ImmuCell Provides Update on Regulatory Status of Product Development Initiative for Re-Tain®

PORTLAND, Maine , June 05, 2024 — **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 provided a regulatory update on the status of its product development initiative for **Re-Tain**®.

As previously disclosed, the Company recently received a Technical Section Incomplete Letter (Incomplete Letter) from the United States Food and Drug Administration (FDA) in response to its third submission of the Chemistry, Manufacturing and Controls (CMC) Technical Section (which is its fifth and final major Technical Section required for its New Animal Drug Application (NADA)). Since then, the Company has prepared the fourth submission of its CMC Technical Section, responding to the comments provided in the Incomplete Letter that are not complex.

This submission has not been made yet because all inspectional observations must be cleared at both the Company's Drug Substance facility and at the Drug Product facility of its contract manufacturer before the FDA will issue a Technical Section Complete Letter. The FDA recently confirmed ImmuCell's inspectional status as acceptable. ImmuCell's contract manufacturer expects to submit responses to its inspectional observations around the end of June of 2024. Clearing the outstanding inspectional observations with the FDA defines the critical path timeline.

Once the facility inspection at the Drug Product facility of the Company's contract manufacturer is cleared by the FDA, the Company anticipates submitting a Non-Administrative NADA that would include the Company's fourth submission of the CMC Technical Section, together with the minor technical sections covering All Other Information and Product Labeling. By statute, this submission would be subject to a review period of up to 180 days. However, the Company believes that a shorter review period may be provided because the responses to the CMC Incomplete Letter are not complex. The goal of submitting this combined filing would be to eliminate the need for an additional 60-day review period of an Administrative NADA submission at the end of the application process, after all five major Technical Section Complete Letters are received.

Upon FDA approval, the Company intends to implement its previously disclosed limited distribution, controlled launch strategy with product expiration dating estimated at between the second quarter of 2025 and the first quarter of 2026, subject to final product shelf-life disposition by the FDA.

“We will remain focused on the commercial opportunity we have with **First Defense**®, as we push forward to finish this regulatory process to bring **Re-Tain**® to market,” commented Michael F. Brigham, President and CEO of ImmuCell.

Cautionary Note Regarding Forward-Looking Statements (Safe Harbor Statement):

This Press Release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by the fact that they do not relate strictly to historical or current facts and will often include words such as “expects”, “may”, “anticipates”, “aims”, “intends”, “would”, “could”, “should”, “will”, “plans”, “believes”, “estimates”, “targets”, “projects”, “forecasts”, “seeks” and similar words and expressions. Such statements include, but are not limited to, any forward-looking 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; future demand for our products; the scope and timing of ongoing and future product development work and commercialization of our products; the expected efficacy or impact 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; the 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 robustness of our manufacturing processes and related technical issues; estimates about our production capacity, efficiency and yield; the salability of products currently held in inventory pending regulatory approval; future regulatory requirements relating to our products; and any other statements that are not historical facts. These statements are intended to provide management’s current expectation of future events as of the date of this Press Release, are based on management’s estimates, projections, beliefs and assumptions as of the date hereof; and are not guarantees of future performance. Such statements involve known and unknown risks and uncertainties that may cause the Company’s actual results, financial or operational performance or achievements to be materially different from those expressed or implied by these forward-looking statements, 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**®), customer acceptance of our new and existing products, product performance, alignment between our manufacturing resources and product demand, adverse impacts of supply chain disruptions on our operations and customer and supplier relationships, commercial and operational risks relating to our current and planned expansion of production capacity, and other risks and uncertainties 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. In addition, there can be no assurance that future risks, uncertainties or developments affecting us will be those that we anticipate. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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 FDA-required milk discard or meat withhold claims that provides an alternative to traditional antibiotics. Press releases and other information about the Company are available at: http://www.immucell.com.

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