ImmuCell

ImmuCell Receives FDA Response To First CMC Submission for Re-Tain™

Second Submission Anticipated Around Q3 2020

For Immediate Release

PORTLAND, Maine – August 29, 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 that it has received a response from the U.S. Food and Drug Administration (FDA) to its first phased Nisin Drug Substance submission of the Chemistry, Manufacturing and Controls (CMC) Technical Section for **Re-Tain**™, the Company's novel treatment in development for subclinical mastitis in lactating dairy cows.

Under the FDA's phased submission process, Phase 1 concerns the Nisin Drug Substance, and Phase 2 concerns the **Re-Tain**™ Drug Product (formulated Nisin filled in a syringe). As part of the phased submission process, the FDA issued a Technical Section Incomplete Letter with various requests and queries in addition to referring to the fact that the second phased submission has yet to be submitted. This process allows a sponsor to respond to identified deficiencies from the first phased submission at the time of the second phased submission. The second phased Drug Substance and Drug Product CMC Technical Section submission is expected to be made around the third quarter of 2020. In addition to responding to comments raised by the FDA regarding the first phased submission, one of the key components of the second phased submission is demonstrating stability of the product over time using the commercial process and the commercial syringe.

"Having reviewed the comments from the FDA, we see no road blocks on our path to FDA approval for **Re-Tain**™," commented Michael F. Brigham, President and CEO. "We believe we can respond effectively to the FDA's comments without significant additional cost or time delays."

Having previously achieved four different Technical Section Complete Letters from the FDA, approval of the CMC Technical Section is the fifth and final significant step required before **Re-Tain**™ product sales can be initiated in the U.S.

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 **First Defense**®, providing **Immediate Immunity**™ to newborn dairy and beef livestock, and is in the late stages of developing **Re-Tain™**, 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.

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 timing and outcome of pending or anticipated applications for regulatory approvals; factors that may affect the dairy and beef industries and future demand for our products; 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 anticipated costs of (or time to complete) planned expansions of our manufacturing facilities and the adequacy of our funds available for these projects; 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; 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 Nisin Drug Substance; 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; the value of our net deferred tax assets; projections about depreciation expense and its impact on income for book and tax return purposes; 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 the **First Defense**® product line 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 reliance upon third parties for financial support, products and services, changes in laws and regulations, decision making by regulatory authorities, currency values and fluctuations and other risks detailed from time to time in filings we make with the SEC, 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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