Immunic Reports Positive Data from Maintenance Phase of Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Moderate-to-Severe Ulcerative Colitis

– 50-Week Maintenance Phase Data Shows Dose-Linear Increase in Clinical Remission for Vidofludimus Calcium as Compared to Placebo –

– 30 mg Once-Daily Dose of Vidofludimus Calcium Demonstrated Statistically Significant Rates of Clinical Remission (p=0.0358) and Endoscopic Healing (p=0.0259) at Week 50 –

– To Focus Resources on High Performing Vidofludimus Calcium and IMU-856 Programs, Immunic Decided to Deprioritize Izumerogant (IMU-935) Program –

– Conference Call and Webcast to be Held today, April 5, 2023 at 8:00 am ET –

NEW YORK, April 5, 2023 – Immunic, Inc. (Nasdaq: IMUX), a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, today reported positive data from the maintenance phase of its phase 2b CALDOSE-1 trial of lead asset, vidofludimus calcium (IMU-838), in patients with moderate-to-severe ulcerative colitis (UC) (clinicaltrials.gov: NCT03341962). The maintenance phase efficacy data at week 50 are as follows:

	Placebo	10 mg IMU-838	30 mg IMU-838
Clinical remission rate[1]	27.8% (N=5/18)	42.3% (N=11/26)	61.5% (N=16/26)
Steroid-free clinical remission rate	27.8% (N=5/18)	38.5% (N=10/26)	61.5% (N=16/26)
Steroid-free clinical remission rate of patients who received corticosteroids during induction phase	27.3% (N=3)	38.5% (N=5)	66.7% (N=8)
Endoscopic healing rate[2]	35.3% (N=6/17)	53.6% (N=15/28)	73.1% (N=19/26)

As shown above, data from the maintenance phase of CALDOSE-1 showed a dose-linear increase in clinical remission as compared to placebo at week 50. Moreover, an exploratory statistical analysis confirmed the 30 mg dose of vidofludimus calcium to be statistically superior (p=0.0358) in achieving clinical remission at week 50, with a 33.7% absolute improvement over placebo. A similar effect on clinical remission rates at week 50 was also found among those patients who received corticosteroids during the induction phase. Finally, a dose-linear increase in endoscopic healing was observed, with the 30 mg dose of vidofludimus calcium being associated with a 37.8% absolute improvement over placebo and also achieving statistical significance in an exploratory statistical analysis (p=0.0259).

Immunic believes that the maintenance phase data of CALDOSE-1 confirms vidofludimus calcium's impressive activity in the absence of chronic corticosteroid co-administration. Data from the induction phase, released in June of 2022, showed clinical remission rates of 14.7% for the pooled vidofludimus calcium arms and 3.3% for the placebo arm among those patients not being treated concurrently with

chronic corticosteroids. At the same time, this benefit was not seen among the population to whom corticosteroids were chronically co-administered. During the maintenance phase, all corticosteroids were required to be tapered, if possible. Hence, the maintenance phase results are in line with the induction data without chronic concomitant use of corticosteroids and underline the performance of vidofludimus calcium in this steroid-free UC population. On a related note, the previous phase 2a ENTRANCE study had already shown that vidofludimus has a high response rate in replacing steroids among steroid-dependent UC patients.

Consistent with prior data sets in other patient populations, administration of vidofludimus calcium in the maintenance phase of this trial was observed to be safe and well-tolerated. No new safety signals were observed. The incidence of treatment-emergent adverse events in both the 10 mg and 30 mg dose groups of vidofludimus calcium was comparable with placebo. There were no increased rates of liver events, liver enzyme elevations, renal events or adverse events of special interest, when compared to placebo, and no Hy's Law cases were observed.

"These impressive results from the maintenance phase of our CALDOSE-1 trial in patients with UC are extremely encouraging as they demonstrate statistically significant activity of vidofludimus calcium as compared to placebo. We believe this data compares favorably to available maintenance data for other UC drugs," commented Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Although we do not intend to initiate phase 3 development of vidofludimus calcium in UC on our own and without additional funding and resource allocation, based on this encouraging outcome, we will explore an exciting variety of options for the UC program as well as other inflammatory bowel disease (IBD) indications."

