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Spinifex phase II postherpetic neuralgia trial is a success

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Spinifex announces positive phase 2 results in postherpetic neuralgia

Singapore: Spinifex Pharmaceuticals, an Australian pain drug development company, revealed positive headline results from the phase II clinical trial of its lead product, 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. EMA401 is an angiotensin II type 2 (AT 2) receptor antagonist.

The clinical trial met its primary endpoint, which was reduction in mean daily pain score versus placebo over the last week of 28 days of treatment. Results showed a statistically significant and clinically meaningful reduction in mean pain intensity from baseline to week four for subjects on active treatment when compared to placebo. EMA401 was generally safe and well tolerated with no serious treatment related adverse events reported. The double-blind, placebo-controlled randomised trial was recruited at 29 centres in six countries and enrolled 183 patients.

Spinifex will be presenting an overview of the clinical development of EMA401 at the 14th World Congress of Pain in Milan, a major international meeting organised by the International Association for the Study of Pain (IASP). Full results of the phase II trial are expected to be published in a leading pain clinical research journal.

Dr Milton Raff, Christiaan Barnard Memorial Hospital, Cape Town, South Africa, who is the principal investigator for the study, said, "These headline results are very promising with a clear reduction in pain versus placebo and a good safety and tolerability profile. EMA401 offers an entirely novel approach to the treatment of PHN and could represent a valuable new option in an area where there is a clear need for new medicines. Current treatments for the condition 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."

Mr Tom McCarthy, CEO, Spinifex Pharma, said that, said: "It is tremendously gratifying for the Spinifex team to have taken a scientific discovery through to proof of clinical concept in what is a notoriously difficult field and one where new treatments are clearly needed. We look forward to advancing EMA401 further in PHN and other neuropathic pain indications including cancer chemotherapy induced neuropathic pain and painful diabetic neuropathy. Ultimately we hope EMA401 becomes a

broad treatment for chronic pain in general."

EMA401 is being developed as a potential first -in-class oral treatment for neuropathic pain and related symptoms without central nervous system side effects. In addition to PHN, Spinifex's clinical program for EMA401 includes a phase II study in the treatment of neuropathic pain in cancer chemotherapy patients and this trial is currently recruiting.

In addition to positive phase II results, EMA401 has shown efficacy in a number of relevant pre-clinical models and good human safety and pharmacokinetics in phase I studies. Spinifex continues to conduct research into the role of the AT2 receptor in nociceptive, inflammatory and neuropathic pain states and these fundamental studies support not only the EMA401 clinical program but also Spinifex's ongoing AT2 receptor antagonist drug discovery program.