BioSpectrum the business of Bio & Health Sciences ASIA EDITION

UK, Belgium nod for Bone Therapeutics' therapy

04 October 2013 | News | By BioSpectrum Bureau

Singapore: Europe-based Bone Therapeutics, a biopharmaceutical company focused on innovative cell therapy products for the treatment of bone diseases, received clearance from authorities in Belgium and the UK for a phase I/IIa trial with its allogeneic cell therapy product Allob for the treatment of delayed union fractures.

Allob is an allogeneic, osteoblastic (bone-forming) cell therapy product. Allob has already shown safety and efficacy in preclinical studies and has the potential to become a first-line treatment for impaired fracture healing, thanks to its minimally invasive percutaneous administration, avoiding the need for surgery.

This first-in-human, proof-of-concept, phase I/IIa study is a six months open-label trial to evaluate the safety and efficacy of Allob in the treatment of delayed union fractures of long bones. Thirty two patients will be enrolled in 10 centers. They will receive a single percutaneous administration of Allob directly into the fracture site. Allob-treated patients will be assessed in comparison to baseline at two weeks, one, three and six months using clinical (pain, weight-bearing) and radiological evaluation.

Bone Therapeutics has secured both 'tissue establishment' and 'GMP' accreditation for the in-house manufacturing of ALLOB. This not only allows Bone Therapeutics to have enhanced control over ALLOB's production, but secures the manufacturing runway for scale up of production to support ALLOB's further development.

Mr Enrico Bastianelli, CEO, Bone Therapeutics, commented that, "This new clinical trial clearance from the competent authorities in Belgium and the UK is an important milestone in the development of Allob and further validates Bone Therapeutics' clinical, regulatory and manufacturing capabilities. The only way to address delayed union fractures currently is invasive surgery which could have severe complications and a long hospital stay. With Allob's bone regenerative mode of action and minimally invasive administration, Bone Therapeutics' allogeneic product could become a first-line treatment."