



Vital Therapies and Immunic Therapeutics Announce Transaction to Create Leading Inflammatory and Autoimmune Disease Company

January 7, 2019

– Transaction Expected to Create NASDAQ-listed Biopharmaceutical Company Focused on Advancing Immunic's Compelling Pipeline of Clinical-Stage and Late Preclinical Assets –



– Lead Program, IMU-838, an Orally Available, Small Molecule Inhibitor of DHODH, Already Advanced into Phase 2 Studies in Ulcerative Colitis –

– Companies to Host Conference Call to Discuss Transaction at 8:00 a.m. ET on January 7 –

SAN DIEGO and PLANEGG-MARTINSRIED, Germany, Jan. 07, 2019 (GLOBE NEWSWIRE) -- Vital Therapies, Inc. (Nasdaq: VTL), and Immunic AG (Immunic), a private clinical-stage biotechnology company in Planegg-Martinsried, Germany, today announced that they have entered into a definitive agreement under which Vital Therapies is expected to acquire all of the outstanding shares in Immunic in exchange for newly issued shares of Vital Therapies in an all-stock transaction. The company will focus on advancing Immunic's pipeline of novel and potentially transformative treatments for chronic inflammatory and autoimmune diseases. Upon closing of the transaction, the company is expected to operate under the name Immunic, Inc. and trade on the NASDAQ Global Market.

An investor syndicate including Life Sciences Partners, Omega Funds, Fund*, LifeCare Partners, Bayern Kapital, High-Tech Gründerfonds and IBG Beteiligungsgesellschaft Sachsen-Anhalt has committed to invest approximately EUR 26 million in the company at the closing of the transaction. This financing will help fund the further development of Immunic's pharmaceutical product candidates and is expected to be consummated before or concurrently with the closing of the transaction, which is contingent upon this financing. The total cash balance of the company following the closing of the transaction and concurrent financing is expected to be between USD 35 to 40 million and would be sufficient to fund development into the third quarter of 2020.

Immunic is a privately-held clinical-stage biopharmaceutical company focused on developing best-in-class therapies for the treatment of chronic inflammatory and autoimmune diseases. Immunic's lead program, IMU-838, is an orally available, next-generation selective immune modulator which inhibits the intracellular metabolism of activated immune cells by blocking the enzyme dihydroorotate dehydrogenase (DHODH). 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. Immunic intends to initiate additional phase 2 trials in patients with Crohn's disease and multiple sclerosis throughout the course of 2019. Furthermore, the Mayo Clinic plans to start a phase 2 study testing IMU-838 activity in patients with primary sclerosing cholangitis (PSC) in the first quarter of 2019.

Immunic's second asset is IMU-935, an orally available small molecule inverse agonist of ROR γ t, a nuclear receptor known to influence the production of cytokines involved in autoimmune disease. The IMU-935 program, currently in preclinical development, is expected to enter clinical phase 1 trials in mid-2019.

In November 2018, Immunic entered into an exclusive global option and license agreement with Tokyo-based Daiichi Sankyo Co., Ltd. for IMU-856, a novel, orally available small molecule currently in preclinical development. IMU-856 targets the restoration of the intestinal barrier function, whose disruption is known to be prominently involved in the initiation of inflammatory bowel diseases like ulcerative colitis and Crohn's disease, and also in disease relapse. Restoration of the intestinal barrier function may provide an important new therapeutic option by lessening or avoiding the immuno-suppression associated with current therapies. Immunic currently expects IMU-856 to enter clinical trials in the first half of 2020.

"We are truly excited about the opportunity created by this transaction to further advance our three next-generation programs in chronic autoimmune and inflammatory diseases. Our objective has always been to develop new and better options for patients with debilitating diseases, and with this transaction and the compelling data from our programs, we believe that we are well positioned to deliver on this vision," said Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "We believe that the proposed transaction will be transformative for Immunic stockholders and create a company with the potential to generate substantial stockholder value. We expect that the company will have the financial resources and experienced leadership to accomplish our multiple value inflection points and key near-term objectives: first, to deliver phase 2 read-outs for our lead program IMU-838 in multiple indications; and second, to further advance our preclinical programs, IMU-935 and IMU-856, towards clinical proof-of-concept."

