

## **ImmuCell Receives Technical Section Incomplete Letter from FDA Pertaining to Re-Tain<sup>®</sup>**

### **For Immediate Release**

**PORTLAND, Maine – July 27, 2022 – ImmuCell Corporation (Nasdaq: ICCG)**

(“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 regarding its New Animal Drug Application (NADA) for **Re-Tain<sup>®</sup>**.

The Company received a Technical Section Incomplete Letter from the FDA with regards to its second full submission of the Chemistry, Manufacturing and Controls (CMC) Technical Section, which had been submitted for review during the first quarter of this year. The principal issue remaining is a successful pre-approval re-inspection of its manufacturing facility. The Company is completing preparations for such and intends to notify the FDA of its readiness for the re-inspection during the third quarter. Continued focus on these preparations is critical to a successful re-inspection outcome. This clarifies the required path to product approval, if not the precise timing.

Substantive issues that could have caused further significant delays did not appear in the FDA comments, indicating that they have been resolved to the FDA’s satisfaction. The six comments received appear not to be substantive and are not related to the safety nor efficacy of the product. The Company intends to make a third submission of its CMC Technical Section in response to these questions during the third quarter. The Company is also finalizing the remaining minor technical sections (Labeling and All Other Information) and preparing to file the Administrative NADA while planning for market launch.

“We are pleased that the safety and efficacy of **Re-Tain<sup>®</sup>** is not in question, and we remain poised and excited to revolutionize the way that subclinical mastitis is treated,” commented Michael F. Brigham, President and CEO. “During this extended regulatory review period, we will double-down our focus on growing sales of the **First Defense<sup>®</sup>** product line with increased, and further increasing, production capacity while continuing the regulatory work on **Re-Tain<sup>®</sup>**.”

Management will take the next few days to review and consider this ruling by the FDA and plans to disclose its full assessment in its Quarterly Report on Form 10-Q after the market closes on Thursday, August 11, 2022. The Company has scheduled a conference call the next morning, Friday, August 12, 2022, at 9:00 AM ET to review its second quarter financial results and discuss this regulatory update further. Interested parties can access the conference call by dialing

(844) 855-9502 (toll free) or (412) 317-5499 (international) at 9:00 AM ET. A teleconference replay of the call will be available until August 19, 2022 at (877) 344-7529 (toll free) or (412) 317-0088 (international), utilizing confirmation #5413900.

The Company brought **First Defense**® to market in 1991 after less than five years of USDA regulatory work and since then has created value for dairy and beef producers by delivering **Immediate Immunity**™ to newborn calves. With **Re-Tain**®, the Company hopes to create more value for dairy producers by treating subclinical mastitis without the use of traditional antibiotics and without a milk discard once the FDA authorizes commercial sales.

#### **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 calves. 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>.

**Contacts:** Michael F. Brigham, President and CEO  
ImmuCell Corporation  
(207) 878-2770

Joe Diaz, Robert Blum and Joe Dorame  
Lytham Partners, LLC  
(602) 889-9700  
[iccc@lythampartners.com](mailto:iccc@lythampartners.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 our production activities, operating results and financial condition and on the customers and markets that we serve; the impact of Russia’s unprovoked military invasion of Ukraine and attack on its people on the world economy including inflation and the price and availability of grain and oil; the impact of the global supply-chain disruptions on our ability to obtain, in a timely and cost-effective fashion, all the supplies and components we need to produce our products; the challenges in attracting and retaining needed personnel in this current employment environment; the impact of inflation and rising interest rates on our operating expenses and financial results; 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 per unit; 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 current operations and attaining such compliance for our facilities to produce the Nisin Drug Substance and Drug Product; 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; 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 (including the consequences of backlogs or excess inventory buildup), uncertainty associated with the timing and volume of customer orders as we come out of a prolonged backlog, adverse impacts of supply chain disruptions on our operations and customer relationships, 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 and its impact on our customers’ order patterns, 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.