# ImmuCell Announces an Agreement Covering the Formulation and Aseptic Filling of Syringes for Re-Tain™

**PORTLAND, Maine, Sept. 11, 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 entered into a new agreement with Norbrook Laboratories, Limited of Newry, Northern Ireland covering the formulation and aseptic filling of its Nisin Drug Substance into syringes for **Re-Tain**™, the Company's novel treatment in development for subclinical mastitis in dairy cows.

The new agreement (which replaces an expiring agreement) expires as of December 31, 2021 and allows for product ordered before the expiration date to be delivered into the early part of 2022. This new agreement covers the final development work required to achieve FDA approval and also provides product for market launch. The Company's **Re-Tain**™ production facility has been equipped to manufacture Drug Substance (the active pharmaceutical ingredient, Nisin) with a commercial sales value of approximately $10 million per year. This new agreement with Norbrook covers the formulation and aseptic filling of Drug Product (Nisin filled in a syringe) with a commercial sales value of approximately $7 million. The Company is building its own Drug Product formulation and aseptic filling capability to support sales in excess of the first $7 million.

"We have always believed that the fastest route to FDA approval and market launch is with Norbrook," commented Michael F. Brigham, President and CEO. "At the same time, we have initiated an investment of approximately $4 million to establish the capability of performing the Drug Product formulation and aseptic filling in our own facility after the expiration of this new agreement with Norbrook."

Completion of the FDA's review of the first phased Drug Substance submission of the Chemistry, Manufacturing and Controls (CMC) Technical Section was announced on August 29, 2019. One of the key components of the second phased Drug Product CMC submission is demonstrating stability of the product over time in its final packaged form. Given a current assessment of the work that needs to be performed and allowing for statutory review periods by the FDA, the Company anticipates achieving FDA approval of **Re-Tain**™ during 2021.

Brigham concluded, "This is a great solution for us. We benefit from Norbrook's world-class expertise in aseptic filling, while working to own this process in-house for the long-term, which is the goal of both companies."

**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.

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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 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; 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 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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