

# ImmuCell

---

FOR IMMEDIATE RELEASE:

## **IMMUCELL'S MASTITIS DRUG MEETS PIVOTAL EFFECTIVENESS STUDY END POINT**

PORTLAND, Maine – September 30, 2009 -- **ImmuCell Corporation (NASDAQ: ICCC)** today announced initial results from its pivotal effectiveness study of **Mast Out**<sup>®</sup>. All data, results and conclusions discussed in this press release are subject to review and approval by the U.S. Food and Drug Administration (FDA), Center for Veterinary Medicine.

In a study of approximately 300 qualified cows with subclinical mastitis that was conducted at sixteen sites across the United States, the **Mast Out**<sup>®</sup> treatment group showed a statistically highly significant ( $p < 0.0001$ ) overall cure rate in comparison to the placebo group. The preliminary breakdown of the data by species suggests both the necessary numerical superiority and clinical relevancy to support robust product performance in the field. The primary objective of this study was to demonstrate effectiveness in the field, at a level similar to currently marketed intramammary antibiotics.

“We accomplished our objective and confirmed results from two major field studies conducted since 2003,” commented Michael F. Brigham, President and CEO. “The main competitive advantage of **Mast Out**<sup>®</sup> is that it may qualify for use in the United States without a requirement to discard milk or withhold meat from human consumption for the period of treatment and for a defined period of time thereafter. All mastitis treatment products on the market today are sold subject to such ‘discard’ and ‘withhold’ requirements.”

These positive results justify a continued product development effort. Commercial introduction of **Mast Out**<sup>®</sup> in the United States is subject to review and approval of a New Animal Drug Application (NADA) by the FDA, which approval cannot be assured. The NADA is comprised of several Technical Sections under the FDA’s phased review of a NADA. The pivotal effectiveness data described in this press release would be used to prepare the submission of the Effectiveness Technical Section. The current objective is to complete all the Technical Sections required for submission of the administrative NADA to the FDA in approximately 12 months. The Company intends to continue disclosing the current status of each Technical Section in its periodic filings with the Securities and Exchange Commission.

By acquiring certain rights and patents in April 2000, ImmuCell began its development of **Mast Out**<sup>®</sup>, which is an intramammary infusion product containing Nisin for the treatment of subclinical mastitis in lactating dairy cows. The dual purpose of such a subclinical treatment would be to both clear the infection at an early stage and earn premiums for higher quality milk (low Somatic Cell Counts). The use of antibiotics in food-producing animals may be a contributing factor to the rising human public health problem of bacterial drug resistance. As an alternative to traditional antibiotics that are on the market, **Mast Out**<sup>®</sup> could potentially reduce the use of traditional antibiotics in the treatment of mastitis.

####MORE####

**ImmuCell Corporation**

---

56 Evergreen Drive • Portland, Maine 04103  
Telephone (207) 878-2770 • Fax (207) 878-2117  
[www.ImmuCell.com](http://www.ImmuCell.com)

Preparations for this pivotal effectiveness study included the production of registration batches of drug product to fulfill the pivotal regulatory requirements of effectiveness, target animal safety, and stability at no less than 10% of the scale anticipated for commercial manufacture. The treatment phase of this study was initiated in June 2008.

Nisin, the same active ingredient contained in ImmuCell's product, **Wipe Out<sup>®</sup> Dairy Wipes**, is an antibacterial peptide that is commonly used as a preservative in dairy food products. Nisin is known to have activity against most gram positive and some gram negative bacteria.

ImmuCell Corporation is a public, animal health biotechnology company dedicated to developing, manufacturing and selling products that improve animal health and productivity in the dairy and beef industries. Press releases and other information about the Company are available at <http://www.immucell.com>.

**Contact:** Michael F. Brigham, President and Chief Executive Officer  
(207) 878-2770 Ext. 3106

***Forward-Looking Statement Disclaimer:***

*The foregoing press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, such as, but not limited to, the likelihood of regulatory approval of **Mast Out<sup>®</sup>** and certain label claims and our product development timeline. Factors that could cause the Company's future results to differ materially from those described in the forward-looking statements, together with other risk factors, are detailed from time to time in filings we make with the Securities and Exchange Commission, including our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. Forward-looking statements in this press release are based on our current information and expectations. Actual results may differ materially due to various factors, including those risks.*

###