# RADSHIELD™

**Clinical-Stage Pharma**

*First-in-Class Oral Therapy for Acute Radiation Syndrome*

**THE SCIENCE**

## How RadShield Works.

### The GI-ARS Crisis

Acute Radiation Syndrome (ARS) occurs when whole-body radiation exposure exceeds approximately 1 Gy (Gray). Above 6-7 Gy, the primary cause of death is **Gastrointestinal ARS (GI-ARS)** — a cascade of intestinal barrier breakdown, toxic translocation, sepsis, and multi-organ failure. The window for intervention is narrow: 24 hours from exposure to achieve maximum protective effect.

**Current medical countermeasures** address hematopoietic (bone marrow) ARS. GI-ARS remains without approved therapy. RadShield™ fills this gap.

### The YK-4-250 Mechanism

**RadShield™ (YK-4-250)** is a patented Diindolyl methane (DIM) analog that operates through three complementary mechanisms:

• **Intestinal Stem Cell Regeneration:** Activates crypt stem cell proliferation, accelerating repair of radiation-damaged intestinal epithelium.

• **Anti-Inflammatory Suppression:** Blocks pro-inflammatory cytokine cascades (IL-1β, TNF-α, IL-6) that drive barrier failure.

• **Oxidative Stress Mitigation:** Antioxidant activity reduces reactive oxygen species (ROS) in intestinal tissue.

Result: **Intestinal barrier integrity is preserved. Bacterial translocation is prevented. Lethal cascade is halted.**

## Clinical Validation

Preclinical dosimetry studies conducted at the Armed Forces Radiobiology Research Institute (AFRRI) and Georgetown University have demonstrated:

• **30%+ Improvement in Survival** at GI-ARS-lethal dose levels (8–13 Gy)

• **Oral Administration:** Dosed within 24 hours; easy to stockpile and deploy

• **Favorable Toxicity Profile:** No dose-limiting toxicities in pharmacology studies

• **Animal Rule Pathway:** FDA pre-IND meeting completed; path to approval mapped without human trials

## Intellectual Property

**Georgetown University Exclusive License Agreement** (No. 2022-0493, executed June 29, 2022) grants Trocar Pharma exclusive global rights to RadShield™ and the YK-4-250 platform. Trocar holds four U.S. patents covering:

- **Compound composition and synthesis**
- **Dose optimization for GI-ARS and beyond**
- **Formulation and delivery**
- **Combination therapy approaches**

**Patent protection extends 15+ years from filing.** No generics threat in the strategic stockpile era.

## Regulatory Pathway

Trocar is targeting FDA approval via the **Animal Rule (21 CFR 314.80)** for radiation countermeasures — a pathway specifically designed for threats that cannot be ethically studied in humans.

- **Pre-IND Meeting (Complete):** FDA alignment on efficacy, dosimetry, and approval pathway

- **IND Application (Planned):** 30 days to clearance; Phase 1 and CMC studies concurrent

- **BLA Submission (Timeline: 36–48 months):** Supported by AFRRI data, animal studies, and CMC manufacturing validation

- **Strategic Stockpile Pre-positioning (Concurrent):** DoD and SNS procurement discussions active; licensing deals likely upon IND filing

**No human clinical trials required. FDA pathway is paved. First approval in the category is first-mover advantage.**

Trocar Pharma, Inc. | RadShield™ (YK-4-250)
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