First patient with ulcerative colitis entered the 'CALDOSE-1' trial with Immunic's oral investigational drug IMU-838, a best-in-class DHODH inhibitor

Multiple sites have already been initiated in the US and first patient has been enrolled

Several approvals for the 'CALDOSE-1' study from regulatory agencies have already been granted in European countries as well and Immunic expects patients to be enrolled in more than 80 sites in 10 countries

CALDOSE-1 trial (NCT03341962, EudraCT No: 2017-003703-22) will evaluate the activity of IMU-838 in induction of remission in patients with active ulcerative colitis.

Planegg-Martinsried, Germany, **April 26th, 2018** – Immunic AG (Immunic Therapeutics), a clinical stage biotech company in Martinsried near Munich, Germany, today announced that it has started the clinical Phase 2 trial (CALDOSE-1) in patients with ulcerative colitis (UC). First active sites are located in the US and the first patient has been enrolled into the 'CALDOSE-1' study.

This clinical trial in patients with ulcerative colitis is the first Phase 2 trial as part of the global development plan with the goal to demonstrate clinical efficacy of IMU-838 for inflammatory bowel disease (IBD). The trial is planned to include patients from 10 countries including US and European countries. It is planned to include approximately 200 patients from more than 80 clinical sites (https://clinicaltrials.gov/ct2/show/NCT03341962).

"After preparing this trial for many months in collaboration with international experts, we are very excited that the trial has now entered its enrollment phase", says Dr. Andreas Muehler, Chief Medical Officer of Immunic, "Demonstration of clinical efficacy and confirmation of the most appropriate dose brings IMU-838 a step closer to be available for patients with active ulcerative colitis in the future, something that the Immunic team hopes will potentially give these patients better therapeutic options for oral therapies that are more compatible with their daily life and work activities."

Dr. Daniel Vitt, CEO of Immunic adds, "The commencement of this large international trial is the important first step in a series of planned Phase 2 studies with the goal to position IMU-838 as the best oral choice for treatment of IBD and other chronic inflammatory and autoimmune diseases. Achieving clinical proof of concept of IMU-838 in patients with ulcerative colitis is one of the major near-term goals for Immunic."

Immunic initiated this first Phase 2 trial of IMU-838 (CALDOSE-1) after having received green light for its IND from the US-FDA in early January of 2018. The trial will investigate the efficacy of multiple doses of IMU-838 or placebo to induce symptomatic and endoscopic remission in patients with active UC, and monitor the ability of IMU-838 to maintain remission. The trial will be carried out as trans-Atlantic trial in the US and Europe in a total of 10 countries. An interim analysis is planned to be conducted after an approximate 60 patients have concluded the induction phase of this trial. In addition, Immunic is preparing a second Phase 2 trial (CALDOSE-2) in patients with Crohn's disease.

– Press release ends –

Further Information

About Immunic AG

Immunic is the specialist for selective oral drugs in immunology. As a clinical stage company, Immunic delivers clinical proof-of-concept for best-in-class therapies of Th1 and Th17 mediated chronic inflammatory diseases. The company's two development programs include orally available, small molecule inhibitors of DHODH (IMU-838 program) and inverse agonists of RORγt (IMU-366 program) relevant to diseases such as ulcerative colitis, Crohn's disease and psoriasis. The final aim is to develop these oral drug candidates to clinical proof of concept. The company was founded in 2016 with headquarters in Planegg-Martinsried near Munich, Germany, and is privately held and supported by several renowned sector investors.

About IMU-838

IMU-838 is an orally available, next-generation selective immune modulator. IMU-838 targets intracellular metabolism of activated immune cells by inhibition of the enzyme “dihydroorotate dehydrogenase” (DHODH). With this mode of action, IMU-838 is a potent inhibitor of Th17 and Th1 subsets of T-lymphocytes as well as activated B-cells without potentially increasing the risk of viral infections. IMU-838 was successfully tested for PK and safety in two Phase 1 studies. IMU-838 is currently tested in a clinical Phase 2 trial (CALDOSE-1) in patients with ulcerative colitis. Immunic is planning to start a further Phase 2 clinical trial in Crohn’s disease (CD).

Further information: www.immunic-therapeutics.com

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