

# ImmuCell

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FOR IMMEDIATE RELEASE:

## IMMUCELL RECEIVES EFFECTIVENESS TECHNICAL SECTION INCOMPLETE LETTER FROM FDA

PORTLAND, Maine – February 16, 2011 -- **ImmuCell Corporation (NASDAQ: ICC)** today announced that it received an Effectiveness Technical Section Incomplete Letter from the Center for Veterinary Medicine, U.S. Food and Drug Administration (FDA).

“While this is a setback to our development program in terms of timing, there is nothing in this communication that suggests the FDA will not ultimately concur with our fundamental conclusions about the effectiveness of **Mast Out**<sup>®</sup>,” commented Joseph H. Crabb, Vice President and Chief Scientific Officer.

Additional clinical studies are not required. The FDA has requested additional information in the areas of raw data, subject eligibility and statistical analyses and has requested that certain treatment outcomes be changed or justified.

“It is a disappointment not to have received approval of this lengthy submission, but this is not an unusual path for a drug development program of this magnitude,” added Michael F. Brigham, President and CEO.

This Technical Section submission was comprised of data from a study completed in 2009 of approximately 300 qualified cows with subclinical mastitis 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 response to the items detailed in the Technical Section Incomplete Letter is not expected to materially change these initial conclusions.

Commercial introduction of **Mast Out**<sup>®</sup> in the United States is subject to review and approval of our administrative New Animal Drug Application (NADA) submission by the FDA, which approval cannot be assured. The NADA is comprised of five Technical Sections under the FDA’s phased review of a NADA. The Effectiveness Technical Section is one of these. The Company intends to continue disclosing the current status of each Technical Section in its periodic filings with the Securities and Exchange Commission.

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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). Many fear that the possible overuse of antibiotics in livestock could undermine the effectiveness of drugs to combat human illnesses and may be a contributing factor to the rising problem of bacterial drug resistance. The FDA is committed to addressing its concern with respect to this important public health issue. **Mast Out**<sup>®</sup> could potentially reduce the use of traditional antibiotics that are currently approved for use in the treatment of mastitis.

Nisin (which is 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. The label claim allowing the use of **Mast Out**<sup>®</sup> without a milk discard requirement is subject to approval of the Human Food Safety Technical Section that was submitted to the FDA for review during the fourth quarter of 2010. **Mast Out**<sup>®</sup> could be the first product of its kind with such a claim, which would allow it to compete effectively against products currently on the market that are all used subject to a requirement to discard milk during treatment and for a period of time thereafter.

About ImmuCell:

ImmuCell Corporation's (NASDAQ: ICCC) purpose is to create scientifically-proven and practical products that result in a measurable economic impact on animal health and productivity in the dairy and beef industries. Press releases and other information about the Company are available at our web-site, (<http://www.immuCell.com>).

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