

- European Investment Bank and Immunic sign a financing agreement of up to €24.5 million to support the development of Immunic's lead asset, IMU-838, in moderate COVID-19

- IMU-838 is an orally available small molecule, which, because of its broad-spectrum antiviral effect and selective immunomodulatory properties, is currently being evaluated for the treatment of COVID-19

- The EIB venture loan is financed under the Infectious Diseases Finance Facility set up as part of Horizon 2020, the European Union's research and innovation program for 2014-2020

LUXEMBOURG and GRÄFELFING, Germany and NEW YORK, Oct. 20, 2020 /PRNewswire/ -- The European Investment Bank (EIB) and Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, today announced the signing of a €24.5 million financing agreement. The venture loan is intended to support Immunic's ongoing phase 2 CALVID-1 trial of its lead asset, IMU-838, in patients with moderate coronavirus disease 2019 (COVID-19). In addition, it is also intended to support the potential expansion of the CALVID-1 trial into a confirmatory phase 3 trial and the commercial-scale manufacturing for IMU-838. Immunic AG, the German subsidiary of Immunic, Inc., will receive the EIB loan in three tranches upon the completion of pre-defined milestones.

IMU-838, an orally available small molecule, has successfully demonstrated preclinical activity against SARS-CoV-2 in multiple assays and is currently undergoing a phase 2 clinical trial in hospitalized COVID-19 patients with moderate disease activity. IMU-838 is also being tested in other phase 2 trials evaluating the use of the drug as a potential treatment for chronic inflammatory and autoimmune diseases, such as multiple sclerosis or ulcerative colitis.

"While SARS-CoV-2 infections are on the rise, many of Europe's top scientists are working relentlessly to help better control the pandemic," said [Ambroise Fayolle, EIB Vice-President](#) in charge of innovation and lending in Germany. "The role of European institutions is to support their research and innovation to the best of our ability. I am therefore very pleased that EIB financing can contribute to the R&D activities of Immunic. If successful, Immunic's drug may reduce the number of critically ill COVID-19 patients, thereby relieving the burden on health systems, patients and families alike."

[Mariya Gabriel, European Commissioner for Innovation, Research, Culture, Education and Youth](#) said: "The European Union is actively involved in the worldwide race to find better solutions for the COVID-19 disease. With this loan to Immunic, we continue to accelerate the development of innovative treatments against coronavirus and other severe diseases faced by our society."

"The funding commitment by the EIB is a confirmation of its faith in Immunic's ability to advance our lead asset, IMU-838, a selective oral DHODH inhibitor, which has shown strong antiviral activity in preclinical testing, as a potential treatment for COVID-19," stated [Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic](#) "This investment will enable us to continue to advance our CALVID-1 clinical program and we look forward to reporting the results of a pre-planned interim efficacy analysis from the phase 2 trial later this year, after which we plan to evaluate whether the program may be expanded into a confirmatory phase 3 trial."

One of Immunic's goals is to develop IMU-838 not only as a treatment option for COVID-19, but also for potential use against other, future viral pandemics. The drug's antiviral effect has been shown to be host-based, which suggests that it is independent of virus-specific proteins and their structure, shielding it from resistance or mutations of SARS-CoV-2, and also expanding its potential application to other viruses. For instance, IMU-838 has previously demonstrated activity *in vitro* against Influenza A virus, HIV, and Hepatitis C virus, amongst others. Importantly, IMU-838 has already been tested in about 650 individuals with an attractive pharmacokinetic, safety and tolerability profile, to date.

The EIB loan to Immunic is backed by the [Infectious Diseases Finance Facility](#) (IDFF) set up as part of the European Union's [Horizon 2020 Program](#). The IDFF is an example of successful collaboration between the European Commission and the EIB in the face of a health crisis. Through this facility, the EIB has supported European companies via total lending of about €400 million for developing cures, vaccines and diagnostics for various infectious diseases, most prominently coronavirus.

About the EIB

The European Investment Bank is the long-term lending institution of the European Union owned by its Member States. It makes long-term finance available for sound investments in order to contribute towards EU policy goals. The EIB also supports investments outside the European Union.

About the InnovFin Infectious Diseases Finance Facility

The InnovFin Infectious Diseases Finance Facility (IDFF) is dedicated to supporting the fight against infectious diseases. This joint European Commission and EIB Group initiative is part of Horizon 2020, the 2014-2020 EU research and innovation program. The IDFF enables the EIB to provide between €7.5 million and €75 million of funding to innovative players active in developing vaccines, drugs, medical and diagnostic devices and research infrastructure for combating infectious diseases. The financing mainly goes to projects that have completed the preclinical stage and need clinical approval for further development. The IDFF has been increased by €400 million to boost its capacity for tackling the outbreak of the coronavirus. The total EU contribution to the IDFF via Horizon 2020 is estimated at almost €700 million.

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. Immunic is developing three small molecule products: its 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 ROR γ t; and IMU-856 targets the restoration of the intestinal barrier function. On August 2, 2020, Immunic announced positive top-line results from its phase 2 EMPHASIS trial of IMU-838 in patients with relapsing-remitting multiple sclerosis, reporting achievement of both primary and key secondary endpoints with high statistical significance, indicating activity for IMU-838 in this indication. IMU-838 is also in phase 2 clinical development for ulcerative colitis and COVID-19, 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.

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; 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 future use of the EIB venture loan; 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 June 30, 2020, filed with the SEC on August 3, 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.

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