

SAN DIEGO, June 24, 2019 /PRNewswire/ -- **Immunic, Inc.** (Nasdaq: IMUX), a clinical-stage biopharmaceutical company focused on developing potentially best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, announced that Hella Kohlhof, Ph.D., Chief Scientific Officer of Immunic, will present today previously unpublished data regarding the company's lead program, IMU-838, at the GI Inflammatory Diseases Summit (GIIDS) in Boston. The presentation, entitled, "IMU-838 in Clinical Phase 2 – New Selective Oral Treatment for IBD," will take place at 3:30 pm ET. IMU-838, currently in phase 2 clinical development for the treatment of ulcerative colitis (UC) and relapsing-remitting multiple sclerosis (RRMS), 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).

Highlights of Dr. Kohlhof's presentation will include these newly released findings:

- Preclinical data shows that IMU-838 appears selective towards those T cells producing high amounts of the pro-inflammatory cytokines, IFN $\gamma$  and IL-17.
- In mixed lymphocyte reaction assays in combination with the anti-TNF $\alpha$  antibody infliximab, IMU-838 was shown to act synergistically with regard to the induction of regulatory macrophages, important for the efficacy of such anti-TNF $\alpha$  antibodies.
- In addition to previous inflammatory bowel disease animal models, IMU-838 also demonstrated activity in a therapeutic animal colitis model with improvement of diarrhea score and significant TNF $\alpha$  reduction in the gut.

Dr. Kohlhof's presentation will also highlight the following advantages of IMU-838:

- As a DHODH intrinsic effect, IMU-838 is, in-vitro, able to inhibit reactivation of several viruses. Other immunosuppressive drugs used for the treatment of inflammatory bowel disease and multiple sclerosis are known to have virus reactivation as one of the clinically significant adverse drug effects.
- In comparison to other DHODH inhibitors, IMU-838 does not target any kinases and does not exhibit an increased rate of side effects, such as diarrhea, alopecia, or neutropenia. Notably, these attributes do not seem to be a class effect of DHODH inhibitors. No signal for an increased rate of liver enzyme elevation has been seen, to date, in the clinical trials. With a terminal half-life of 30 hours in blood plasma, IMU-838 is well suited for convenient, once daily oral dosing, reaching steady state exposure after 5-7 days of treatment and washing out within 10-14 days in most patients.
- In a phase 2a clinical study in steroid dependent UC and Crohn's disease patients, the active moiety of IMU-838 (vidofludimus) has shown activity in the ability to wean off steroids, with a total response rate of 88.5%.

"The data we have generated thus far for IMU-838 remains encouraging and supports our thesis that it may represent a potential new, best-in-class, oral treatment for patients with UC, RRMS and other underserved immunologic diseases," stated Dr. Kohlhof. "In particular, we are pleased to report previously unpublished data confirming the drug's activity in key preclinical models, as well as evidence of its potency on high producer T cells and ability to work in a symbiotic fashion with today's anti-TNF $\alpha$  antibodies such as infliximab."

#### **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.

#### **About Immunic, Inc.**

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including ulcerative colitis, Crohn's disease, relapsing-remitting multiple sclerosis, and psoriasis. The company is developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of ROR $\gamma$ t; and IMU-856 targets the restoration of the intestinal barrier function. Immunic's lead development program, IMU-838, is in phase 2 clinical development for ulcerative colitis and relapsing-remitting multiple sclerosis, with an additional phase 2 trial in Crohn's disease planned for 2019. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is planned to start at the Mayo Clinic. For further information, please visit: [www.immunic-therapeutics.com](http://www.immunic-therapeutics.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, IMU-935 and IMU-856 to safely and effectively target diseases; preclinical and clinical data for IMU-838; the timing of future clinical trials; 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, 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. 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.

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<https://ir.imux.com/2019-06-24-Immunic-Inc-to-Present-Previously-Unpublished-Data-Regarding-Lead-Program-IMU-838-at-the-GI-Inflammatory-Diseases-Summit-in-Boston>