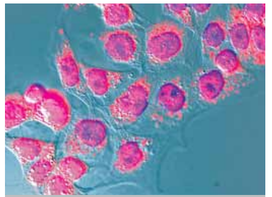
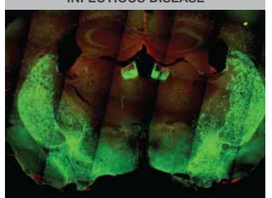
From *Idea to IND*®

Basic Research



ONCOLOGY

INFECTIOUS DISEASE



NEUROSCIENCE

IMMUNOLOGY & INFLAMMATION

Drug Discovery

Target Discovery, Validation & Assay Development

- Cell-Based Assays
- Mechanism-Based Animal Models
- Design and Validation of Biochemical and Cellular Screens
- Proteomics
- Expression Analysis
- Imaging and Analysis

Lead Identification & Optimization

- Screening Hits-to-Leads
- Medicinal Chemistry
- Structure Activity Relationships (SAR)
- Computational Chemistry and Structure-Based Design
- Mechanism-of-Action Studies

Pharmacology, Efficacy & Predictive ADMET

- *In Vitro* and *In Vivo* Efficacy
- Custom Animal Models
- Predictive ADMET Assays
- Radiolabeled Synthesis
- Synthesis and Scale-Up
- Preformulation

Preclinical Development

Select Development Candidates

Safety, Drug Metabolism & Pharmacokinetics

- Range-Finding Toxicity
- Pharmacokinetics
  - Bioavailability and ADME
  - Biodistribution
- GLP Toxicology
  - Mammalian Toxicology
  - Safety Pharmacology
  - Genetic Toxicology
  - Reproductive Toxicology
  - Immunotoxicology
  - Immunogenicity
  - Clinical Laboratory Services
  - Toxicogenomics and Biomarkers

Chemistry, Manufacturing & Controls, Regulatory Support

- Formulation Development
- Analytical Method Development and Validation
- GMP Clinical Trial Materials (Formulated Drug Product)
- Stability and Release Testing
- Project Management
- Quality Assurance
- IND Preparation and Submission

SRI Drug Discovery & Preclinical Development Capabilities

Clinical Trials

File IND at FDA

Phase I	Phase II	Phase III
Determine safety, tolerability, PK, PD, and dose-ranging in 20 to 80 healthy volunteers	Evaluate effectiveness, look for side effects in 20 to 300 patient volunteers	Confirm effectiveness, monitor adverse reactions from long-term use in 300 to 3,000 patients
SR13668 Anticancer (Phase 0)	**SR16234 (TAS-108)** Breast Cancer	**Tirapazamine** Head and Neck Cancer

Approval

File NDA at FDA for Approval to Market

Phase IV

FDA-required post-marketing surveillance and testing

Marketed SRI Drugs

- **Bexarotene** Cutaneous T-Cell Lymphoma
- **Halofantrine** Antimalarial
- **Pralatrexate** Peripheral T-Cell Lymphoma
- **Vidarabine** Antiviral

SRI Clinical Development Pipeline

IMAGE SOURCES **Infectious Disease:** Rocky Mountain Laboratories, NIAID, NIH ■ **Immunology and Inflammation:** Dr. Triche. National Cancer Institute, Sep 20, 1976

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