Avaxia Biologics Receives IND Clearance from FDA to Initiate Clinical Program to Evaluate AVX-470 as Therapy for Ulcerative Colitis

LEXINGTON, Mass. – November 27, 2012 – Avaxia Biologics, Inc., a privately-held biotechnology company developing oral antibody drugs that act locally within the digestive tract, announced today that the US Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for AVX-470 for the treatment of ulcerative colitis. AVX-470 is an anti-TNF polyclonal antibody and is the first clinical candidate to come from Avaxia's oral antibody platform. The Company expects to initiate a Phase 1b clinical trial of AVX-470 in patients with active ulcerative colitis in the near term.

"Clearance of the IND allows us to advance AVX-470 into clinical development, which furthers our goal of providing patients afflicted with inflammatory bowel disease with a promising new treatment option," stated Barbara S. Fox, CEO of Avaxia. "Because AVX-470 is delivered directly to the GI tract, it has a lower potential for systemic immunosuppression than injectable anti-TNF therapies while potentially retaining the proven benefits of anti-TNF antibody therapy for inflammatory bowel disease."

About AVX-470

Avaxia has created a technology platform and a broad patent portfolio around orally administered antibodies that affect targets in the digestive tract. AVX-470 is the first product from Avaxia's platform to reach clinical development. AVX-470 is a bovine polyclonal antibody to tumor necrosis factor (TNF), a pro-inflammatory protein that has been implicated in inflammatory bowel disease (IBD), including ulcerative colitis and Crohn's disease. Today, injectable anti-TNF antibodies are used as an effective treatment for many IBD patients, with about $2.5 billion in sales in 2011. However, as injected drugs, they suppress the immune system throughout the body, not just locally in the gastrointestinal (GI) tract, where the disease occurs. The potentially serious side effects resulting from this systemic immunosuppression warrant a "black box" warning label.

AVX-470 is administered orally, rather than injected, and is intended to remain in the GI tract where the inflammation occurs, rather than distributing throughout the body. The goal is to have a safer anti-TNF drug for IBD. This goal may be attainable because AVX-470, unlike all currently marketed antibody therapies, resists digestion and is therefore suitable for oral administration and direct delivery to the GI tract. The unique stability of AVX-470 comes from its source—the colostrum (early milk) of cows immunized with TNF. Bovine colostral antibodies are naturally resistant to digestion.

About Avaxia Biologics

Avaxia is developing orally administered antibody therapeutics that act locally within the digestive tract. Our lead product is AVX-470, an oral antibody against tumor necrosis factor for inflammatory bowel

disease. Avaxia also has programs in GI acute radiation syndrome, celiac disease, oral mucositis and diabetes.