A clinical trial of lithium-targeted accelerator-based boron neutron capture therapy at National Cancer Center Hospital

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National Cancer Center and Cancer Intelligence Care Systems, Inc. started co-operative research and development for accelerator-based boron neutron capture therapy (BNCT) system in 2011. Then, we installed a RFQ type linear accelerator with a maximum current of 20 mA, which accelerates protons up to 2.5 MeV. Neutron beams were generated as fast neutron of a maximum energy of 800 keV by collision of proton beam to the solid lithium target, and then, moderated to epithermal neutron. The accelerator is working stably at a mean current of 12 mA with a thermal neutron flux of about 1.41 x 10^9 /cm^2/s in the peak depth of the beam axis. We are now preparing a first-in-human clinical trial of BNCT using this solid lithium-targeted accelerator-based BNCT system, CICS-1 and para-boronophenylalanine (BPA), SPM-011, as a single-institutional single-arm study. The target diseases of this clinical trial are melanoma and angiosarcoma of the skin. The protocol is almost completed and under advisement with in-hospital ethical committee and the Japanese regulatory authority, Pharmaceuticals and Medical Devices Agency (PMDA) at the time of this abstract submission. The purpose of this clinical trial is to examine the safety of the BNCT system with a primary endpoint of the rate of acute adverse event and to determine the maximum tolerable dose of the skin after BNCT. But we will also document the treatment efficacy and late adverse events as secondary endpoints. Patients' accrual will be started within the year of 2019. We are sure that our clinical trial will make a contribution in propelling the development of new accelerator for BNCT, because our system is the world's first solid lithium-targeted machine for BNCT and different from the preceding beryllium-targeted machine.

Keywords: boron neutron capture therapy, first-in-human clinical trial, solid lithium target, melanoma, angiosarcoma