NEW YORK, Aug. 16, 2022 /PRNewswire/ -- **Immunic, Inc.** (NASDAQ: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases, today announced that the company has received a Notice of Allowance from the U.S. Patent and Trademark Office (USPTO) for patent application 16/646130, entitled, "Compound Having Cyclic Structure." The patent covers composition-of-matter of IMU-856 and related pharmaceutical compositions and is expected to provide protection into at least 2038, without accounting for potential Patent Term Extension (PTE).

The patent application was originally filed by Daiichi Sankyo Co., Ltd. (Daiichi Sankyo), which discovered IMU-856. In 2018, Immunic and Daiichi Sankyo entered into a global option and license agreement, granting Immunic the exclusive right to license IMU-856, which was subsequently exercised by Immunic in 2020. The license included exclusivity on the composition-of-matter patent.

"Allowance of this composition-of-matter patent significantly strengthens our intellectual property estate and is key to the clinical development of IMU-856, which we believe to be a highly potent small molecule oral epigenetic regulator. In particular, IMU-856 appears to influence the tightly regulated network of genes and proteins associated with intestinal epithelial cell interaction and adhesion which could present an entirely new and innovative approach to the treatment of a significant number of gastrointestinal diseases," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "In May 2022, we reached an important milestone with the initiation of part C of our phase 1 clinical trial of IMU-856 in patients with celiac disease, to confirm the drug's ability to restore intestinal barrier function without affecting the immune system. We also look forward to reporting unblinded safety data from the single and multiple ascending dose parts of the phase 1 clinical trial in healthy human subjects in the third quarter of this year."

About IMU-856

IMU-856, which Immunic believes to be novel, is an orally available small molecule modulator that targets a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium. Based on preclinical data, the compound may represent a new treatment approach, as the mechanism of action targets the restoration of the intestinal barrier function and bowel wall architecture in patients suffering from gastrointestinal diseases such as celiac disease, inflammatory bowel disease, irritable bowel syndrome with diarrhea and other intestinal barrier function associated diseases. Immunic believes that, because IMU-856 has been shown in preclinical investigations to avoid suppression of immune cells, it may therefore maintain immune surveillance for patients during therapy, an important advantage versus chronic treatment with potentially immunosuppressive medications. IMU-856 is an investigational drug product that has not been approved in any jurisdiction.

IMU-856 was discovered by Daiichi Sankyo Co., Ltd. (Daiichi Sankyo). In November 2018, Immunic and Daiichi Sankyo entered into a global option and license agreement, granting Immunic the exclusive right to license IMU-856. The license also includes exclusivity on a patent application filed by Daiichi Sankyo, covering IMU-856's composition of matter. Immunic exercised the option in January 2020.

About Immunic, Inc.

Immunic, Inc. (NASDAQ: IMUX) is a clinical-stage biopharmaceutical company with a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases. The company is developing three small molecule products: its lead development program, vidofludimus calcium (IMU-838), a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH and exhibits a host-based antiviral effect, is currently being developed as a treatment option for multiple sclerosis, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγ/RORγt, is targeted for development in psoriasis, and castration-resistant prostate cancer. IMU-856, which targets the restoration of the intestinal barrier function, is targeted for development in diseases involving bowel barrier dysfunction. For further information, please visit: www.imux.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, sufficiency of cash, expected timing and results of clinical trials, 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-856 to safely and effectively target diseases; preclinical and clinical data for IMU-856; the timing of current and future clinical trials and anticipated clinical milestones; the nature, strategy and focus of the company and further updates with respect thereto; 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 substantial 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, the COVID-19 pandemic, impacts of the Ukraine – Russia conflict on planned and ongoing clinical trials, 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 financial and other resources to meet business objectives and operational requirements, the fact that the results of earlier preclinical studies and clinical 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 "Risk Factors," in the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 24, 2022, 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.imux.com/sec-filings. 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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