"Following an extensive and thorough review of strategic alternatives, we believe that this transaction with Immunic is the best path forward and has the potential to deliver significant and near-term value to Vital Therapies stockholders," said Russell J. Cox, Chief Executive Officer of Vital Therapies. "We believe that the strength and dedication of the Immunic leadership team will provide our company with the capabilities to develop new and much-needed therapies for patients with inflammatory and autoimmune diseases."

Proposed Transaction Details

Under the terms of the agreement, on a pro forma basis and after giving effect to the concurrent financing, current Vital Therapies stockholders are expected to own approximately 11% of the company and current Immunic stockholders are expected to own approximately 89% of the company. The actual allocation will be subject to adjustment based on Vital Therapies' net cash balance at the closing of the transaction. Prior to closing, Vital Therapies will seek stockholder approval to effect a reverse split of its outstanding common stock to satisfy listing requirements of the NASDAQ Global Market.

The company will be led by Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic, and will be headquartered in Boston, MA, USA. The board of directors is expected to be composed of five members, including four members of the current Immunic board, Daniel Vitt, Ph.D., CEO of Immunic, Joerg Neermann, Ph.D., Life Science Partners, Vincent Ossipow, Ph.D., CFA, Omega Funds, Jan von den Bossche, Fund+, and Vital Therapies' current President and member of the management team, Duane Nash, MD, JD, MBA.

With the signing of the Exchange Agreement between the two parties, Russell J. Cox, Vital Therapies' Chief Executive Officer, will be leaving the company in the near term. "We are tremendously grateful to Russ for his leadership in so quickly and effectively delivering to our stockholders the compelling strategic option of this transaction with Immunic," said Faheem Hasnain, Chairman of the Board of Vital Therapies. "It has been a privilege to work with the board and management team at Vital Therapies," said Russell J. Cox. "However, it is important that we maximize cash available for post-closing operations. We believe we are well-positioned for a successful outcome to the transaction, and I, as well as the entire board, have full confidence in our team's ability to finalize this process." Upon Russ' departure, Dr. Duane Nash, Vital Therapies' current President, will serve as interim Chief Executive Officer.

The transaction has been approved by the board of directors of both companies and the stockholders of Immunic. The transaction is expected to close in the second quarter of 2019, subject to the approval of Vital Therapies stockholders at a special meeting of stockholders, as well as other customary conditions.

Ladenburg Thalmann & Co. Inc. is acting as exclusive financial advisor to Vital Therapies for the transaction and Pillsbury Winthrop Shaw Pittman LLP is serving as legal counsel to Vital Therapies. BMO Capital Markets is acting as exclusive financial advisor to Immunic for the transaction and Dentons is serving as legal counsel to Immunic.

Conference Call and Webcast

Vital Therapies and Immunic will host a conference call at 8:00 a.m. ET on January 7, to discuss the proposed transaction. The conference call may be accessed by dialing +1 (855) 765-5682 for U.S. callers and +1 (919) 825-3204 for international callers at least five minutes prior to the start of the call and providing the passcode 6963969. Additionally, the live, listen-only webcast of the conference call can be accessed by visiting the investors relations section of the Vital Therapies website at www.vitaltherapies.com, or the News section of the Immunic website at www.immunic-therapeutics.com. A replay of the webcast can be accessed at the same location beginning two hours following completion of the call and will be available for 90 days.

About Vital Therapies

Vital Therapies, Inc. is a biotherapeutic company that has been developing a cell-based therapy targeting the treatment of acute forms of liver failure. The Company's ELAD® System is an extracorporeal human allogeneic cellular liver therapy that was in phase 3 clinical trials through late 2018. In September of 2018, the Company announced that its phase 3 clinical trial did not achieve its primary or secondary endpoints and that further development of ELAD® was halted. In October of 2018, the Company announced that it had retained Ladenburg Thalmann & Co. Inc. as its strategic financial advisor to assist in an exploration of strategic opportunities for enhancing stockholder value. Vital Therapies, Inc. is based in San Diego, California, USA. Vital Therapies® and ELAD® are trademarks of Vital Therapies, Inc.

About Immunic Therapeutics

Immunic 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, multiple sclerosis, and psoriasis and include orally available, small molecule inhibitors of DHODH (IMU-838 program), an inverse agonist of RORγt (IMU-935 program), and IMU-856 (undisclosed novel target). Immunic's lead development program, IMU-838, an orally available, small molecule inhibitor of DHODH, is currently in phase 2 clinical development for ulcerative colitis, with additional phase 2 trials in Crohn's disease, multiple sclerosis, 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.

