Oncology, Nuclear Medicine and Transplantology
(eISSN 3105-8760)

Congress Abstract

Development of a Pharmacological Agent for the Prevention of Complications of Radiotherapy for Solid Tumors: Results of Preclinical Studies

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Proceedings of International Scientific and Practical Conference *"ONCO FUTURE KAZAKHSTAN 2026: Precision Oncology Theranostics, Artificial Intelligence,"* **September 24-26, 2026, Astana, Kazakhstan**

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Introduction: The problem of developing effective and safe pharmacological agents for the prevention and treatment of acute and late complications of radiation therapy for malignant neoplasms is highly relevant for the entire global community. Currently, various modalities of radiation therapy are used in the treatment of 50–70% of patients with oncological diseases. At the same time, despite continuous improvement of medical radiological devices and methods of planning radiation exposure, a significant proportion of patients (from 10–20% to 40–60%, depending on localization) receiving radiotherapy develop acute or late complications caused by radiation-induced damage to normal, non-malignant tissues.

At the A.F. Tsyb Medical Radiological Research Center, an innovative agent for the prevention of radiotherapy complications has been developed – a unique radioprotector T1082, capable of selectively protecting healthy tissues without reducing the efficacy of radiation therapy for solid tumors. Its high efficacy has been demonstrated with both parenteral and oral administration in small and large laboratory animals using models of acute and late radiation injuries and in experimental radiation therapy of tumors.

It has been shown that T1082, when administered as a single oral dose at safe doses of 180–220 mg/kg (constituting 1/13–1/10 of LD10), provides pronounced (DRF – 1.6–1.9) prevention of bone marrow and intestinal acute radiation sickness in mice and rats under total-body gamma irradiation, without being inferior in efficacy to the best known radioprotectors. Moreover, the radioprotective effect of T1082 is systemic in nature, which allows it to also effectively (DRF – 1.4–1.7) counteract the development of and mitigate the course of acute and late local radiation injuries to normal somatic tissues, as demonstrated in models of radiation skin burn, radiation mucositis, and radiation pneumofibrosis.

At the same time, in malignant tissues of solid neoplasms, the radioprotective effect of T1082 is practically not realized: in models of radiotherapy of transplantable solid tumors of animals of various histogenesis and organ specificity, T1082, when administered as a single oral dose at 1/13–1/10 of LD10, reliably protected irradiated normal tissues but did not attenuate the antitumor effects of gamma and β radiation against experimental solid neoplasms.

Thus, the results of preclinical studies demonstrate the efficacy and safety of the developed agent and create the conditions for the development and introduction into clinical practice of an innovative domestic medicinal product capable of qualitatively limiting the toxicity of existing methods of radiation therapy for solid tumors and, overall, improving the efficacy and quality of treatment of oncological diseases.

Keywords: 1-Isobutanoyl-2-Isopropylisothiourea Phosphate; NOS Inhibitor; Hypoxic Radioprotector; Safety; Radiotherapy Complications; Selective Protection of Healthy Tissues