

## **Transdel Enrolls First Patient for Ketotransdel(TM) Phase 3 Clinical Trial with Cato Research**

LA JOLLA, Calif., Sept. 22 -- **Transdel Pharmaceuticals, Inc.** (OTC Bulletin Board: TDLP), a specialty pharmaceutical company focused on developing non-invasive, topically administered medications, today announced it has enrolled its first patient in the Phase 3 registration trial for Ketotransdel(TM). Ketotransdel(TM), a novel analgesic and anti-inflammatory topical cream, contains 10% ketoprofen (a non-steroidal anti-inflammatory drug, 'NSAID'), and is intended for use in the treatment of acute pain from musculoskeletal conditions.

The Ketotransdel(TM) Phase 3 registration study entitled: 'A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Parallel-Group, Phase 3 Study to Assess the Efficacy and Safety of Ketotransdel(TM) in the Treatment of Pain Associated with Mild to Moderate Acute Soft Tissue Injury,' will be conducted at approximately 25 to 35 sites in the United States and potentially in Canada. The Company expects to enroll approximately 350 patients of which 50% will be provided Ketotransdel(TM) and 50% a placebo vehicle. The Phase 3 study currently has three sites that are actively screening for patients. It is expected that the majority of the sites will be activated during October and November. The Company expects to report top-line results in the second half of 2009.

In the Phase 3 study, the primary efficacy endpoint will be the difference in the change of baseline pain between Ketotransdel(TM) and placebo at Day 3. This endpoint is measured by using the Visual Analogue Scale (VAS), a validated and widely used scale for recording pain which 0 indicates 'no pain' and 100 indicates 'the worst imaginable pain.' The secondary endpoints will include safety assessments and other efficacy parameters measured by VAS at Day 3 and Day 7. In addition to evaluating for efficacy and safety over the one week period, the study will also assess safety at one week post-treatment.

'We are excited about reaching this important milestone, the dosing of our first patient. Along with our strategic partner and contract research organization, **Cato Research Ltd.**, we continue to be extremely focused on enrolling appropriate patients and initiating new sites to meet our corporate goals,' stated Dr. Juliet Singh, President and Chief Executive Officer of Transdel Pharmaceuticals. 'Ketotransdel(TM) could address a significant unmet medical need for patients and physicians seeking a potentially safer effective pain alternative to existing pain management approaches, such as oral NSAIDs. We are committed to aggressively advancing this program to fulfill this unmet medical need.'

Ketotransdel(TM) which consists of an elegant cream formulation is designed to be applied directly to the site of the pain. It is absorbed within minutes and is not associated with the limitations of patches. Musculoskeletal pain conditions are defined as pain that affects the muscles, ligaments and tendons. If approved, Ketotransdel(TM) could be the first topical cream in the United States for treatment of acute pain related to musculoskeletal conditions.

Industry estimates indicate that the market for NSAIDs and Cox-2 inhibitors exceeds \$6 billion per year and that more than 30 million people worldwide use NSAIDs daily. Due to the recognition of known risks associated with orally administered NSAIDs, including cardiovascular, gastrointestinal and other medical complications, and the decline in the use of Cox-2 inhibitors due to safety concerns, the Company believes that there is a significant demand for topical pain management products such as Ketotransdel(TM).

If and when the FDA approves Ketotransdel(TM) for treatment of acute pain, the Company intends to pursue FDA approval of Ketotransdel(TM) for other indications, such as osteoarthritis. The Company believes that the clinical success of Ketotransdel(TM) will facilitate the use of the Transdel(TM) delivery technology, which is utilized in Ketotransdel(TM), in other products. Accordingly, the Company is investigating other drug candidates and treatments for transdermal delivery using the Transdel(TM) platform technology for products in pain management and other therapeutic areas. Furthermore, the Company is exploring potential partnerships with U.S. and foreign based companies that have sales and marketing infrastructures to support Ketotransdel(TM) in the event that the product is approved and commercialized. The Company is also looking to out-license its Transdel(TM) drug delivery technology for the development and commercialization of additional innovative drug products.

#### **About Transdel Pharmaceuticals, Inc.**

Transdel Pharmaceuticals, Inc. (OTC Bulletin Board: TDLP) is a specialty pharmaceutical company developing non-invasive, topically-delivered medications. The Company's innovative patented proprietary Transdel(TM) cream formulation technology is designed to facilitate the effective penetration of drugs through the tough skin barrier to reach the target underlying tissues. In the case of Ketotransdel(TM), the Transdel(TM) cream allows the active ingredient ketoprofen to reach the target soft tissue and exert its well-known anti-inflammatory and analgesic effects. The Company is also investigating other drug candidates and treatments for transdermal delivery using the patented Transdel(TM) platform technology for products in pain management and other therapeutic areas. For more information, please visit <http://www.transdelpharma.com> .

#### **About Cato Research**

Founded in 1988 by Allen Cato, M.D., Ph.D., and Lynda Sutton and headquartered near Research Triangle Park, Cato Research is a global, full-service contract research and development organization providing strategic and tactical support for clients in the pharmaceutical, biotechnology, medical device, and medical diagnostic industries. With a staff of more than 300 employees located in the United States, Europe, Canada, Israel, and South Africa, Cato Research's services range from design and management of preclinical and clinical studies to submission of regulatory documents required for marketing approval. For more information, visit Cato's website at <http://www.cato.com>.

## **Safe Harbor Statement**

Statements made in this release that are not historical in nature constitute forward-looking statements within the meaning of the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by the use of words such as 'expects,' 'plans' 'will,' 'may,' 'anticipates,' 'believes,' 'should,' 'intends,' 'estimates,' and other words of similar meaning. These statements are subject to risks and uncertainties that cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with the uncertainty of future financial results, additional financing requirements, development of new products, government approval processes, the impact of competitive products or pricing, and technological changes. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission, including the Company's Annual Report on Form 10-KSB filed with the SEC on March 26, 2008. Such documents may be read free of charge on the SEC's web site at [www.sec.gov](http://www.sec.gov). All forward-looking statements included in this release are made as of the date of this press release, and the Company assumes no obligation to update any such forward-looking statements.

SOURCE: Transdel Pharmaceuticals, Inc. and Cato Research Ltd.