Top-Line Data of the CALDOSE-1 Trial Expected to be Available in June of 2022

NEW YORK, Feb. 18, 2022 /PRNewswire/ -- **Immunic, Inc.** (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, today announced that Evelyn Peelen, Ph.D., Senior Manager Translational Pharmacology at Immunic, will present preclinical data on the potent anti-inflammatory activity of vidofludimus calcium (IMU-838), the company's selective oral DHODH inhibitor, at the 17th Congress of European Crohn's and Colitis Organization (ECCO).

The poster, entitled, *"Vidofludimus Calcium (IMU-838), a Small Molecule DHODH Inhibitor in Phase 2 Clinical Trial for Ulcerative Colitis, Shows Potent Anti-inflammatory Activity in Cell-Culture-Based Systems"* (Abstract Number: EC22-1109, Poster Number: P064), will be presented during the Virtual Poster Exhibition – Basic Science / ePosters being held today. The poster presentation will also be accessible on the "Events and Presentations" section of Immunic's website at: https://ir.imux.com/events-and-presentations.

Highlights include:

- Vidofludimus calcium reduces proinflammatory immune cell responses by inducing regulatory macrophages, reducing pro-inflammatory cytokine secretion and reducing T cell proliferation.
- Vidofludimus calcium shows an additive to synergistic effect with anti-TNF antibodies in a mixed lymphocyte reaction assay, suggesting a new and promising potential combination treatment opportunity for ulcerative colitis (UC).
- DHODH is important in cells that receive a strong immune stimulus and are highly metabolically active. In support, vidofludimus calcium was observed to show a biological selectivity by only targeting these hyperactive cells and, thus, allows for a normal immune response against pathogens and towards vaccines, representing a medically relevant advantage for treatment of patients with inflammatory bowel disease.

Additionally, Immunic announces the blinded baseline characteristics of its phase 2 CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe UC. In October 2021, Immunic announced the completion of enrollment of the trial. At completion of patient recruitment, the trial had randomized a total of 263 patients into four arms: three active dosing arms of 10 mg, 30 mg and 45 mg, as well as placebo. Top-line data for the induction phase is expected to be available in June of 2022.

The main blinded baseline characteristics of the CALDOSE-1 trial include:

- 263 moderate-to-severe UC patients were enrolled in 78 study sites with the Ukraine and Poland representing the countries with highest number of patients and U.S. sites contributing 12.5% of the overall enrollment.
- Of the 263 patients, 148 (56.3%) were male and 115 (43.7%) were female patients. The mean age at baseline was 41.7 (18-77) years.
- All patients had to have failed at least one prior therapy option. Of the 263 patients, 83% were biologically naïve and 17% were biologically experienced (received at least 1 prior treatment with any biological agent approved in the UC indication).
- Enrolled patients had to show evidence of active moderate-to-severe UC disease. This is reflected in their baseline characteristics for patient-reported outcomes:
    - The baseline Mayo stool frequency scores were: (i) score of 3 for 59% of patients, (ii) score of 2 for 36% patients and (iii) score of 1 for 5% of patients.
    - The Mayo rectal bleeding scores were: (i) score of 3 in 10% of patients, (ii) score of 2 for 54% of patients and (iii) score of 1 for 31% of patients.
    - The average value for fecal calprotectin at baseline was approximately 1,320 µg/g for currently available, yet incomplete data.
- The trial employed a central independent reader to evaluate the endoscopic eligibility criteria and the following modified Mayo endoscopic scores were assessed at baseline:
    - 55% of patients with a score of 3; and
    - 45% of patients with a score of 2.
- At week 10 (the time point of the primary efficacy analysis), an adjudication procedure was used for

endoscopy assessments. In the case of disagreement between two independent readers, a third independent reader was used for adjudication.

Immunic believes that these blinded baseline characteristics of randomized patients and the methodology regarding endoscopic assessments contributes to ensuring an optimized study read-out.

About Vidofludimus Calcium (IMU-838)
Vidofludimus calcium is an investigational drug in development as an orally available, next-generation selective immune modulator that is designed to inhibit the intracellular metabolism of activated immune cells by blocking the enzyme dihydroorotate dehydrogenase (DHODH). Vidofludimus calcium has been observed to act on activated T and B cells while leaving other immune cells largely unaffected and allows the immune system to stay functioning, e.g. in fighting infections. In previous trials, vidofludimus calcium did not show an increased rate of infections compared to placebo. In addition, DHODH inhibitors, such as vidofludimus calcium, are known to possess a host-based antiviral effect, which is independent with respect to specific virus proteins and their structure. Therefore, DHODH inhibition may be broadly applicable against multiple viruses. Vidofludimus calcium was successfully tested in two phase 1 clinical trials in 2017 and is currently being tested in a phase 2 trial in patients with ulcerative colitis. In the third quarter of 2020, the company reported positive results from its phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting multiple sclerosis, achieving both primary and key secondary endpoints with high statistical significance. In the first quarter of 2021, Immunic announced that vidofludimus calcium showed evidence of clinical activity in its phase 2 CALVID-1 trial in hospitalized patients with moderate COVID-19. Also, in the first quarter of 2021, the company reported positive top-line data from an investigator-sponsored phase 2 proof-of-concept clinical trial of vidofludimus calcium in primary sclerosing cholangitis which was conducted in collaboration with Mayo Clinic. To date, vidofludimus calcium has been tested in more than 800 individuals and has shown an attractive pharmacokinetic, safety and tolerability profile. Vidofludimus calcium is not yet licensed or approved in any country.

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, ulcerative colitis, Crohn's disease, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγ/RORγt, is targeted for development in psoriasis, castration-resistant prostate cancer and Guillain-Barré syndrome. 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, 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 vidofludimus calcium to safely and effectively target diseases, including multiple sclerosis, ulcerative colitis, Crohn's disease and primary sclerosing cholangitis; preclinical and clinical data for vidofludimus calcium; the timing of current and future clinical trials; the availability, safety or efficacy of potential treatment options for patients with ulcerative colitis or other conditions, if any; the potential availability and frequency of administration of vidofludimus calcium as a potential treatment for patients with ulcerative colitis or for patients with other conditions; 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, 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, 2020, filed with the SEC on February 26, 2021, 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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