No Offer or Solicitation

This press release shall not constitute an offer to sell, or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No public offer of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Additional Information About the Proposed Transaction and Where to Find it

This press release is being made in respect of a proposed transaction involving Immunic AG and Vital Therapies, Inc. Vital Therapies intends to file a registration statement on Form S-4 with the U.S. Securities and Exchange Commission (the "SEC"), which will contain a proxy statement/prospectus and other relevant materials, and plans to file with the SEC other documents regarding the proposed transaction. The final proxy statement/prospectus will be sent to the stockholders of Vital Therapies in connection with the Vital Therapies special meeting of stockholders to be held to vote on matters relating to the proposed transaction. The proxy statement/prospectus will contain information about Vital Therapies, Immunic, the proposed transaction, and related matters. STOCKHOLDERS OF VITAL THERAPIES ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS THERETO) AND OTHER DOCUMENTS FILED WITH THE SEC CAREFULLY IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS THEY WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS OF VITAL THERAPIES SHOULD CONSIDER BEFORE MAKING A DECISION ABOUT THE PROPOSED TRANSACTION AND RELATED MATTERS. In addition to receiving the proxy statement/prospectus and proxy card by mail, Vital Therapies stockholders will also be able to obtain the 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.

Participants in the Solicitation

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 will be set forth in the proxy statement/prospectus that Vital Therapies intends to file with the SEC in connection with its stockholder vote on matters relating to the proposed transaction. Vital Therapies stockholders will be able to obtain this information by reading the proxy statement/prospectus when it becomes available.

Cautionary Statement Regarding Forward-Looking Statements

Certain statements contained in this release regarding matters that are not historical facts are forward-looking statements within the meaning of Section 21E of the Securities and Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. These include statements regarding management's intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them.

No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. We use words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on management expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the forward-looking statements due to a number of factors, including, but not limited to, risks relating to the completion of the transaction, including the need for Vital Therapies stockholder approval and the satisfaction of closing conditions; the anticipated financing to be completed concurrently with the closing of the transaction; the cash balance of the company following the closing of the transaction and the financing, and expectations with respect thereto; the potential benefits of the proposed transaction; the business and prospects of the company following the proposed transaction; and the ability of Vital Therapies to remain listed on the Nasdaq Capital Market. 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: the closing of the proposed transaction; Immunic’s plans to develop and commercialize its product candidates, including IMU-838, IMU-935 and IMU-856; the timing, costs and outcomes of Immunic’s planned clinical trials; expectations regarding potential market size; the timing of the availability of data from Immunic’s clinical trials; the timing of any planned investigational new drug application or new drug application; Immunic’s plans to research, develop and commercialize its current and future product candidates; Immunic’s ability to successfully collaborate with existing collaborators or enter into new collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Immunic’s product candidates; Immunic’s commercialization, marketing and manufacturing capabilities and strategy; Immunic’s ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Immunic’s competitors and our industry; the impact of government laws and regulations; Immunic’s ability to protect its intellectual property position; and Immunic’s estimates regarding future revenue, expenses, capital requirements, and the need for and timing of additional financing following the proposed transaction.

These risks, as well as other risks associated with the transaction, will be more fully discussed in the proxy statement/prospectus that will be included in the registration statement that will be filed by Vital Therapies with the SEC in connection with the proposed transaction. Additional risks and uncertainties are identified and discussed in the “Risk Factors” section of Vital Therapies’ Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other documents filed from time to time with the SEC. Forward-looking statements included in this press release are based on information available to Vital Therapies and Immunic as of the date of this press release. Neither Vital Therapies nor Immunic undertakes any obligation to update such forward- looking statements to reflect events or circumstances after the date of this press release.

Contact Information

Vital Therapies, Inc.

Investor Relations
15222-B Avenue of Science
San Diego, CA 92128, USA
+1-858-673-6840
InvestorRelations@vitaltherapies.com

Immunic AG

Jessica Breu
Manager IR and Communications
Am Klopferspitz 19
82152 Planegg-Martinsried, Germany
T: +49 89 250 0794 69
jessica.breu@immunic.de



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