

Report Date March 2017

## CONFIDENTIAL -

# Clinical Experience Study – The Villages

# **Overall Clinical Experience Design**

**Clinical Experience Study:** A multicenter study of the safety and effectiveness of Panoxol for health of patients with Hypertensive Conditions

Investigator:	
Medical Monitor:	
Study Locations: The Villages,	

**Clinical Objective:** To demonstrate the safety and effectiveness Panoxol for health of patients with Hypertensive Condition.

Structure: Multicenter, randomized, no control group

**Duration:** 8 week enrollment and a 16-week usage plan with Panoxol Formula Panoxol.

Controls: A fifty (50) "No Initial Treatment Group" is utilized vs. standard therapy.

**Clinical Hypotheses:** At least sixty percent (60%) of Subjects utilizing Panoxol will be responders within sixteen (16) weeks and show an improvement of twenty percent (20%) in the JACKSON HYPERTENSION STUDY questionnaire measurement technique by Subject Self-Assessment.

**Product:** Vasonoxol® is the name C&HII gave to the US patented formula which was used in the Villages study. Panoxol™ is one of the brand names by which Vasonoxol is currently being marketed.

**Dose Regimen:** Daily use of the Panoxol. The Treating Investigator will instruct the Subjects to swallow two tablets of Panoxol with at least eight ounces (8 oz.) of water twice daily. The Treating Investigator can increase the maximum usage for Subjects with larger frames (over BMI 32).

# **Highlight of Subject Reports:**

Question # 1 "Over the past 6 months: How do you rate your confidence that you blood pressure is under control?"

**Observed Summary:** Thirty-five participants reported improved confidence in their ability to control their blood pressure. More detailed analysis demonstrates those who initially responded, "very poorly" (meaning they were not confident their blood pressure was under control) 100% (4) of them reported improvement by the end of the study (average score 4). For those who responded poorly (2 out of 5), 100% of them (9) reported improvement by the end of



the study (average score 4.1). Meaning that those who were most concerned with controlling their blood pressure found confidence through Panoxol.

- Question # 2 "When you awake in the morning, how often were you dizzy when you woke up?"
  Observed Summary: Twenty-seven participants reported improvement on question # 2.
- Question # 3 "During your normal day, how often were you dizzy or have problems with maintaining your balance?"
  - **Observed Summary:** Thirty-six participants reported improvement on question # 3.
- Question # 4 "During your normal day, how often did you feel "light headed" or dizzy?"
  Observed Summary: "Thirty-nine participants reported improvement on question # 4.
- Question # 5 "When you attempted sexual interlude, how often was it satisfactory for you?"
  Observed Summary: No significant change was observed during the study.
- Overall, 92 participants would recommend Panoxol to family and friends.

## **Participant Feedback**

"Panoxol taken with my blood pressure medicine has made a huge difference. I Henry feel so much better now that my blood pressure has been under control for 3 months." "This has made me feel 100% better." Jacob 9 "I have had a lot of improvement with taking Panoxol" Maryann H "Panoxol has helped me so much" Shawn ( "Seems to help a lot" "I plan on taking this medication from now on." Stacy I "This product is amazing!" Caleen ( "I haven't seen a big change but I don't normally have high blood pressure. I do Ammon S however think it will help people that do. I do feel more energetic."

# **Special Report on Blood Pressure Findings**

#### Overview:

Seventy-eight participants out of ninety-seven completed records reported lowered blood pressure at the end of the study. The participants reported systolic pressure was lowered on average 7 points (5%) and diastolic pressure was lowered an average 11 points (20%). However, detailed analysis demonstrates Panoxol has a greater impact on lowering blood pressure for those suffering from stage 1, or stage 2 hypertension.



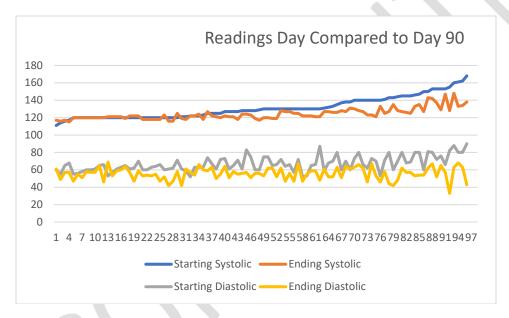
#### **AVERAGE SCORES BY HYPERTENSION STAGES**

## **Sorted Systolic**

Category		# Participants	Systolic/Diasolic
Normal Blood Pressure	(90-119)	[four]	-7 / -11.2
Pre-Hypertension	(120-139)	[sixty five]	-3.5 / -8.8
Hypertension Stage 1	(140 -159)	[twenty three]	-15.1 / 16.7
Hypertension Stage 2	(160 - 179)	[four]	-24.5 / -25

#### **Sorted by Diastolic**

Category		# Participants	Systolic/Diastolic
Normal Blood Pressure	(less than 80)	[eighty one]	-5/-9
Pre-Hypertension	(80-89)	[fourteen]	-15/-24
Hypertension Stage 1	(90-99)	[one]	-30/-47
Hypertension Stage 2	(99+)	[none]	



## REDUCTION OF SYSTOLIC SCORES BASED ON HYPERTENSION STAGE

#### SUMMARY OF RESULTS BY CATEGORY

	Day 1	Day 90
Normal	4	20
Prehypertension	65	69
Hypertension Stage 1	23	3
Hypertension Stage 2	4	1

#### **BLOOD PRESSURE SUMMARY**

Those who began the study with Normal Systolic Blood Pressure (90-119), experienced an average of 7 mm drop in their systolic pressure. At the end of the study, all four remained in the "Normal" range.



Those who began the study with readings in the Prehypertension category (120-139) [sixty five] reported an average of 3.5mm drop in systolic pressure. At the end of the study, 16 had sufficiently dropped their blood pressure to return to Normal blood pressure range, while 49 remained in Prehypertension. Twenty-eight of those forty-nine reported lower scores but remained in the same category. The more striking discovery was from those who started the study in Hypertension Stage 1 (140 -159) [twenty three]. They reported an average reduction of 15.1mm and eighty seven percent [20 participants] experienced a drop in blood pressure significant enough to lower them to Prehypertension category. Only three who started in Stage 1 remained in Stage1 at the conclusion of the study. The most striking results came from those who began the study in Hypertension Stage 2 (160—179), one hundred percent (4) successfully dropped their blood pressure at least one category and three out of four experienced a significant drop in pressure which classifies them in the Prehypertension Category (2 Stage categories lower).

## Conclusion

Our participant's responses corresponded with the aim of this study. They did not report any hypoactive results (patients' blood pressure dropping below the normal range). They reported experiencing some reduction in side effects common to high blood pressure medications.

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These observations from the data of reporting subjects is for internal use only. For public purposes only use document: "DH.CHI. Panoxol Clinical Experience.pdf"