



Avaxia Biologics Awarded Patent with Broad Coverage over Oral Anti-TNF Antibodies for Inflammatory Bowel Disease

LEXINGTON, Mass. – February 11, 2014 – [Avaxia Biologics, Inc.](#), a clinical-stage biopharmaceutical company developing gut-targeted therapeutics, announced today that the company was awarded U.S. Patent No. 8,647,626, entitled “Compositions Comprising TNF-specific Antibodies for Oral Delivery.”

The patent covers milk-derived anti-TNF antibodies that are orally administered within a broad dose range for the treatment of inflammatory bowel disease (IBD). The claims also cover use of these antibodies for the treatment of IBD. Importantly, the patent broadly covers Avaxia’s lead product, AVX-470, which recently completed a Phase 1b clinical trial in ulcerative colitis.

Barbara S. Fox, Ph.D., Chief Executive Officer of Avaxia, said, “This patent award is an important milestone for our company. This is the first in a series of patents that Avaxia expects to receive on the composition of our lead clinical-stage candidate, AVX-470. Avaxia will continue to build on its strong intellectual property portfolio in the gut-targeted antibody therapeutics field.”

About Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is a serious disease affecting more than 2.5 million people. IBD refers to two related but different diseases: ulcerative colitis and Crohn's disease. These diseases cause chronic inflammation of the intestinal tract, resulting in a significant reduction in quality of life and the risk of life-threatening complications and diseases, including cancer. As a chronic autoimmune disease, IBD is characterized by periods of active disease that alternate 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 the first gut-targeted anti-TNF antibody in clinical development. The lead indication is inflammatory bowel disease (IBD). Currently marketed anti-TNF drugs are highly effective for the treatment of IBD. However, despite their success, these drugs have two significant drawbacks. One is that they must be injected, whereas patients prefer oral medications. More importantly, they cause rare but serious side effects, such as risk of serious infection, because they dampen the immune system throughout the body, not just in the intestines where the disease occurs. As a result, these drugs are used mostly as a second- or third-line therapy, despite evidence that earlier use may improve patient outcomes. In contrast, AVX-470 is an orally administered antibody therapeutic that targets the gut,

potentially improving safety and efficacy over existing anti-TNF therapies. Avaxia believes that AVX-470 has the potential 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. AVX-470 offers potentially improved safety and efficacy over existing anti-TNF therapies by focusing immune suppression only where needed in the diseased gut. Avaxia plans to use its gut-targeted antibody platform to develop therapeutics to address many other serious diseases such as celiac disease, metabolic disease, and GI acute radiation syndrome. www.avaxiabiologics.com

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