



Avaxia Biologics Announces First Patient Dosed in Phase 1b Study of AVX-470 in Ulcerative Colitis

LEXINGTON, Mass. – Feb. 25, 2013 – [Avaxia Biologics, Inc.](#), a clinical-stage biopharmaceutical company developing gut-targeted therapeutics, announced today that the first patient has been dosed in a Phase 1b clinical study of AVX-470, an oral anti-TNF antibody, for the treatment of ulcerative colitis. Ulcerative colitis is a serious disease characterized by chronic inflammation in the colon. This chronic inflammation causes numerous debilitating effects for patients and often results in colon removal for patients with uncontrolled disease.

This first-in-human study is designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of multiple ascending doses of AVX-470 in ulcerative colitis patients. Avaxia plans to enroll 24 patients in three dose groups, with six patients receiving the study drug and two patients receiving placebo in each dose group for a period of 28 days. The study also has exploratory endpoints for clinical efficacy and inflammation biomarkers. Avaxia is enrolling patients in the U.S., Canada and Europe and expects to have top-line results by the end of this year.

“Avaxia is thrilled to take this first step in the clinical development of AVX-470. Patients need better treatments for inflammatory bowel disease (IBD), including ulcerative colitis,” said Barbara S. Fox, CEO of Avaxia. “Although currently marketed injectable anti-TNF therapeutics are effective in IBD, they also come with potentially dangerous side effects due to generalized immunosuppression. We hope that AVX-470 will provide patients with an important new treatment option. As a gut-targeted therapeutic, AVX-470 is an oral anti-TNF antibody that is designed to stay in the gut, suppressing inflammation only where the disease occurs. We believe that this approach has the potential to reduce or eliminate the side effects associated with other anti-TNF therapeutics while retaining their efficacy in IBD.”

About Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a serious disease that has a major societal impact. IBD refers to two related but different diseases: ulcerative colitis and Crohn's disease. More than 2.5 million people are afflicted with IBD. These diseases cause chronic inflammation of the intestinal tract, which leads to a variety of debilitating symptoms resulting in a significant reduction in quality of life and the risk of life-threatening complications and diseases, including cancer. A chronic autoimmune disease, IBD is characterized by periods of active disease alternating with periods of disease control (remission). The

annual worldwide market for IBD medications exceeds \$4.5 billion, approximately \$2.5 billion of which represents sales of currently marketed anti-TNF antibodies.

About AVX-470

AVX-470 is a gut-targeted anti-TNF antibody that has the potential to be a transformative first-line therapy for inflammatory bowel disease (IBD). Currently marketed anti-TNF antibodies have proven highly effective for IBD. These antibodies are injected and then distribute throughout the body, where they suppress the immune system to reduce inflammation. This untargeted suppression of the immune system may cause serious side effects, such as the reactivation of tuberculosis. Because of these side effects, anti-TNF antibodies are most often used only as a second- or third-line therapy, despite evidence that earlier use could improve patient outcomes. In contrast, AVX-470 is an orally administered anti-TNF antibody that targets its immunosuppressive effects specifically to the gastrointestinal tract to minimize the potential for side effects in other parts of the body. This potential to confine immunosuppression to where the disease occurs differentiates AVX-470 from other anti-TNF antibodies and offers the possibility for AVX-470 to become a first-line therapy that transforms the treatment of IBD.

About Avaxia Biologics

Avaxia is a leader in the growing field of gut-targeted therapeutics — orally administered, minimally absorbed drugs that are designed to act locally in the gastrointestinal tract. Avaxia's lead clinical candidate, AVX-470, is an oral anti-TNF antibody for inflammatory bowel disease. This transformative product offers potentially improved safety and efficacy over existing anti-TNF therapies by focusing immune suppression only where needed in the diseased gut. Avaxia is using its proprietary oral antibody platform to develop gut-targeted therapeutics to address many other serious diseases such as type 2 diabetes, celiac disease, GI acute radiation syndrome and oral mucositis. www.avaxiabiologics.com

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