NEW YORK, Sept. 30, 2021 /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 enrollment of the first patient in its phase 2 CALLIPER trial of lead asset IMU-838, the company's selective oral DHODH inhibitor, in patients with progressive multiple sclerosis (PMS). The trial, which is intended to run concurrently with and as a complement to the company's twin phase 3 ENSURE trials in relapsing-remitting multiple sclerosis (RRMS), is focused on progressive forms of multiple sclerosis (MS) and designed to corroborate IMU-838's neuroprotective potential in this patient population.

CALLIPER is an international, multicenter, randomized, double-blind, placebo-controlled phase 2 trial expected to enroll approximately 450 patients at more than 70 sites in North America, Western, Central and Eastern Europe, with patients randomized to either 45 mg daily doses of IMU-838 or placebo. The trial's primary endpoint is the annualized rate of percent brain volume change up to 120 weeks. Key secondary endpoints include the annualized rate of change in whole brain atrophy and time to 24-week confirmed disability progression based on the expanded disability status scale (EDSS). An interim analysis comprising an unblinded analysis of serum neurofilament light chain (NfL) is planned to occur once approximately half of the enrolled patients have completed 24 weeks of treatment.

"Enrollment of the first PMS patient in our phase 2 CALLIPER trial, on schedule, is another important clinical milestone for our lead asset, IMU-838, and we continue to anticipate initiating our phase 3 ENSURE program in RRMS patients in the fourth quarter of this year," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "We believe that if the CALLIPER trial is successful in showing a beneficial neuroprotective effect of IMU-838, this data, along with that of the ENSURE program and IMU-838's already proven, strong safety and tolerability profile, may allow us to draw a clear clinical differentiation for IMU-838 versus other oral MS medications, resulting in an attractive commercial positioning as a transformative therapeutic treatment."

"The CALLIPER trial is designed to further explore IMU-838's neuroprotective potential, as exemplified by a slowing of brain atrophy and delay in disability worsening, which is often caused by axonal and neural damage," added Andreas Muehler, M.D., Chief Medical Officer of Immunic. "The interim analysis to assess NfL is key, as it has been shown to consistently correlate with disease activity in neurological disorders and has become one of the most important serum biomarkers for axonal damage over the past few years. If the CALLIPER trial is successful in showing beneficial data, we believe this could be an essential differentiator for IMU-838 in the MS market."

For more information on this clinical trial, please visit: www.clinicaltrials.gov, NCT05054140.

About Progressive Multiple Sclerosis
Multiple sclerosis (MS) is an autoimmune disease that affects the brain, spinal cord and optic nerve. In MS, myelin, the coating that protects the nerves, is attacked and damaged by the immune system. Thus, MS is considered an immune-mediated demyelinating disease of the central nervous system. Progressive multiple sclerosis (PMS) includes both primary progressive MS (PPMS) and secondary progressive MS (SPMS). PPMS is characterized by steadily worsening neurologic function from the onset of symptoms without initial relapse or remissions. SPMS is identified following an initial relapsing remitting course, after which the disease becomes more steadily progressive, with or without other disease activity present.

About IMU-838
IMU-838 is an orally available, next-generation selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme dihydroorotate dehydrogenase (DHODH). IMU-838 acts 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, IMU-838 did not show an increased rate of infections compared to placebo. In addition, DHODH inhibitors, such as IMU-838, 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. IMU-838 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 IMU-838 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 IMU-838 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 IMU-838 in primary sclerosing cholangitis which was conducted in collaboration with Mayo Clinic. To date, IMU-838 has been tested in more than 800 individuals and has shown an attractive pharmacokinetic, safety and tolerability profile.

IMU-838 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, 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 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 IMU-838 to safely and effectively target diseases, including progressive multiple sclerosis; preclinical and clinical data for IMU-838; the timing of current and future clinical trials; the availability, safety or efficacy of potential treatment options for patients with progressive multiple sclerosis or other conditions, if any; 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 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 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. 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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