

Selenium Modulation



The Opportunity

In pre-clinical model systems, researchers and clinicians at Roswell Park Cancer Institute have demonstrated substantial therapeutic synergy between varieties of chemotherapeutic agents and radiation with selenium-based compounds such as selenomethionine (SLM) and methylselenocysteine (MSC).

Therapeutic and mechanistic preclinical data have provided the scientific rationale for design implementation and evaluation of Phase 1 clinical trials to define the optimal selenium dose in patients -- alone and in combination with chemotherapy.

The data obtained in Phase 1 clinical trials have now been applied to design Phase 2 clinical trials of selenium in combination with chemoradiotherapy in a variety of solid tumor malignancies.

Although the major focus at this time is with SLM, which is currently approved for clinical trials, expectations in the near future are that other selenium-containing compounds with more favorable pharmacological properties, such as MSC, will be clinically implemented.

Benefits

In the treatment of human tumor models (two colon; two head & neck), when added to IRINOTECAN, SLM:

- **Significantly increases complete and partial tumor regressions and decreases host toxicity** -- even when IRINOTECAN is administered at double and triple the reported maximum tolerated dose.
- **Potentiates antitumor efficacy of other anticancer drugs** -- including cisplatin, oxaliplatin, taxol, doxorubicin, and cyclophosphamide against these human tumor models.
- **Protects against hematological and drug-induced organ toxicities** (intestine, kidney, bladder, skin).

The effects of Roswell's selenium compounds are selective and *not drug-specific*.

Proper treatment with selenium compounds has demonstrated preclinical effectiveness in protecting against toxicity *and* resistance induced by common chemotherapeutics.

Further confirmation was observed in a retrospective Non-Hodgkin's Lymphoma study, in which selenium-modulated chemotherapy reduced chemotoxicity, increased chemotherapy intensity, and improved overall outcomes.

Intellectual Property

The technology is protected by an issued patent, a non-US equivalent, and several pending patent applications including:

- Patent 6,939,893: "Method of reducing toxicity of anticancer agents" (also published as 2004/0110838 and 2004/0180099);
- Application: "Method of augmenting the antitumor activity of anticancer agents" (also published as 2006/0258697, 2005/0197399, and 20050026852);
- Application: "Method of reducing alopecia and bladder toxicity of cyclophosphamide";
- Application: "Optimizing cancer therapeutic strategies through tumor vessel maturation caused by selenium."

The Principal Investigator, Dr. Youcef M. Rustum, has more than 30 years of experience in cancer research. Dr. Rustum is currently the Senior Vice President for Science Administration and Chairman of the Department of Cancer Biology at Roswell Park Cancer Institute.

Contact Information

First Principals, Inc., a full-service technology transfer firm, is seeking qualified partners interested in collaborating, developing, and licensing the commercial applications of this technology.

For more information, contact:

Mike Allan, Vice President
FIRST PRINCIPALS, INC.
Tel: 216-881-8526
Web: www.firstprincipals.com
Email: mfallan@firstprincipals.com

Roswell Park Cancer Institute (RPCI), founded in 1898, is the nation's first cancer research, treatment and education center. RPCI is a member of the prestigious National Comprehensive Cancer Network, an alliance of the nation's leading National Cancer Institute-designated comprehensive cancer centers. Visit RPCI's website at www.roswellpark.org.

