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SymBio Pharma completes patient enrollment

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Singapore: Japan-headquartered SymBio Pharmaceuticals has completed patient enrollment for its phase II clinical trial of Treakisym (bendamustine hydrochloride, SyB L-0501) in frontline low-grade non-Hodgkin's lymphoma (NHL) and mantle cell lymphoma (MCL) patients in Japan. This randomized trial is evaluating the combination of Treakisym and rituximab versus R-CHOP.

SymBio initiated this multicenter open-label phase II trial as a line extension study for Treakisym in November 2011 in collaboration with Eisai. "Thus far, the study has progressed smoothly with no serious adverse events being reported," saidÃ?Â Mr Fuminori Yoshida, president and CEO of SymBio. Trial results with data analysis and evaluation will be finalized as soon as possible.

In partnership with Eisai, SymBio received marketing approval of Treakisym (SyB L-0501) in October, 2010, for the treatment of patients with relapsed or refractory low-grade NHL and MCL in Japan.

The number of low-grade non-Hodgkin's lymphoma patients in Japan is estimated to be approximately 11,000, including 4,000 refractory or relapsed patients and 7,000 untreated patients. Currently, R-CHOP is prescribed as a standard therapy, however, clinical trial results in the US and Europe have shown superiority of the combination of rituximab and bendamustine (R-B) over R-CHOP in terms of safety and efficacy, leading to the inclusion of R-B in the National Comprehensive Cancer Network guidelines, which are used by the US physicians in prescribing oncology drugs.

SymBio has also initiated development of Treakisym in refractory or relapsed intermediate and high-grade non-Hodgkin's lymphoma, and refractory or relapsed multiple myeloma. The company also continues to pursue other indications in the hematology setting in order to maximize the potential of this 'pipeline within a molecule' and address other unmet medical needs.