Immunic Therapeutics Successfully Completes two Phase 1 Studies for IMU-838

- Two phase 1 studies for IMU-838 in healthy volunteers have been completed
- Compound was safe and well tolerated at all doses tested
- New dosing regimen was determined allowing safe administration of higher doses

Planegg-Martinsried, Germany, **December 12th, 2017** – Immunic AG (Immunic Therapeutics), a clinical stage biotech company in Martinsried near Munich, Germany, today announced that it has completed its clinical phase 1 program for IMU-838 exploring its pharmacokinetic properties, as well as its safety and tolerability. The program comprised a single ascending dose (SAD) and multiple ascending dose (MAD) study in healthy volunteers. In the completed phase 1 trials, IMU-838 was well tolerated at all tested dose levels. IMU-838 also demonstrated a favorable pharmacokinetic profile supporting once daily oral dosing of a tablet formulation of the drug. Immunic was also able to confirm that dosing under fed conditions does not negatively influence exposure of IMU-838 as compared to fasted conditions, allowing increased flexibility for future dosing regimens.

'We are very pleased with the results in our phase 1 trials. This will position IMU-838 as a promising candidate for well tolerated once daily dosing for therapies of chronic inflammatory and autoimmune diseases', says Dr. Andreas Mühler, Chief Medical Officer of Immunic, 'We are currently preparing for continued clinical trials in patients with inflammatory bowel diseases and exploring options for additional uses of IMU-838.'

Dr. Daniel Vitt, CEO of Immunic adds, 'The excellent safety data obtained in the two completed phase 1 clinical trials will accelerate our upcoming phase 2b trials in ulcerative colitis and Crohn's disease.' He further added, 'We are certainly proud to deliver this data within the proposed timelines and are progressing well on our way to deliver a phase III ready product in three years from now.'

In the trials, no dose limiting toxicities have been observed. All together 5 dose levels have been explored with respect to their safety ranging from 10 mg single dose to 50 mg daily oral dosing over a period of up to 14 days.

– 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 increase of 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 2b clinical trials in the two inflammatory bowel disease (IBD) indications ulcerative colitis (UC) and Crohn's disease (CD). The UC trial is planned to start in early 2018.

Further information: www.immuic-therapeutics.com

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