

## NIPPON CHEMIPHAR ANNOUNCES PROGRESS ON ITS HYPERURICEMIA/GOUT PROJECTS; NC-2500 SHOWS FAVORABLE PROFILE TO LOWER SERUM URIC ACID IN PHASE-1 STUDY

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Nippon Chemiphar Co., Ltd. has announced that the Phase-1 clinical trial of NC-2500, a novel xanthine oxidoreductase (XOR) inhibitor, was completed, indicating that it has potential to reduce the risk of gout flare, one of major issues of current treatments for hyperuricemia/gout. The randomized, single-blind, placebo-controlled, dose-escalation study was conducted to evaluate safety, pharmacological characteristics and pharmacokinetics of NC-2500 in healthy volunteers with single and multiple dosing, once daily for 7 days.

NC-2500 showed favorable urate-lowering properties which may make a difference in gout treatment. NC-2500 lowered serum urate levels gradually to the same extent as current XOR inhibitors through 7 days, which could decrease the risk of acute flare in gout. Acute flare due to rapid urate reduction is one of the major issues in the initial phase of current therapy, which impairs patients' quality of life and adherence, frequently resulting in failing sufficient control of serum urate and then worsening the disease. NC-2500 is expected to have potential to resolve these issues by its unique urate-lowering property to avoid acute flare, with no or minimal titration. As for safety, NC-2500 was well-tolerated and adverse events were infrequent, transient, mild, and comparable to placebo. Furthermore, NC-2500 was hardly excreted through the kidneys, which can be a favorite profile for patients with renal impairment, frequently observed in gout.

Nippon Chemiphar also completed pre-clinical studies on NC-2700, a novel urate transporter 1 (URAT1) inhibitor, enhancing excretion urate to urine. NC-2700 showed not just a potent uricosuric effect, but also pH-raising of the urine with lowered pH in an animal model, which could decrease the risk of renal calculus and nephrotoxicity with urate crystals in the urine, the most common issue with uricosuric therapy. NC-2700 is now ready for a phase-1 clinical study.

Focusing on research in hyperuricemia/gout, Nippon Chemiphar has been developing NC-2500 and NC-2700, attractive product candidates which may resolve current issues in treating gout and offer new treatment options to patients for their better outcomes and quality of life. To accelerate development and make them available for patients earlier, Nippon Chemiphar is considering collaboration or partnering for further development and welcomes proposals.