

ASANO-1: Introduction of the world first commercially approved drug for BNCT

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1. Company overview

-Stella Pharma is a marketing and manufacturing company of BNCT drug established in Japan in 2007.

2. Characteristics of BNCT drug “Steboronine[®]”

- (1) Highly enriched ¹⁰B API (Boronophenylalanine, INN Borofalan(¹⁰B))
- (2) Ready to use soft bag formulation
- (3) Stored for 3 years
- (4) GMP grade drug

3. The world’s first approved drug for BNCT

-Steboronine[®] received marketing and manufacturing approval in Japan for head and neck cancer as the world's first drug for BNCT using Accelerator manufactured by Sumitomo Heavy Industries on March 25, 2020.

-It was covered by National Health Insurance in Japan on May 20, 2020.

4. Clinical trial result in head and neck cancer

-In the phase II trial, 21 patients with head and neck cancer were enrolled, and the objective response rate was 71.4%. The result of this trial demonstrated acceptable safety profile and a promising antitumor activity.

5. Ongoing clinical trials using Steboronine[®] in Japan

-Recurrent malignant glioma is now on phase II study, and its primary end point (1-year survival rate) was 79.2% for recurrent glioblastoma.

-In addition, clinical trials for melanoma, angiosarcoma, and malignant meningiomas are in progress.

6. Future collaboration

-We would like to collaborate with overseas medical institutions to introduce BNCT using our drugs.