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Spinifex capitalizes on pain management market

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Realizing the need for improved therapies in the highly unmet field of pain management, Australia-based Spinifex has been working on bringing new therapies that can deliver improved efficacy with simplified dosing.

The company, winner of BioSpectrum Asia Pacific Bioscience Industry Emerging Company of the Year 2012, is focused on developing innovative treatments for inflammatory and neuropathic pain, and related peripheral neuropathy disorders.

Spinifex is progressing on EMA 401, as a potential first-in-class oral treatment for neuropathic pain and related symptoms without causing side effects to the central nervous system (CNS). The initial phase II clinical trial of EMA 401 is being carried out in post-herpetic neuralgia (PHN) patients. Parallel to the clinical development of EMA 401, Spinifex has an active medicinal chemistry program aimed at the discovery and development of highly selective AT2 receptor.

EMA 401 targets the angiotensin II type 2 (AT2) receptor and according to Spinifex, it is the only company targeting this receptor. The target product profile for EMA 401 is an orally bioavailable molecule that provides pain relief in people failing frontline therapy (gabapentin/pregabalin and duloxetine), with no CNS side effects and with a faster onset of efficacy.

In 2003, Prof Maree Smith, School of Pharmacy, University of Queensland, discovered that AT2 receptor antagonists may have the potential to treat neuropathic pain. She later studied a molecule using a widely utilized model of neuropathic pain and showed for the first time that this molecule had anti-neuropathic effects in accordance with her hypothesis. She, subsequently, demonstrated the effectiveness of the same class of molecules in inflammatory pain. Progressing ahead with the discovery, this intellectual property was licensed to Uniquest, the commercialization-focused organization that works closely with the University of Queensland, and they established the company Spinifex Pharmaceuticals in 2005.

The objective of Spinifex is to further develop the discoveries made by Prof Smith into a therapeutic drug for neuropathic and inflammatory pain. The founder CEO, Dr Michael Thurn, was successful in securing seed funding from an initial Australia-

based venture capital syndicate.

Spinifex submitted an investigational new drug application to the US FDA for the development of EMA 401 to treat neuropathic pain in 2008. "We continue to submit data to this IND and keep FDA updated on our worldwide development activities. The ultimate aim is to submit an NDA for EMA401 and also seek approval in other jurisdictions, like Europe and Japan. The timing of submitting a marketing authorization will depend on the progress of our clinical program. We hope to conclude our initial phase II neuropathic pain clinical trial in patients suffering from post herpetic neuralgia. We also hope to make good progress in our phase II clinical trial in chemotherapy-induced neuropathy patients. In five years, we hope to have shown that an angiotensin II type 2 receptor antagonist is an important new treatment for neuropathic pain," says Dr Tom McCarthy.