# - Phase 2 Trial in Relapsing-Remitting Multiple Sclerosis Expected to be the First Efficacy Read-Out of IMU-838; Top-line Data Anticipated in Q3 2020 -

SAN DIEGO, June 21, 2019 /<u>PRNewswire</u>/ -- **Immunic, Inc. (Nasdaq: IMUX),** a clinicalstage biopharmaceutical company focused on developing potentially best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced that it has filed an amended Current Report on Form 8-K containing certain financial statements and pro forma financial information required to be provided in connection with the stock-for-stock exchange transaction between Immunic, Inc. (then known as Vital Therapies, Inc.) and Immunic AG, which was completed on April 12, 2019. Management also provided an update on the progress of its key development programs.

The amended Current Report on Form 8-K contains the audited consolidated financial statements of Immunic AG as of and for the years ended December 31, 2018 and December 31, 2017, and the unaudited condensed consolidated financial statements as of and for the three months ended March 31, 2019 and the corresponding period of the preceding fiscal year. The filing also includes pro forma combined financial information of Immunic AG and Vital Therapies, Inc.

# **Clinical Development Progressing Well**

- Although all ongoing phase 2 trials with IMU-838 remain blinded, the observed safety results from these trials are consistent with the previously defined reference safety information and no new safety signals have been observed to date.
- Patient recruitment for the company's phase 2, international, multicenter, double-blind, placebocontrolled, randomized, parallel-group trial of IMU-838, in development for the treatment of relapsingremitting multiple sclerosis (EMPhASIS), is progressing faster than anticipated and is expected to be completed in the first half of 2020. Top-line data is anticipated to be available during the third quarter of 2020.
- Patient recruitment for the phase 2, multicenter, randomized, double-blind, placebo-controlled, dose-finding study of IMU-838 in patients with moderate-to-severe ulcerative colitis (CALDOSE-1) was updated based on current recruitment rates and the anticipated impact of supportive measures. Study enrollment is projected to conclude during the second half of 2020. Top-line data is expected to be available in the first quarter of 2021.
- Initiation of the phase 2, multicenter, randomized, double-blind, placebo-controlled, dose-finding trial
  of IMU-838 for the treatment of active Crohn's disease (CALDOSE-2) is expected to occur during the
  second half of 2019, as per previous guidance. All preparations are in the advanced stage in
  anticipation of the interim dosing analysis of CALDOSE-1 in the third quarter of 2019, which will
  inform the dose selection for CALDOSE-2.
- The investigator-sponsored trial of IMU-838 in patients with primary sclerosing cholangitis, which will be conducted at the Mayo Clinic, is expected to start enrollment soon.
- Immunic's earlier stage programs are on track. The company expects to begin its phase 1 doubleblind, placebo-controlled, single and multiple ascending dose trials of IMU-935 during September 2019. Immunic also plans to extend these studies in the first half of 2020 to assess safety and mechanism-related biomarkers in patients with psoriasis.
- Immunic has started preclinical regulatory safety studies of IMU-856, a drug candidate targeting the intestinal barrier function. Initiation of phase 1 clinical trials is expected in the first half of 2020.

### 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 ulcerative colitis, Crohn's disease, relapsing-remitting multiple sclerosis, 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 RORyt; 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 ulcerative colitis and relapsing-remitting multiple sclerosis, with an additional phase 2 trial in Crohn's disease planned for 2019. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is planned to start 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; 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. 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.

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<u>https://ir.imux.com/2019-06-21-Immunic-Inc-Files-Financial-Statements-and-Pro-Forma-Financial-Information-in-Accordance-with-Previously-Completed-Stock-for-Stock-Exchange-Transaction-and-Provides-Corporate-Update</u>