ImmuCell Announces Submission of Manufacturing Technical Section for its Purified Nisin Product

PORTLAND, Maine, Feb. 28, 2019 — **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 a critical milestone in the development of **Re-Tain**™, its Nisin-based intramammary treatment of subclinical mastitis in lactating dairy cows.

The Company has made its first phased submission to the U.S. Food and Drug Administration (FDA) of the manufacturing technical section (known as the Chemistry, Manufacturing and Controls (CMC) Technical Section) with respect to the Nisin Drug Substance under the Company's New Animal Drug Application (NADA). This submission is subject to a six-month review period and will be followed by a second phased submission covering the Nisin Drug Product, which is also subject to a six-month review period before anticipated product approval can occur. This is the fifth of five major Technical Sections required for NADA approval by the FDA and product launch. ImmuCell has previously received four Technical Section Complete Letters from the FDA, most recently for the Human Food Safety Technical Section during the third quarter of 2018. Also, the FDA recently approved "**Re-Tain**™" as the Company's tradename for the anticipated commercial product.

"This is a huge milestone for ImmuCell and for our team that has worked so hard over the past years to develop and optimize the manufacturing process and to design, construct and qualify our new Drug Substance facility," commented Elizabeth L. Williams, Vice President of Manufacturing Operations. "The capstone was the recent manufacture and analysis of Registration Batches bridging back to the pivotal batches used in key studies. Our team has persisted through the many stages of development and has consistently demonstrated the needed tenacity, creativity and energy to reach this milestone. I am honored to work with them."

This Technical Section includes data from the Nisin Drug Substance (the active pharmaceutical ingredient) Registration Batches produced at commercial scale in the Company's new manufacturing facility. The timing of this first comprehensive and complex submission will not itself impact the regulatory timeline because the second phased Nisin Drug Product submission defines the critical path to product approval.

The second phased Nisin Drug Product submission will not be made in time to achieve product approval by December 2019 due to unexpected difficulties and delays at this stage of the Drug Product development. In order to facilitate the fastest path to market, the Company has made requests to its third-party manufacturer to modify certain provisions of its agreement, including the provision entitling the manufacturer to terminate the agreement if FDA approval is not achieved by December 17, 2019. Any such amendment could increase

manufacturing costs or shorten the term during which those manufacturing services remain available to the Company.

At the same time, the Company is actively investigating multiple paths to secure alternative FDA-approved manufacturing services for the Nisin Drug Product, including, but not limited to, finding another qualified third party or performing the services in-house by installing filling equipment in the Company's new Drug Substance facility. The latter option would provide the Company the longer-term advantage of controlling the entire production process in one facility (thereby, ultimately reducing manufacturing costs), but it would require additional capital to be raised. Both alternate paths could extend the timeline to FDA approval past the currently projected goal of the first half of 2020 and could cause interruptions to the production and sale of **Re-Tain**™.

"We are working through these challenges. In the meantime, we are fortunate for the growth in our **First Defense**® product line and are working to capitalize on that opportunity over the near-term," added Michael F. Brigham, President and CEO. "Our longer-term goal is to revolutionize mastitis treatment practices with **Re-Tain**™, by reducing the use of traditional antibiotics in food-producing animals and making the early treatment of sick animals economically feasible by removing the milk discard penalty that is incurred whenever a cow is treated with any of the common antibiotics on the market today."

Nisin is a bacteriocin that is not used in human medicines and could alleviate some of the social concerns that the widespread use of antibiotics encourages the growth of antibiotic-resistant bacteria ("superbugs"). Mastitis, which costs the dairy industry about $2 billion per year, is currently treated with traditional antibiotic products, and treatment is generally reserved for clinical infections when the cow produces non-saleable milk. The "zero milk discard" product feature approved for **Re-Tain**™ would make earlier treatment of sick cows economically feasible, while these cows are still producing saleable milk. No other existing product can provide this kind of value proposition.

About ImmuCell:

ImmuCell Corporation's (**Nasdaq: ICCC**) purpose is to create scientifically-proven and practical products that improve the health and productivity of dairy and beef cattle. ImmuCell markets products that provide **Immediate Immunity**™ to newborn dairy and beef livestock and is in the late stages of developing a novel treatment for mastitis, the most significant cause of economic loss to the dairy industry. Press releases and other information about the Company are available at: http://www.immucell.com.

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Cautionary Note 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: our plans and strategies for our business; 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 continuing availability to us on reasonable terms of third-party providers of critical products or services; the robustness 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, which could in turn weaken 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 (including **First Defense**® and **Re-Tain**™), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand, 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 involve risks and uncertainties and are based on our current expectations, but actual results may differ materially due to various factors, including the risk factors summarized above.

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