- Study Being Conducted in Collaboration with University Hospitals Coventry and Warwickshire NHS Trust -

NEW YORK, July 27, 2020 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX),** a clinical-stage biopharmaceutical company focused on developing best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced enrollment of the first patients in an investigator-sponsored phase 2 clinical trial of the company's selective oral DHODH inhibitor, IMU-838, for the treatment of patients with coronavirus disease 2019 (COVID-19). The IONIC trial is a prospective, randomized, parallel-group, open-label phase 2b study, designed to evaluate efficacy and safety of IMU-838 in combination with the neuraminidase inhibitor, Oseltamivir (Tamiflu®), in approximately 120 adult patients with moderate-to-severe COVID-19.

The IONIC trial has been set up with the support of the in-house Trial Management Unit (TMU) of the sponsor and lead site, University Hospitals Coventry and Warwickshire (UHCW) NHS Trust. The IONIC trial has commenced recruitment at the lead site and the TMU is actively engaging with other NHS trusts interested in participating in the trial to facilitate recruitment.

"The healthcare community has never faced a more urgent need for new therapies than the unprecedented situation we currently face with the COVID-19 pandemic," commented Prof. Ramesh Arasaradnam, Gastroenterology Consultant at UHCW NHS Trust, Chair of the British Society of Gastroenterology (BSG) Research Committee and Chief Investigator of the IONIC trial. "Recent third-party research has highlighted the powerful synergy between direct antiviral drugs and DHODH inhibitors in preclinical models. We believe that the combination of Oseltamivir, which is a licensed drug in the United Kingdom, and IMU-838, may offer a promising approach for the treatment of severe viral infections, including mid-to-late-stage COVID-19 patients."

IMU-838 has successfully demonstrated preclinical activity against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Specifically, IMU-838 was observed to inhibit replication of clinical isolates of SARS-CoV-2 associated with COVID-19. In cellular assays, IMU-838 demonstrated this antiviral activity at concentrations which are well below the blood concentrations associated with IMU-838 dosing regimens studied in ongoing and previous clinical trials. In addition, IMU-838 has an attractive pharmacokinetic, safety and tolerability profile and, to date, has already been tested in about 650 individuals.

The IONIC trial, for which Immunic is providing the study medication, is expected to enroll approximately 120 hospitalized patients, 60 in each treatment arm, with moderate-to-severe COVID-19 who will receive IMU-838 plus Oseltamivir, or Oseltamivir alone, for 14 consecutive days. All patients are also eligible to receive standard-of-care therapy throughout the duration of the study. Inclusion criteria are adult patients with a confirmed or suspected SARS-CoV-2 infection fulfilling clinical status category 3 to 5, as assessed with the seven-point ordinal scale proposed by the World Health Organization (WHO) master protocol.

"We are honored to be collaborating with the UHCW NHS Trust on this important clinical trial, in order to find a new treatment option for COVID-19 patients," noted Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Due to its unique host-based mode of action, which avoids dependence on specific viral proteins and, therefore, offers broad-spectrum antiviral activity, as well as the attractive pharmacokinetic, safety and tolerability profile, we believe that IMU-838 is particularly suitable for combination with other antiviral drugs such as Oseltamivir. We also believe that this trial can provide valuable insights as to whether the host cell-based antiviral mechanism of IMU-838 has a synergistic effect with a direct antiviral drug in order to provide a combination treatment approach for COVID-19."

In support of the IONIC trial, the UHCW NHS Trust has received funding from the medical research charity LifeArc through its COVID-19 drug repurposing initiative. LifeArc CEO Dr Melanie Lee said, "LifeArc is pleased to be able to support the IONIC trial, as part of our £10 million initiative to find new therapeutics against COVID-19. We believe repurposing already available medicines or those at a late stage of development, like those being studied in the IONIC trial, offers the fastest route to bring benefit to patients during this pandemic."

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 phase 2 trials in patients with COVID-19, relapsing-remitting multiple sclerosis, where top-line data is expected in the first half of August 2020, and ulcerative colitis. Furthermore, Immunic's collaboration partner, the Mayo Clinic, has started an investigator-sponsored proof-of-concept clinical trial testing IMU-838 activity in patients with primary sclerosing cholangitis. To date, IMU-838 has already been tested in about 650 individuals and has shown an attractive pharmacokinetic, safety and tolerability profile.

About Immunic, Inc.
Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company with a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. The company is developing three small molecule products: lead development program, IMU-838, is 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; IMU-935 is an inverse agonist of RORγt; and IMU-856 targets the restoration of the intestinal barrier function. IMU-838 is in phase 2 clinical development for COVID-19, relapsing-remitting multiple sclerosis and ulcerative colitis, with an additional phase 2 trial considered in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. For further information, please visit: www.imux.com.

About UHCW NHS Trust
University Hospitals Coventry and Warwickshire (UHCW) NHS Trust is one of the largest acute teaching Trusts in the UK, comprising University Hospital in Coventry and the Hospital of St Cross in Rugby and working in partnership with Warwick University Medical School and Coventry University.

It has over 9,000 staff and delivers services across the West Midlands region. This includes hosting region-wide services such as the Coventry and Warwickshire Pathology Network and the North West and Midlands Bowel Cancer Screening hub. The Trust works closely with its partners in health and social care in Coventry/Warwickshire to develop patient-focused services that meet the needs of communities.

The Research and Development Department at the Trust supports and delivers a wide range of high quality health research for the benefit of our patients. In 2019-20, the department recruited 4,295 patients into research projects - demonstrating the Trust's commitment to improving the quality of care and contributing to wider health improvement.

The team recruited more COVID-19 patients per head of population than the national average, supporting the World Health Organisation 'ISARIC' trial and the National Institute for Health Research 'Recovery' study which demonstrated the efficacy of low dose Dexamethasone as an effective treatment for COVID-19.

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; preclinical and clinical data for IMU-838; the timing of current and future clinical trials; the potential for IMU-838 as a treatment for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections associated with coronavirus disease 2019 (COVID-19) and any clinical trials, collaborations and approvals relating to such potential treatment; 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, 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, 2019, filed with the SEC on March 16, 2020, the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, filed with the SEC on May 8, 2020, 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.

Contact Information

Immunic, Inc.
Jessica Breu
Head of Investor Relations and Communications
+49 89 2080 477 09
jessica.breu@imux.com

Immunic, Inc. US IR Contact
Rx Communications Group
Melody Carey
+1-917-322-2571
immunic@rxir.com

Immunic, Inc. US Media Contact
Speak Life Science, LLC
Amy Speak
+1-617-420-2461
amy@speaklifescience.com

UHCW NHS Trust – TMU team
Keith Bull
Communications Manager
University Hospitals Coventry & Warwickshire
+44 (0) 2476966197
communications@uhcw.nhs.uk

SOURCE Immunic, Inc.
