new product in development. The Phase 2 study has now been initiated and the first patients have been dosed.”

#### **About Overactive Bladder (OAB)**

OAB is a disease of ageing that is characterized by an increase in urinary frequency, urinary incontinence, and nocturia. In addition, there is often an increase in the frequency and intensity of urinary urgency in patients. It is estimated that OAB is prevalent in approximately 16% to 17% of the population world-wide, and therefore, is at least as common of a disorder as diabetes. As the world population continues to age over time, the prevalence of OAB is only expected to increase.

#### **About THVD-201**

THVD-201 is a novel, patent-protected product that combines tolterodine with a modified-release formulation of a salivary stimulant. This product incorporates unique combination drug technology developed by TheraVida that can be applied to any of the standard anti-muscarinic therapies used to treat OAB, to overcome the problematic dry mouth side effect that is typically associated with this class of therapy. TheraVida combination drug products such as THVD-201 also have the potential for greater efficacy in the treatment of OAB, and better patient compliance, when compared to tolterodine alone.

#### **About TheraVida**

TheraVida, Inc., is a privately-held California biopharmaceutical company that was founded with the objective of improving patient care. There is a widely recognized need by patients, physicians, and regulatory agencies, for new medicines that are able to successfully treat disease with improved side effect and safety profiles. Our company is committed to this objective. Using a unique and patent-protected combination drug technology, TheraVida is able to develop products that have significantly better side effect and safety profiles, when compared with predecessor therapies. This same technology also has the ability to generate products that provide better efficacy to patients, in the treatment of various disorders.

#### **About Novotech**

Headquartered in Sydney with a regional hub in Malaysia, Novotech is a clinical research organization (CRO) focused on the Asia Pacific region with operations in nine countries including India and South Korea. Novotech also has worldwide reach through the company’s network of strategic partners. Novotech, described by Frost & Sullivan as the best in its industry class for Australia based CROs, brings its global reputation for high quality service and regional expertise to the high-growth Asia Pacific area. Additional information about Novotech is available at [www.novotech-cro.com](http://www.novotech-cro.com).

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