

## **ImmuCell Required to Prepare Second Submission of Final Major Technical Section for Re-Tain®**

PORTLAND, Maine, Aug. 24, 2021 — **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 the FDA has issued a Technical Section Incomplete Letter covering the Chemistry, Manufacturing and Controls (CMC) Technical Section for **Re-Tain®** (Nisin A intramammary solution).

The CMC Technical Section covers the commercial manufacturing requirements for the Drug Substance and resulting Drug Product. The Company previously received Technical Section Complete Letters from the FDA covering the other four major Technical Sections required for product approval.

**Re-Tain®** is the Company’s new subclinical mastitis treatment for lactating dairy cows without a milk discard or meat withhold requirement. The Company’s objective is to demonstrate that its bacteriocin, Nisin A, can play a productive role in the treatment of subclinical mastitis in today’s dairy industry by providing a novel alternative to traditional antibiotics.

“We have evaluated the FDA comments and believe we can respond with a re-submission of the CMC Technical Section during the fourth quarter of 2021 without incurring significant costs or delays,” commented Michael F. Brigham, President and CEO. “While this is disappointing to us, a second review of a consolidated CMC submission like this, covering Drug Substance and sterile Drug Product, is common. If after another six-month review the FDA issues a Technical Section Complete Letter, the next step would be to file the Administrative New Animal Drug Application, which could lead to a New Animal Drug Approval after a 60-day review by the FDA, thereby positioning us for potential market launch of **Re-Tain®** during the third quarter of 2022, pending ongoing FDA input and concurrence.”

### **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 manufactures and markets **First Defense®**, providing **Immediate Immunity™** to newborn dairy and beef calves, and is in the late stages of developing **Re-Tain®** a novel treatment for subclinical mastitis in dairy cows without a milk discard requirement that provides an alternative to traditional antibiotics. 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 or operational 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 extent, nature and duration of the COVID-19 pandemic and its consequences, and their direct and indirect impacts on the Company’s production activities, operating results and financial condition and on the customers and markets the Company serves; 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 and producers’ level of interest in treating subclinical mastitis given the current economic and market conditions; 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; 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 impacts of backlogs on customer relationships; 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, efficiency and yield, which are highly subject to biological variability and the product format mix of our sales; 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; costs associated with sustaining compliance with current Good Manufacturing Practice (cGMP) regulations in our operations; 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 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**<sup>®</sup> product line and

**Re-Tain<sup>®</sup>**), competition within our anticipated product markets, customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand (including the consequences of backlogs or excess inventory buildup), our reliance upon third parties for financial support, products and services, our small size and dependence on key personnel, changes in laws and regulations, decision making and delays by regulatory authorities, a recurrence of inflation, currency values and fluctuations and other risks detailed from time to time in filings we make with the Securities and Exchange Commission (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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**ImmuCell**

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