

Studies Completed by Accium BioSciences

Select List

Preclinical Studies

Investigation of the pharmacokinetic and ADME properties of a candidate drug in CD-1 mice Distribution and uptake of ¹⁴C-X into vertebral and cortical bone of rats

Distribution of dual-labeled ¹⁴C-¹⁸⁷Re-EC-DG in SCID Mice

A non-GLP Single Dose Pharmacokinetic and Biodistribution Study of ¹⁴C-Labeled Monoclonal Antibody X in Cynomolgus Monkeys

Penetration and Biotransformation of ¹⁴C-Carbamazepine and ¹⁴C-Phenytoin in a Dynamic *in vitro* Blood-Brain Barrier Model Measured by Accelerator Mass Spectrometry (internal Accium study)

Distribution of ¹⁴C-temozolomide in nude mice bearing U87 glioblastoma xenografts (internal Accium study)

Co-administration of ¹⁴C-Paclitaxel and ¹⁴C-5-Fluorourcil and measurement of tumor uptake in xenograft mice bearing HT-29 human colon cancer or MCF-7 human breast cancer cells (internal Accium study).

Plasma pharmacokinetics in male dogs after oral gavage administration of [¹⁴C]-X

Clinical Studies

Indication

An open-label, single center study to determine the absorption, distribution, metabolism, and excretion (ADME) of X following a single subcutaneous injection of [¹⁴C]-X (600 μ g) in healthy subjects

Acromegaly and gastroenteropancreatic tumors

Two-dose, fixed-sequence pharmacokinetic study of intranasal and intravenous oglufanide disodium (IM12-10) in healthy volunteers

Treatment of infectious diseases

A Phase 1, Open-Label, Mass Balance and Excretion Study of [¹⁴C]-X Following Oral Administration in Healthy Male Subjects

Improves pain sensitivity

Total ¹⁴C measurements in human fat tissue biopsies after administration of X to healthy female volunteers

Refractory Endometriosis

Total radioactivity analysis in blood, urine, and feces samples collected from patients with advanced cancer and dosed orally with [¹⁴C]-X

Solid tumor

Absorption, Metabolism, Excretion and the Determination of Absolute Bioavailability of X in Healthy Male Subjects

Nausea

A mass balance study to investigate the absorption, excretion and metabolism of a single subcutaneous dose of radiolabeled [¹⁴C]-X in healthy young women

Contraceptive agent

An Open-Label, Single-Dose Study of the Mass Balance and Metabolic Disposition of Orally Administered [¹⁴C]-X in Healthy Male Subjects

Breast cancer

A Phase 1, Open-Label, Mass Balance and Excretion Study of [¹⁴C]-X Following Oral Administration in Healthy Male Subjects

Rheumatoid arthritis

Pharmacokinetics and Metabolism of [¹⁴C]-X in Healthy Male Subjects

Non small cell lung cancer

Absorption, Metabolism, Excretion and the Determination of Absolute Bioavailability of X in Health Adult Male Subjects

Asthma

Absorption, Metabolism, Excretion and the Determination of Absolute Bioavailability of X in Health Adult Male Subjects

Hepatitis C

Pharmacokinetics and metabolism of [¹⁴C]-X in healthy male subjects

Alzheimer

A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Sequential Dose Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of X in Healthy Male Subjects

Inflammatory diseases, including asthma and allergic rhinitis

A Phase 1, Open-Label, Mass Balance and Excretion Study of [¹⁴C]-X Following Oral Administration in Healthy Male Subjects

Secondary prevention of atherothrombotic events in patients with acute coronary syndrome

Analysis of Microdosing Portion of a Phase 1, Randomized, Double-Blind, Placebo-Controlled, Sequential Dose Escalation Study to Investigate the Safety, Pharmacokinetics, and Pharmacodynamics of X in Healthy Male Subjects

Inflammatory diseases, including asthma and allergic rhinitis

A Phase 1, Single and Multiple Dose Study to Evaluate the Safety and Pharmacokinetics of X in Healthy Male Subjects

Inflammatory diseases, including asthma and allergic rhinitis

Phase 1, Open-Label, Mass Balance and Excretion Study of [¹⁴C]-X Following Oral Administration in Healthy Male Subjects

Gastroesophageal reflux disease (GERD)

Analysis of plasma fractions, derived from healthy men following a single oral administration of 25 mg free base (3.4 MBq) of [¹⁴C]-X

Bipolar disorder

Placebo-Controlled, Ascending Single-Dose Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of X in Healthy Subjects

Accelerated Intimal Hyperplasia

An Exploratory Early Phase 1, Randomized, Double-Blind, Placebo-Controlled, Sequential-Panel, Ascending Single-Dose Study of X to Evaluate Its Pharmacokinetic and Safety Profile in Healthy Male Subjects

Hypertension

Determination of the absolute bioavailability and characterization of the excretion profile of X using a ¹⁴C-microdosing technique in healthy, adult, male volunteers

Acute coronary syndrome chest pain

Phase 1 Study of the Metabolism and Distribution of a Subpharmacologic Dose of Lightly-labeled ¹⁴C-Temozolomide in Newly Diagnosed Glioblastoma Patients

Glioblastoma multiforme
(internal Accium study)



Accium BioSciences
measure more. learn more.

550 17th Avenue, Suite 550, Seattle, WA 98122 USA
(206) 281-3915 info@acciumbio.com www.acciumbio.com
