

Sosei completes phase I trial for SO-1105 in Japan

03 July 2012 | News | By BioSpectrum Bureau

Sosei completes phase I trial for SO-1105 in Japan



Singapore: Sosei has successfully completed a Japanese phase I trial for SO-1105 for the treatment of oropharyngeal candidiasis. SO-1105 was originally developed by a French pharmaceutical company, BioAlliance Pharma, which received its first marketing authorization for SO-1105 in France in October 2006. SO-1105 has since been registered in 26 European countries, South Korea, and the US, under the trade names Loramyc or Oravig.

The clinical study was conducted in a single study center in Japan, and was designed to evaluate the pharmacokinetics and safety of SO-1105 in healthy Japanese adults.

SO-1105, a once daily muco-adhesive buccal tablet containing 50 mg of miconazole, administered to the buccal mucosa in 12 healthy volunteers provided a 24-hours sustained high concentration in saliva and on the infection site (upper surface of the tongue). In addition, low plasma concentration indicates that no serious systemic adverse events can be expected. Results from the phase I study also showed that SO-1105 had a good overall safety profile, and that usability and compliance were good.

SO-1105 has the potential to become the first long-acting, sustained-release treatment in tablet form for oropharyngeal candidiasis in Japan that could enhance patients' compliance and quality of life.

Shinichi Tamura, CEO of Sosei Group, said: "This is an important step forward in development of SO-1105. We will continue our efforts to bring this widely used drug to the Japanese market as quickly as possible."