ImmuCell

ImmuCell Announces Issuance of Human Food Safety Technical Section Complete Letter for its Purified Nisin Product

For Immediate Release

PORTLAND, Maine – September 25, 2018 – ImmuCell Corporation (Nasdaq: ICCC) ("ImmuCell" or the "Company"), a growing animal health company that develops, manufactures and markets scientifically-proven and practical products that improve the health and productivity of dairy and beef cattle, today announced an important milestone in the development of its purified Nisin product.

ImmuCell learned today that the FDA has issued a Technical Section Complete Letter for the Human Food Safety Technical Section of ImmuCell's New Animal Drug Application ("NADA") for its Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows. There are five major Technical Sections to a NADA with the FDA. ImmuCell previously received three of the five Technical Section Complete Letters required for NADA approval. This fourth Complete Letter leaves just the manufacturing technical section (known as the Chemistry, Manufacturing and Controls ("CMC") Technical Section) remaining for product approval and market launch.

"This milestone confirms the previously announced zero milk discard and zero meat withhold claims for our Nisin product in the US," commented Michael F. Brigham, President and CEO. "Subject to final NADA approval by the FDA, we seek to bring this novel mastitis treatment to market in 2020."

"This approval is the result of the FDA's review of many years of studies addressing the important food safety issues of antimicrobial resistance, effects of residues on human intestinal flora, toxicology and residue chemistry," added Joseph H. Crabb, Vice President and CSO. "It is rewarding to achieve zero withdrawal status supporting our objective to bring a product to market that poses minimal risks to public health from antimicrobial resistant organisms originating from Nisin-treated cattle."

A first submission of the CMC Technical Section is anticipated in the coming weeks. At least two sequential submissions (the first covering the Drug Substance and the second covering the Drug Product) will be required. Each submission is subject to a six-month review period by the FDA.

Cautionary Statement Regarding Forward-looking Statements (Safe Harbor Statement):

This Press Release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to: projections of future financial performance; the value of our deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; the scope and timing of ongoing and future product development work and commercialization of our products; future costs of product development efforts; the estimated prevalence rate of subclinical mastitis; the expected efficacy of new products; estimates about the market size for our products; future market share of and revenue generated by current products and products still in development; our ability to increase production output and reduce costs of goods sold associated with our new product, **Tri-Shield™ First Defense®**; the future adequacy of our own manufacturing facilities or those of third parties with which we have contractual relationships to meet demand for our products on a timely basis; the efficiency and effectiveness of our manufacturing processes and related technical issues; estimates about our production capacity; the future adequacy of our working capital and the availability and cost of third party financing; the timing and outcome of pending or anticipated applications for regulatory approvals; future regulatory requirements relating to our products; future expense ratios and margins; future compliance with bank debt covenants; future cost of our variable interest rate exposure on most of our bank debt; costs associated with sustaining compliance with current Good Manufacturing Practice (cGMP) regulations in our current operations and attaining such compliance for the facility to produce the Drug Substance; factors that may affect the dairy and beef industries and future demand for our products; implementation of international trade tariffs that could reduce the export of dairy products weakening the price received by our customers for their products; our effectiveness in competing against competitors within both our existing and our anticipated product markets; the cost-effectiveness of additional sales and marketing expenditures and resources; anticipated changes in our manufacturing capabilities and efficiencies; anticipated competitive and market conditions; and any other statements that are not historical facts. Forward-looking statements can be identified by the use of words such as "expects", "may", "anticipates", "aims", "intends", "would", "could", "should", "will", "plans", "believes", "estimates", "targets", "projects", "forecasts", "seeks" and similar words and expressions. In addition, there can be no assurance that future developments affecting us will be those that we anticipate. Such statements involve risks and uncertainties, including, but not limited to, those risks and uncertainties relating to difficulties or delays in development, testing, regulatory approval, production and marketing of our products, competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand, the uncertainties associated with product development and Drug Substance manufacturing, our potential reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities, possible dilutive impacts on existing stockholders from any equity financing transactions in which we may engage, currency values and fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission, including our Quarterly Reports on Form 10-Q, our Annual Reports on Form 10-K and our Current Reports on Form 8-K. Such statements are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors discussed above.

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