

3SBio, Selecta join hands to develop gout therapy

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Singapore: China based biotech firm, 3SBio, has partnered with Selecta Biosciences to license out pegsiticase (Uricase PEG-20), a pegylated recombinant uricase from candida utilis.

Pegsiticase has shown the ability to efficiently reduce plasma uric acid levels in gout patients in successful US Phase 1 clinical tests. The exclusive license enables Selecta to develop pegsiticase in patients with refractory and tophaceous gout and apply its immunomodulatory Synthetic Vaccine Particle (SVP) platform to optimize the safety and efficacy profile for patients at risk of immunogenicity. SEL-212 is a novel product that combines Selecta's proprietary SVP with 3SBio's pegsiticase and is designed to be the first non-immunogenic version of uricase.

"Pegsiticase has already shown significant efficacy signals in gout patients.

We have the opportunity to develop a novel therapeutic approach with the goal of preventing the inhibitory antibodies and other complications of immunogenicity that have been a significant barrier to the widespread use of uricase-based drugs," Mr Werner Cautreels, president and chief executive officer of Selecta said.

He added, "With the combination of SVP and pegsiticase, we believe we can dramatically improve treatment for patients with refractory and tophaceous gout."

"Working with 3SBio, we have the potential to fulfill a key medical need expressed by physicians, the first non-immunogenic uricase. 3SBio's strength of enzyme manufacturing combined with Selecta's proprietary antigen-specific tolerance platform will ensure fast progress towards human proof of concept. If successful, Selecta's SVP platform may unlock the full

therapeutic potential of many other biologic therapies adversely affected by immunogenicity," he explained.

Selecta will work with 3SBio to advance pegsiticase-based therapeutics as potential treatments for refractory and tophaceous gout as well as tumor lysis syndrome, with the ultimate goal of expeditiously moving toward regulatory approvals. Selecta and 3SBio have agreed to work together to achieve clinical proof of concept for SEL-212 and pegsiticase in human clinical trials in their territories; Selecta's territory includes US and all of Europe. Proof-of-concept clinical studies are expected to be initiated in 2015.

"Patients with refractory and tophaceous gout have currently very limited treatment options. Indeed, these patients generally cannot be successfully treated by conventional oral gout drugs," said Dr Jing Lou, CEO, 3SBio. "We are impressed with SVP's potential to greatly expand the safe and effective use of biological therapeutics. Our proven capabilities in manufacturing and development of biological therapeutics combined with Selecta's strong development capabilities and unique SVP platform, promise to be an effective partnership for expanding the use of pegsiticase. Together, we are committed to meeting the significant unmet needs of refractory and tophaceous gout patients."