Immunic Presents Data From Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Ulcerative Colitis at the United European Gastroenterology Week 2023

NEW YORK, October 16, 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 announced the presentation of data from the company's phase 2 CALDOSE-1 trial of vidofludimus calcium (IMU-838) in an oral presentation at the United European Gastroenterology Week (UEGW) 2023, taking place October 14-17 in Copenhagen.

Geert R. D'Haens, M.D., Ph.D., Full Professor, AGEM - Amsterdam Gastroenterology Endocrinology Metabolism and Gastroenterology and Hepatology, Amsterdam University Medical Centers, The Netherlands, commented, "The maintenance phase results of the phase 2b CALDOSE-1 trial demonstrate statistically significant activity of vidofludimus calcium compared to placebo and reaffirm the drug's favorable safety and tolerability profile. The data, therefore, validates the potential of vidofludimus calcium in UC and other inflammatory bowel disease indications."

The CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe ulcerative colitis (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. Data presented today show that the induction phase did not achieve the primary endpoint of clinical remission for the total population, possibly because of interaction by corticosteroids started shortly before randomization. In contrast, in the maintenance phase, at the start of which concomitant corticosteroids were mandatorily tapered, vidofludimus calcium showed a dose-linear increase in clinical remission compared to placebo at week 50 (10 mg: 42.3%, 30 mg: 61.5%, placebo: 27.8%). Similarly, patients treated with vidofludimus calcium achieved dose-linear increases in steroid-free clinical remission, endoscopic healing and microscopic healing. An exploratory statistical analysis showed superiority of the 30 mg vidofludimus calcium treatment group over placebo for both clinical remission (p=0.0358) and endoscopic healing (p=0.0259). Consistent with prior data sets in other patient populations, administration of vidofludimus calcium in this trial was found to be safe and well-tolerated.

Presentation Details:

- **Title**: *Efficacy and Safety of Vidofludimus Calcium (IMU-838) In Patients With Moderately to Severely Active Ulcerative Colitis (UC): Results From the Prospective Placebo-Controlled Phase 2 CALDOSE-1 Trial*
- **Abstract Number:** AS-UEG-2023-01648
- **Presenting Author:** Dr. Geert R. D'Haens
- **Presentation Session:** The new kids on the block in IBD: Part 2
- **Location:** Abstract Session, A3
- **Date:** Monday, October 16, 2023
- **Time:** 3:18 – 3:30 pm CET
- The poster presentation is accessible on the "Events and Presentations" section of Immunic's website at: https://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 activates the neuroprotective transcription factor nuclear receptor related 1 (Nurr1), which is associated with direct neuroprotective properties. Additionally, vidofludimus calcium is a known inhibitor of the enzyme dihydroorotate dehydrogenase (DHODH), which is a key enzyme in the metabolism of overactive immune cells and virus-infected cells. This mechanism is associated with the anti-inflammatory and anti-viral effects of vidofludimus calcium. Vidofludimus calcium has been observed to selectively act on hyperactive T and B cells while leaving other immune cells largely unaffected and enabling normal immune system function, e.g., in fighting infections. 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), is currently in phase 3 and phase 2 clinical trials for the treatment of relapsing and progressive multiple sclerosis, respectively, and has shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis and moderate-to-severe ulcerative colitis. Vidofludimus calcium combines neuroprotective effects, through its mechanism as a first-in-class nuclear receptor related 1 (Nurr1) activator, with additional anti-inflammatory and anti-viral effects, by selectively inhibiting the enzyme dihydroorotate dehydrogenase (DHODH). IMU-856, which targets the protein Sirtuin 6 (SIRT6), is intended to restore intestinal barrier function and regenerate bowel epithelium, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, where it is currently in preparations for a phase 2 clinical trial. IMU-381, which currently is in preclinical testing, is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases. 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, development 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 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, 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.

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