

GB004

Name: GB004

Synonyms: GB 004

Indication: Inflammatory Bowel Disease

Company: Gossamer Bio

GB004 HIF-1a stabilizer – Inflammatory Bowel Disease. Phase 1 ongoing.

is a novel, gut-targeted, oral small molecule in development for the treatment of inflammatory bowel disease, or IBD, including ulcerative colitis, or UC, and Crohn's disease, or CD. GB004 stabilizes hypoxia inducible factor-1a, or HIF-1a, through the inhibition of prolyl hydroxylase domain proteins, or PHDs, key enzymes involved in HIF degradation. Preclinical data from animal models of IBD demonstrated that HIF-1a stabilization restores intestinal epithelial barrier integrity and function and results in immunomodulatory effects that we believe are important in reducing inflammation and enhancing mucosal healing in IBD patients. We have completed a Phase 1 single-ascending-dose, or SAD, study in healthy volunteers and are dosing healthy volunteers in a Phase 1 multiple-ascending-dose, or MAD, study. We plan to pursue clinical development in both UC and CD patients and, following submission of an Investigational New Drug, or IND, application with the FDA, initiate a Phase 1b clinical trial in UC in the first half of 2019. We also plan to initiate a Phase 2 clinical trial in UC in the first half of 2020. We retain worldwide rights to GB004.