FDA approves IND for Immunic Therapeutics' IMU-838 to proceed with Phase 2 study in ulcerative colitis

- FDA has granted IND approval for Immunic's oral investigational drug IMU-838
- Active IND allows Immunic to proceed with Phase 2 clinical trial (CALDOSE-1)
- Patients with active ulcerative colitis will be treated following randomization to multiple doses of IMU-838 or placebo

Planegg-Martinsried, Germany, **January 11th, 2017** – Immunic AG (Immunic Therapeutics), a clinical stage biotech company in Martinsried near Munich, Germany, today announced that it has received communication from the US Food and Drug Administration (FDA) for the Investigational New Drug (IND) application for its oral investigational drug IMU-838. This will allow Immunic to initiate the Phase 2 trial in patients with ulcerative colitis (UC).

This IND approval marks a significant milestone for Immunic. This clinical trial (CALDOSE-1), 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).

'We are very pleased receiving the swift IND approval from the FDA. This will accelerate our development of IMU-838 as a promising candidate for therapies of chronic inflammatory bowel diseases', says Dr. Daniel Vitt, CEO of Immunic, 'This step underlines that we're progressing well on our way to deliver a phase III ready product in due time.'

Dr. Andreas Mühler, Chief Medical Officer of Immunic adds, 'The FDA's approval of our IND application is a big milestone in developing our selective immune modulator IMU-838 into a globally available drug for the treatment of IBD,' he further added, 'This IND approval is a validation of Immunic's development strategy and an important step for commencing this large international trial.'

The US IND enables Immunic to initiate the first Phase 2 trial of IMU-838 (CALDOSE-1) which will investigate the efficacy of multiple doses of IMU-838 or placebo to induce symptomatic and endoscopic remission in patients with active UC. The study is planned to start soon and will be carried out in the US and Europe. In addition, Immunic is preparing a second Phase 2 trial (CALDOSE-2), in patients with Crohn's disease which is planned to commence after receiving interim data from the UC trial.

– 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. Immunic is planning to start Phase 2 clinical trials in the two main inflammatory bowel disease (IBD) indications ulcerative colitis (UC) and Crohn's disease (CD). The UC trial is planned to commence in early 2018.

Further information: www.immunic-therapeutics.com

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