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## Introgen Submits ADVEXIN<sup>®</sup> Regulatory Applications in the U.S. and Europe

*ADVEXIN Targets Gene Defect Common to Majority of Tumors*

AUSTIN, Texas & DUBLIN, Ireland--([BUSINESS WIRE](#))--[Introgen Therapeutics, Inc.](#) (NASDAQ:INGN) submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) requesting marketing approval for ADVEXIN<sup>®</sup> p53 therapy to treat recurrent, refractory head and neck cancer. Simultaneously, Gendux Molecular Limited, an Introgen subsidiary, submitted a Marketing Authorization Application (MAA) to the European Medicines Evaluation Agency (EMA) for the same indication. ADVEXIN represents the first of a new class of tumor suppressor cancer therapy and is the first of its kind to be submitted for regulatory approval in the United States and Europe.

Introgen has requested Priority Review from the FDA for ADVEXIN. Priority Review is typically granted to compounds that provide significant medical benefit compared to existing treatments for a disease. If Priority Review is granted, the FDA will have up to six months from submission date to take action on the dossier. ADVEXIN is considered an 'Orphan Drug' in the US for the treatment of recurrent, refractory head and neck cancer, which, if approved, entitles the drug to extended market exclusivity for the approved indication.

"This is an important milestone in the clinical application of gene therapy for cancer patients," said Jack A. Roth, MD, inventor of ADVEXIN and Professor and Bud Johnson Clinical Distinguished Chair, Department of Thoracic and Cardiovascular Surgery, at [M.D. Anderson Cancer Center](#). "With the use of p53 biomarkers, ADVEXIN will provide more effective and less toxic treatment for head and neck cancer patients who have limited treatment options."

ADVEXIN p53 therapy harnesses the body's natural tumor suppression mechanisms to fight cancer, without the toxicities associated with conventional cancer treatments. Abnormalities in protective tumor suppressor p53 pathways are associated with the majority of all solid cancers. Designed to restore patients' ability to fight cancer using the guardian gene p53, ADVEXIN delivers large doses of the normal tumor suppressor p53 gene to target abnormal p53 function present in tumor cells which triggers natural tumor suppression mechanisms in cancer without harming normal cells.

"These filings represent a significant step toward making this important cancer treatment available to patients in the U.S. and Europe," said Max W. Talbott, PhD, Introgen's senior vice president of Worldwide Commercial Development and Regulatory Affairs. "We are committed to improving the lives of cancer patients and look forward to working with regulators to make this therapy available as soon as possible."

The FDA submission is based on positive pivotal phase II and III clinical trials evaluating survival, tumor response and safety in patients with recurrent, refractory end-stage, squamous cell carcinoma of the head and neck. These trials incorporated common diagnostic tests to identify patients most likely to benefit from ADVEXIN treatment based upon pre-treatment tissue analyses to determine p53 profile status.

The Company plans to host a conference call to be scheduled in July, 2008 to review the ADVEXIN clinical trial results. The call will include principal investigators familiar with the clinical use of ADVEXIN.

“The positive results of the ADVEXIN pivotal trials have significant implications for the management of patients with refractory head and neck cancers who need new effective therapies. Our findings realize the promise of personalized medicine and indicate that ADVEXIN can be an effective treatment for patients who are easily identified by simple diagnostics tests,” said David G. Nance, Introgen’s Chairman and CEO.

### **ADVEXIN PHASE 3 CLINICAL TRIAL**

#### **Summary Results**

The phase III trial achieved the study’s objectives and demonstrated clinical benefit of ADVEXIN in comparison to the control drug methotrexate. The detailed study results will be reviewed at the Company’s upcoming conference call. The patients most likely to benefit from ADVEXIN treatment with increased tumor responses and survival were identified by pre-specified p53 biomarker profiles. The clinical application of these biomarkers allows physicians to select individualized therapy based upon a patient’s p53 profile determined by routine diagnostic tests. This application represents a major advance in the management of this disease. Overall, the study results demonstrate that ADVEXIN addresses an unmet medical need and the combination of biomarker testing and ADVEXIN treatment has the potential to provide recurrent head and neck cancer patients with an effective therapy that is less toxic than standard chemotherapies.

#### **About Introgen**

Introgen Therapeutics, Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of targeted molecular therapies for the treatment of cancer and other diseases. Introgen is developing molecular therapeutics, immunotherapies, vaccines and nano-particle tumor suppressor therapies to treat a wide range of cancers using tumor suppressors, cytokines and genes. Introgen maintains integrated research, development, manufacturing, clinical and regulatory departments and operates multiple manufacturing facilities including a commercial scale cGMP manufacturing facility.

#### **About Gendux Molecular Limited**

Gendux Molecular Limited is a non-resident Irish company based in Dublin, Ireland. The Company is focused on the commercialization of targeted molecular therapies to be applied with molecular diagnostic tools to introduce personalized medical products in European and other markets. Gendux is a subsidiary of Introgen Therapeutics, Inc. For more information on Gendux, or for a menu of archived press releases, please visit Gendux’s Website at: [www.gendux.ie](http://www.gendux.ie).

#### **Forward-Looking Statements**

Statements in this release that are not strictly historical may be “forward-looking” statements, including those relating to Introgen’s future success with its ADVEXIN clinical development programs for treatment of cancer and the use of biomarker



data to support the regulatory approval of ADVEXIN and improve the care of patients. The actual results may differ from those described in this release due to risks and uncertainties that exist in Introgen's operations and business environment, including Introgen's stage of product development and the limited experience in the development of gene-based drugs in general, dependence upon proprietary technology and the current competitive environment, history of operating losses and accumulated deficits, reliance on collaborative relationships, and uncertainties related to clinical trials, the safety and efficacy of Introgen's product candidates, the ability to obtain the appropriate regulatory approvals, Introgen's patent protection and market acceptance, as well as other risks detailed from time to time in Introgen's filings with the Securities and Exchange Commission including its filings on Form 10-K and Form 10-Q. Introgen undertakes no obligation to publicly release the results of any revisions to any forward-looking statements that reflect events or circumstances arising after the date hereof.

Only the FDA, EMEA and corresponding regulatory agencies have the authority to approve pharmaceutical products. We cannot predict how such authorities may interpret the information contained in this release or may respond to our regulatory submissions.

Editor's Note: For more information on Introgen Therapeutics, or for a menu of archived press releases, please visit Introgen's Website at: [www.introgen.com](http://www.introgen.com).

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