

## ULURU NEWS

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### **ULURU INC. ANNOUNCES THE FILING OF A 510(K) APPLICATION TO EXPAND**

#### **ALTRAZEAL<sup>®</sup>'S LABEL CLAIM**

**– Management and Mitigation of Pain Claim Filed –**

**– Randomized Clinical Study Principal Data Supporting Claim –**

**Addison, Texas, March 15, 2011; ULURU Inc. (NYSE AMEX: ULU)** announced today that it has filed an abbreviated 510(k) application with the U.S. Food and Drug Administration to expand Altrazeal<sup>®</sup>'s label claim to include the management and mitigation of pain.

The principal data supporting this 510(k) application is a randomized clinical study comparing Altrazeal<sup>®</sup> to Acquacel<sup>®</sup> Ag in skin graft donor sites. This amended label claim is also supported by clinical experience using Altrazeal<sup>®</sup> in various wound types including venous leg ulcers, second degree burns, geriatric wounds and numerous less common wound types.

In the randomized clinical study Altrazeal<sup>®</sup> when compared to Acquacel<sup>®</sup> Ag, a market leading product, used as the standard of care for skin graft donor sites at a number of major burn treatment centers, showed the following results:

- At all 3 time points evaluated Altrazeal<sup>®</sup> demonstrated a statistically significant reduction in pain (P<0.0001) [Statistical significance is (P<0.05)]; and
- Patients also reported a statistically significant improvement in comfort (P<0.001).

Significant pain reduction has also been reported when Altrazeal<sup>®</sup> has been used to treat venous leg ulcers. Wound pain is a significant issue for venous leg ulcer patients with 80% of patients experiencing pain which can lead to poor patient compliance, fatigue, sleep disturbances and depression.

In a group of patients treated with Altrazeal<sup>®</sup>, who had experienced venous leg ulcers for 3 – 27 years where all patients reported pain as an inhibiting factor with adherence to recommended compression treatment and the wounds had not decreased in size for several months:

- All patients reported improvement in pain levels within 15 minutes of application (the patient with the 27 year old wound who previously reported continuous pain of 9-10 (0-10 scale) experienced immediate pain reduction to 2);
- Patients increased compliance to the recommended treatment plan and these stagnated wounds healed; and
- All patients reduced oral pain medication.

In addition, a group of second degree burn patients also reported a dramatic drop in pain upon application of Altrazeal<sup>®</sup> to their wounds. Prior to treatment with Altrazeal<sup>®</sup>, average pain scores were 8.2 (0-10 scale). After application of Altrazeal<sup>®</sup>, pain was reduced to an average of 1.7 and during the treatment period the pain average was 0.4.

Commenting on the 510(k) application, Kerry P. Gray, President and CEO of ULURU Inc., stated, “Altrazeal<sup>®</sup> is a scientifically engineered wound treatment product designed to fill a critical unmet clinical need in chronic wound care. The Company believes that the substantial clinical data we have generated on wound healing and pain management justifies this unique label claim designation. No other wound treatment has demonstrated this major clinical advantage. Patient compliance and improved patient comfort are critical components in the treatment of chronic wounds. Achieving this amended

label claim will be a significant competitive advantage and further differentiate Altrazeal<sup>®</sup> from other wound products.”

The filing of this application is an integral part of the Company’s ongoing product line extension strategy to provide a value added portfolio of products to assist wound care professionals to improve clinical outcomes, as well as provide patients with compliance and comfort benefits.

Mr. Gray added, “In the near term we intend to file additional 510(k) applications and further product line extensions. Also, we intend to initiate an additional randomized clinical study to prove healing benefits associated with Altrazeal<sup>®</sup> that could enable us to further expand the label claim and differentiation of Altrazeal<sup>®</sup>.”

**About ULURU Inc.:**

**ULURU Inc.** is a specialty pharmaceutical company focused on the development of a portfolio of wound management and oral care products to provide patients and consumers improved clinical outcomes through controlled delivery utilizing its innovative Nanoflex<sup>®</sup> Aggregate technology and OraDisc<sup>™</sup> transmucosal delivery system. For further information about ULURU Inc., please visit our website at [www.uluruinc.com](http://www.uluruinc.com). For further information about Altrazeal<sup>®</sup>, please visit [www.Altrazeal.com](http://www.Altrazeal.com).

*This press release contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended including the results of our clinical trial, our belief that the substantial clinical data we have generated on wound healing and pain management justifies this unique label claim designation, our belief that achieving this amended label claim will be a significant competitive advantage and further differentiate Altrazeal<sup>®</sup> from other wound products, and further*

*intended 510(k) filings that are anticipated. These statements are subject to numerous risks and uncertainties, including but not limited to the risk factors detailed in the Company's Annual Report on Form 10-K for the year ended December 31, 2009, and other reports filed by us with the Securities and Exchange Commission.*