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**FOR IMMEDIATE RELEASE**

## **UPSHER-SMITH ANNOUNCES START OF FIRST IN HUMAN CLINICAL TRIAL IN ONCOLOGY WITH NOVEL CXCR4 ANTAGONIST USL311**

Maple Grove, MN – May 16, 2016 – [Upsher-Smith Laboratories, Inc.](http://www.upsher-smith.com) (Upsher-Smith) today announced that it has commenced the first clinical study of its novel small molecule CXCR4 antagonist USL311 in patients with advanced solid tumors. Upsher-Smith has obtained Orphan Drug Designation for USL311 in the US for the treatment of Glioblastoma Multiforme (GBM).

The multicenter, open-label study is designed to explore the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of USL311 alone and in combination with lomustine. The trial will be conducted at sites in the US and Spain. The first phase of the study will be conducted in patients with advanced solid tumors with a planned second phase to be conducted in patients with relapsed/recurrent GBM. Further details of the trial are posted on [clinicaltrials.gov](http://clinicaltrials.gov) under identifier [NCT02765165](https://clinicaltrials.gov/ct2/show/study/NCT02765165).

William Pullman, MB, BS, BMedSc, PhD, FRACP, Chief Scientific Officer and Biotech Research Institute Division President, Upsher-Smith commented, “There is increasing evidence for, and interest in the blockade of CXCR4 receptors as a therapeutic strategy in oncology, particularly the potential for combining with immuno-oncology agents. USL311 is a novel molecule to target CXCR4, and I am pleased that our development team has achieved this important milestone of entry into the clinic.”

### **About USL311**

USL311 is a potent and selective small molecule antagonist of the chemokine receptor 4 (CXCR4), a G-protein coupled receptor that is activated by stromal-derived-factor-1 (SDF-1). CXCR4 is overexpressed in many tumors. USL311 was discovered by the team based at Proximagen, Upsher-Smith’s wholly-owned research subsidiary in Cambridge, U.K., and has been moved into development by Upsher-Smith’s Biotech Research Institute, the division of Upsher-Smith focused on development of new chemical entities.

## **About Upsher-Smith**

Upsher-Smith Laboratories, Inc., founded in 1919, is a growing, fully integrated pharmaceutical company dedicated to its mission of delivering high-value, high-quality therapies and solutions which measurably improve individuals' lives. As a family-owned pharmaceutical company, we are able to adapt and thrive in a dynamic healthcare environment. Our world is constantly evolving, and we are continually adapting to the ever-changing needs of patients, physicians, pharmacists, and healthcare organizations. Where there is a need, we will work to deliver solutions that simplify access to treatment, deliver better health outcomes, and enhance life. Upsher-Smith has a particular focus on developing therapies for people living with central nervous system (CNS) conditions, such as seizure disorders. For more information, visit [www.upsher-smith.com](http://www.upsher-smith.com).

## **About Proximagen**

Since 2012, Proximagen has been the drug discovery and development subsidiary of Upsher-Smith Laboratories, Inc. Located in Cambridge, U.K., Proximagen focuses on small molecule drug discovery, selecting innovative drug targets to build a pipeline of programs with the potential to provide significant advances in the treatment of central nervous system (CNS) disorders, pain and inflammation. For more information, visit [www.proximagen.com](http://www.proximagen.com).

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