

Phase 1 Clinical Studies to begin in First Half of 2020

NEW YORK, Jan. 8, 2020 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX)**, a clinical-stage biopharmaceutical company focused on developing best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced that its subsidiary, Immunic AG, under the terms of its existing option and license agreement with Daiichi Sankyo Co., Ltd. (hereinafter, Daiichi Sankyo), has exercised its exclusive global option to license a group of compounds, designated by Immunic as IMU-856. The company intends to begin phase 1 clinical studies for this program in the first half of 2020. IMU-856 is an orally available, small molecule modulator that targets a yet undisclosed protein which serves as a transcriptional regulator of the intestinal barrier function. As such, IMU-856 represents a new and potentially disruptive approach for the treatment of intestinal diseases with the potential to restore the intestinal barrier function while maintaining immunocompetency.

IMU-856 was discovered and developed by Daiichi Sankyo. The option and license agreement gives Immunic the exclusive rights to commercialization of IMU-856 in all countries, including the United States, Europe and Japan. The option also includes exclusivity on a patent application filed by Daiichi Sankyo, covering IMU-856's composition of matter. Concurrent with the option exercise, Immunic will pay to Daiichi Sankyo a one-time upfront licensing fee. Going forward, Daiichi Sankyo is eligible to receive certain future development, approval and sales milestone payments, as well as royalties related to IMU-856. Financial terms of the agreement have not been disclosed.

"Exercising this option is an important milestone, as it indicates that we are convinced of the preclinical safety profile of IMU-856 and are ready to take this program into phase 1 clinical trials, which we intend to initiate during the first half of 2020," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Our recently presented preclinical data reinforced our belief that IMU-856 has disease-modifying properties for a variety of intestinal diseases and demonstrates potential significant advantages over current immunosuppressive treatments which address inflammation while unintentionally decreasing the body's immune surveillance. We are hopeful that the planned phase 1, single and multiple ascending dose studies will serve as a further important step in the development of IMU-856 as a safe treatment option for patients suffering from gastrointestinal diseases by restoring function to the intestinal barrier without impairing the immune system."

"We are delighted that Immunic executed the option right for IMU-856," said Junichi Koga, Senior Executive Officer and Global Head of R&D, Daiichi Sankyo. "Daiichi Sankyo is committed to delivering innovative medicines to patients across the world as quickly as possible, either by ourselves or through strategic partnerships. We are confident that Immunic is our best partner and will rapidly drive the development of this novel compound for patients with intestinal diseases."

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. The company is developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of ROR γ t; and IMU-856 targets the restoration of the intestinal barrier function. Immunic's lead development program, IMU-838, is in phase 2 clinical development for relapsing-remitting multiple sclerosis and ulcerative colitis, with an additional phase 2 trial planned in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. For further information, please visit: www.immunic-therapeutics.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to Immunic's three development programs and the targeted diseases; the potential for IMU-838, IMU-935 and IMU-856 to safely and effectively target diseases; preclinical data for IMU-856; the timing of future clinical trials; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the company. Immunic may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements.

Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, risks and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources to meet business objectives and operational requirements, the fact that the results of earlier studies and trials may not be predictive of future clinical trial results, the protection and market exclusivity provided by Immunic's intellectual property, risks related to the drug development and the regulatory approval process and the impact of competitive products and technological changes. A further list and descriptions of these risks, uncertainties and other factors can be found in the section captioned "Item 1A. Risk Factors," in the company's Current Report on Form 8-K filed on July 17, 2019, and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or ir.immunic-therapeutics.com/sec-filings and on request from Immunic. Any forward-looking statement made in this release speaks only as of the date of this release. Immunic disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made. Immunic expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.

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