"Results from the maintenance phase of our CALDOSE-1 trial confirm previous observations in the induction phase that vidofludimus calcium provides a benefit regarding clinical remission, as compared to placebo, in UC patients not using concomitant corticosteroids," stated Andreas Muehler, M.D., Chief Medical Officer of Immunic. "Chronic corticosteroid administration is undesirable in clinical practice due to medically important adverse effects that are well documented. Therefore, future clinical trials of vidofludimus calcium could easily be performed without concomitant steroid use. We are also pleased to see that, once again, the study data confirms the very favorable safety and tolerability profile of vidofludimus calcium observed in other trials."

The CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe UC was a phase 2b, multicenter, randomized, double-blind, placebo-controlled, dose-finding study, including a blinded 10-week induction phase and a blinded 50-week maintenance phase. In the induction phase, 263 UC patients were enrolled at 78 study sites in the United States and Western, Central and Eastern Europe, and patients were randomized into three active dosing arms of 10 mg, 30 mg, 45 mg once-daily, as well as placebo. The primary endpoint comprised a composite of a patient-reported outcome and endoscopy-assessed outcome, also referred to as clinical remission, both evaluated following ten weeks of induction treatment. During the maintenance phase, 112 patients were re-randomized to receive 10 mg or 30 mg once-daily doses of vidofludimus calcium, while placebo patients who achieved symptomatic revision were "sham randomized" to continue receiving placebo in the maintenance phase.

Update on Izumerogant (IMU-935) and IMU-856 Development Programs

In order to focus on the rapidly advancing vidofludimus calcium and IMU-856 programs, and considering the positive results from the CALDOSE-1 trial of vidofludimus calcium in UC, as well as the totality of

available data for izumerogant, including changes in expected time to market and increased complexity of potential further development in this competitive field, Immunic has decided to focus its resources and, therefore, deprioritize the clinical portion of its izumerogant development program in psoriasis and castration-resistant prostate cancer.

Regarding IMU-856, the company notes that the part C portion of the ongoing phase 1 clinical trial in celiac disease patients has been proceeding more quickly than anticipated, with initial data expected to become available in the current quarter.

Webcast Information

Immunic will host a webcast today at 8:00 am ET. To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_nNH5sA-7RfOfHTa7a3i5wA or on the "Events and Presentations" section of Immunic's website at: ir.imux.com/events-and-presentations. Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.

An archived replay of the webcast will be available approximately one hour after completion on Immunic's website at: ir.imux.com/events-and-presentations.

About Vidofludimus Calcium (IMU-838)

Vidofludimus calcium is a small molecule investigational drug in development as an oral next-generation treatment option for patients with multiple sclerosis and other chronic inflammatory and autoimmune diseases. The selective immune modulator 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. To date, vidofludimus calcium has been tested in more than 1,400 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 biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases. The company's lead development program, vidofludimus calcium (IMU-838), currently in phase 3 clinical trials for the treatment of multiple sclerosis, selectively inhibits activated immune cells and shows combined anti-inflammatory, anti-viral and neuroprotective effects. IMU-856 is targeted to restore intestinal barrier function and regenerate bowel epithelium, which would be applicable in numerous gastrointestinal diseases, such as celiac disease, where it is currently being evaluated in a clinical proof-of-concept trial. 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 development, 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 development programs and the targeted diseases; the potential for vidofludimus calcium to safely and effectively target diseases; preclinical and clinical data for vidofludimus calcium; 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, increasing inflation, impacts of the Ukraine – Russia conflict on 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, 2022, filed with the SEC on February 23, 2023, 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.

[1] Clinical remission was defined as composite of patient-reported symptomatic remission (stool frequency Mayo subscore of 0 or 1, rectal bleeding Mayo score of 0) and modified Mayo endoscopy subscore of 0 or 1.

[2] Endoscopic healing was defined as modified Mayo endoscopy subscore of 0 or 1.

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