Immunic, Inc. InvestorRoom

Planegg-Martinsried, Germany, February 26, 2019 – Immunic AG (Immunic), a privately held clinical-stage biotechnology company, today announced enrollment of the first patient in a phase 2 clinical study of IMU-838 for the treatment of patients with relapsing-remitting multiple sclerosis (RRMS). 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).

This phase 2 study is an international, multicenter, double-blind, placebo-controlled, randomized, parallel-group trial that is expected to enroll approximately 200 patients in more than 40 centers across four European countries. The study's primary objective is to evaluate the dose response of 30 mg/day and 45 mg/day of IMU-838, once daily, for the treatment of RRMS based on magnetic resonance imaging (MRI) assessments. Patients enrolled in the trial will have shown disease activity based on clinical evidence of relapse and MRI criteria.

The trial includes a blinded 24-week main treatment period with an optional extended treatment period to evaluate long-term safety and tolerability of IMU-838 that will be unblinded when all patients have completed the main treatment portion and the study database has been locked. The primary endpoint of the study is the cumulative number of combined unique active (CUA) MRI lesions, up to week 24.

Daniel Vitt, Ph.D., Chief Executive Officer of Immunic, stated, "Enrollment of the first patient in this trial as planned and on schedule represents another key milestone for Immunic and demonstrates the ability of our company to effectively execute our drug development strategy. We had already advanced IMU-838 into a phase 2 trial for ulcerative colitis, so we are excited about its clinical testing in this additional patient population. This development further advances our goal of expanding the indications for which IMU-838 shows great promise for patients with chronic inflammatory and autoimmune diseases."

"The mode of action of IMU-838, DHODH inhibition, is already commercially proven in RRMS, and the safety and tolerability profiles of IMU-838 are well understood. To date, more than 350 individuals have been treated with the active moiety, with no general detrimental effect on bone marrow observed in animal experiments, no increased rate of alopecia or diarrhea, and no increased rate of infections compared with placebo in earlier clinical trials in other indications," commented Andreas Muehler, MD, Chief Medical Officer of Immunic. "We look forward to carrying out this trial in support of further clinical data showing IMU-838 as a potentially best-in-class, once-daily oral therapy to treat RRMS."

For more information on this clinical trial, please visit: www.clinicaltrials.gov, NCT03846219.

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 direct antiviral effect. 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 ulcerative colitis and relapsing-remitting multiple sclerosis. Immunic intends to initiate an additional phase 2 trial in patients with Crohn's disease later in 2019. Furthermore, Immunic's collaboration partner, Mayo Clinic, plans to start an investigator-sponsored proof-of-concept clinical trial testing IMU-838 activity in patients with primary sclerosing cholangitis (PSC) in the first quarter of 2019.

About Immunic AG

Immunic AG is a specialist in selective oral drugs in immunology and focused on developing novel oral therapies with best-in-class potential for chronic inflammatory and autoimmune diseases. The company's three development programs target inflammatory bowel diseases, relapsing-remitting multiple sclerosis, and psoriasis and include orally available, small molecule inhibitors of DHODH (IMU-838 program), an inverse agonist of RORyt (IMU-935 program), and IMU-856 (targeting intestinal barrier function). Immunic's lead development program, IMU-838, is currently in phase 2 clinical development for ulcerative colitis and relapsing-remitting multiple sclerosis, with additional phase 2 trials in Crohn's disease, and primary sclerosing cholangitis planned for 2019. The company was founded in 2016 with headquarters in Planegg-Martinsried, Germany. Immunic is privately held and supported by several renowned healthcare investors.

On January 6, 2019, Immunic and the shareholders of Immunic entered into an Exchange Agreement with Vital Therapies, Inc. pursuant to which the shareholders of Immunic agreed to contribute all of the outstanding Immunic shares to Vital Therapies in exchange for shares of Vital Therapies common stock. Upon closing of the transaction, the company is expected to operate under the name Immunic, Inc. and trade on the NASDAQ Stock Market under the symbol "IMUX". For further information, please see: www.immunic-therapeutics.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements relating to Immunic AG, including statements about our three development programs and the targeted diseases, our plans for the development of for IMU-838, our existing and planned clinical trials and the clinical utility of Immunic's therapeutic candidates and our pending transaction with Vital Therapies. Risks and uncertainties that may cause actual results to differ materially from those expressed or implied in any forward-looking statement include, but are not limited to: Immunic's plans to develop and commercialize its product candidates, including IMU-838, IMU-935 and IMU-856; the timing of Immunic's planned clinical trials; and the expected listing of Immunic, Inc. on NASDAQ. Forward-looking statements are identified by the use of forward-looking terminology including "believes," "expects," "may," "will," "should," "seeks," "intends," "plans," "pro forma," "estimates," or "anticipates" or the negative of these words and phrases or other variations of these words and phrases or comparable terminology. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These forward-looking statements should not be relied upon as predictions of future events as Immunic cannot assure investors that the events or circumstances reflected in these statements will be achieved or will occur. The forward-looking statements in this press release represent Immunic's views as of the date of this press release. Immunic anticipates that subsequent events and developments will cause its views to change. Immunic may elect to update these forwardlooking statements at some point in the future, however, it has no current intention of doing so except to the extent required by applicable law. Investors should, therefore, not rely on these forward-looking statements as representing Immunic's views as of any date subsequent to the date of this press release.

Additional Information about the Proposed Transaction between Vital Therapies, Inc. and Immunic AG and Where to Find It

In connection with the proposed transaction, Vital Therapies and Immunic intend to file relevant materials with the Securities and Exchange Commission, or the SEC, and Vital Therapies has filed a registration statement on Form S-4 and a final proxy statement/prospectus. The registration statement was declared effective by the SEC on February 14, 2019, and the definitive proxy statement was mailed or otherwise made available to Vital Therapies stockholders on February 19, 2019. Investors and security holders of Vital Therapies and Immunic are urged to read the final proxy statement/prospectus (including any amendments or supplements thereto) and other documents filed with the SEC when they become available because they contain important information about Vital Therapies, Immunic and the proposed transaction. In addition to receiving the final proxy statement/prospectus and proxy card by mail, Vital Therapies stockholders can also obtain the final proxy statement/prospectus, as well as other filings containing information about Vital Therapies, without charge, from the SEC's website (http://www.sec.gov) or, without charge, by directing a written request to: Vital Therapies, Inc., 15222-B Avenue of Science, San Diego, CA, 92128, Attention: Investor Relations.

This communication does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities.

Vital Therapies and its executive officers and directors may be deemed to be participants in the solicitation of proxies from Vital Therapies' stockholders with respect to the matters relating to the proposed transaction. Immunic may also be deemed a participant in such solicitation. Information regarding Vital Therapies' executive officers and directors is available in Vital Therapies' proxy statement on Schedule 14A for its 2018 annual meeting of stockholders, filed with the SEC on April 12, 2018. Information regarding any interest that Vital Therapies, Immunic or any of the executive officers or directors of Vital Therapies or Immunic may have in the transaction with Immunic is set forth in the final proxy statement/prospectus that Vital Therapies has filed with the SEC in connection with its stockholder vote on matters relating to the proposed transaction.

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https://ir.imux.com/2019-02-26-Immunic-Therapeutics-Announces-First-Patient-Enrolled-in-Phase-2-Clinical-Trial-of-IMU-838-an-Oral-Therapy-for-Patients-with-Relapsing-Remitting-Multiple-Sclerosis