STUDY SUMMARY – NUCRYST NPI 32101 PHASE 2A RESULTS

In September 2004, NUCRYST Pharmaceuticals Corp. announced results from its first-ever human clinical trial of NPI 32101, a topical form of NUCRYST's proprietary silver Rx nanocrystals. Based on the results from this study, NUCRYST plans to design and conduct additional Phase 2 clinical studies.

Study Objective

The purpose of the Phase 2a Study was to evaluate the safety and efficacy of NPI 32101 in adults with mild or moderate Atopic Dermatitis (a form of Eczema) in comparison to placebo.

Study Design

This was a double-blind, placebo-controlled study in 224 patients with mild to moderate Atopic Dermatitis, age 18-65. The protocol required twice-daily applications for six weeks of either vehicle alone, 0.5% NPI 32101 cream or 1.0% NPI 32101 cream.

Primary End Point

The Primary End Point was comparison of success (defined as total clearance or 90-99% improvement in the signs and symptoms of Atopic Dermatitis) among the three treatments. The protocol required an Intent To Treat analysis and a Per Protocol analysis of the data and required a P value of ≤ 0.05 for statistical significance.

Efficacy Results

The efficacy results (overall assessment of disease improvement by investigator) were analyzed in three different ways to determine if NPI 32101 cream in either a 0.5% concentration or a 1.0% concentration was more effective than vehicle: Intent to Treat With Last Observation Carried Forward; Per Protocol; and Intent to Treat Without Last Observation Carried Forward.

The table below summarizes the success rates by treatment group and analysis method.

Analysis Method	Vehicle	0.5% NPI	1.0% NPI
ITT-LOCF	12.9%	12.8%	17.4%
PP (at 6 Weeks)	6.3%	12.5%	22.2%*
ITT-WOLOCF (at 6 weeks)	7.4%	15.3%	22.5%*

**Statistically-significant results (p <0.05 compared to vehicle)*

Intent to Treat With Last Observation Carried Forward – Includes all patients who received at least one dose of either the vehicle or the drug, and had at least one clinical result evaluation. Even if the patient dropped out of the study after one application, they were included in the analysis and the score of the last observation by the clinician would be carried forward to the end of the study. Using the ITT-LOCF Analysis Method, there was not a statistically significant difference among vehicle, 0.5% NPI and 1.0% NPI.

Per Protocol – Includes only those patients who complied with the study protocol. The PP Analysis Method showed a statistically significant difference in favor of 1.0% NPI when compared with vehicle at day 43.

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Intent to Treat Without Last Observation Carried Forward (a sensitivity analysis) – Includes all the ITT set of patients who completed the six-week course of treatment and had a clinical observation at the end of the study. Those who may have violated the protocol (e.g. took another medication or didn't apply the study medication as instructed) are included. The ITT-WOLOCF Method also showed a statistically significant difference in favor of 1.0% NPI when compared with vehicle at day 43.

Safety Results

There were no serious adverse reactions/side effects to NPI 32101, and there was a low incidence of non-serious adverse events. Any adverse events reported were not unusual for a topical drug. Based on the results of this first human study, topically applied NPI 32101 appears to have a good safety profile and there was no safety issue that would warrant discontinuation of the development program.

Next Steps

The study demonstrated a statistically significant difference for 1.0% NPI 32101 cream compared to vehicle using two of the three analysis methods commonly used in Phase 2a Study Analysis and there were no serious adverse events. Using information from this study, NUCRYST plans to design and conduct additional Phase 2 clinical studies, including the use of higher concentrations.

NPI 32101 is still investigational and has not been approved by any regulatory agencies for marketing.