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MEDIA RELEASE

Spinifex Announces Start of Phase 2 Proof-of-Concept Trial of EMA401 in Postherpetic Neuralgia

Spinifex Pharmaceuticals, an Australian pain drug development company, today announced the first patients have been treated in its Phase 2 clinical trial of EMA401 in postherpetic neuralgia (PHN), a painful condition that develops in some patients following herpes zoster (shingles) and where existing therapy does not relieve pain in all individuals.

The double-blind, placebo-controlled randomised trial is being conducted at centers in five countries and the first patient was treated at the clinic of Dr. Douwe De Jong in Pretoria, South Africa. Approximately 170 patients are expected to be enrolled in total.

The trial is designed to prove the concept of the use of EMA401, an angiotensin II type 2 (AT₂) receptor antagonist, in PHN and determine its safety, tolerability and pharmacokinetic profile. The primary endpoint of the trial is reduction in mean daily pain score versus placebo over the last week of 28 days of treatment. Secondary endpoints include a number of further measures of pain and quality of life.

The discovery that AT₂ receptor agonists offer an innovative approach to the treatment of neuropathic and inflammatory pain was originally made by Professor Maree Smith at The University of Queensland. Having acquired the technology, Spinifex has conducted a comprehensive pre-clinical and early clinical development program. EMA401 has shown efficacy in a number of relevant models and good human safety and pharmacokinetics in Phase 1 studies.

Spinifex Pharmaceuticals CEO Tom McCarthy said: "Today marks an important new step in the development of EMA401 and of Spinifex. We have successfully applied our development expertise to take a scientific discovery through early clinical development and now into proof-of-concept trials. This is the first of three Phase 2 trials to be initiated and we look forward to confirming the promise for EMA401 we have seen in our earlier clinical and pre-clinical studies."

Dr Milton Raff (Christiaan Barnard Memorial Hospital, Cape Town, South Africa), Principal Investigator for the Study, said: "Current treatments for postherpetic neuralgia are effective in some patients but a significant proportion either don't respond to therapy and are left with debilitating symptoms or suffer significant side effects. EMA401 offers an entirely novel approach to the treatment of the condition and could represent a valuable new option in an area where there is a clear need for new medicines."

In addition to PHN, Spinifex's clinical program for EMA401 will include studies in other neuropathic pain indications including pain and hypersensitivity in peripheral nerve injury patients, and pain and hypersensitivity in cancer chemotherapy patients. The market for neuropathic pain treatments is expected to continue to increase and is projected to reach US\$6.2 billion by 2017. Despite this growth,

current therapy needs to be improved as a significant proportion of neuropathic pain patients don't respond to current therapy and these treatments have dose-limiting side effects. As a result, EMA401 is being developed as a potential first-in-class oral treatment for neuropathic pain and related symptoms without central nervous system side effects.

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Spinifex Pharmaceuticals

Spinifex Pharmaceuticals is an Australian biotechnology company developing new drug candidates for the treatment and management of pain.

Established in 2005 and based in Melbourne, Spinifex has applied its world-class drug development capabilities to advance product candidates. Its lead product EMA401 is under development as a potential first-in-class oral treatment for neuropathic pain and related symptoms without CNS side effects. Spinifex's Phase 2 program for EMA401 will include clinical trials in a number of neuropathic pain conditions. Spinifex investors are GBS Venture Partners, Brandon Capital Partners, Uniseed and UniQuest.

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