

ARGYLL BIOTECHNOLOGIES, LLC

SF-1019 Pre-Clinical Human Study

April 30, 2007

The following summary was compiled under informed consent (EU) and a compassionate waiver program (U.S.).

SF-1019 which is derived from a caprine source is the latest of what may be a series of cutting edge research products developed by the Argyll Biotechnologies Scientific Team.

A number of in vivo studies using earlier, less sophisticated formulations have been conducted. The results of these in vivo studies proved its safety and were encouraging to Argyll Biotechnologies. Although the advance version contains some of the same peptides, these early studies are of no benefit in obtaining regulatory accreditation determining the efficacy and safety of SF-1019 for regulatory purposes as its structure and production methodology is significantly different from the those of the earlier formulations.

While originally designed as a wound healing product, Argyll Biotechnologies believes that the perceived mechanism of action indicates that SF-1019 may have a wide range of applications relating to conditions of an inflammatory nature such as Multiple Sclerosis (MS), Chronic Immune Demyelinating Polyneuropathy (CIDP), Reflex Sympathetic Dystrophy Syndrome, (RSD or RSDS) and possibly others.

The purpose of this pre-clinical human study, which took place at more than one healthcare center, was to informally further examine as "Proof of Concept" and for dosage confirmation based upon earlier studies. This study involved a small cohort of patients with varying conditions.

Following an intradermal test dose, the standard dosage of 1.5ml was administered by subcutaneous injection. The expected positive immune reaction in most cases occurring. Most of the patients continue to receive treatment with its seemingly attending improvement in their quality of life with no reported physical or laboratory adverse reactions occurring. In the small cohort of patients (which takes no account of the "Placebo Effect" or a measured comparator) there appeared to be no apparent biochemical changes in the blood analysis undertaken.

Blood samples were taken pre-treatment and again at four weeks.

The data compiled supported our "Proof of Concept" contention and helped establish an appropriate dosage regime.

MULTIPLE SCLEROSIS:

PATIENT NUMBER – AG 1704

The patient was a 65 year old white female with a 20 year plus history of Multiple Sclerosis (MS). Her original diagnosis was confirmed by a spinal fluid examination and MRI.

Primary symptoms were left spastic hemiparesis, ataxia, tremor and slurred speech. Hand writing was difficult and left leg lift was necessary for correct shortening form the spastic atrophy. In addition she has suffered for the last 10 years left leg sciatic pain.

She was placed on a weekly treatment regime and immediately following her first treatment a light headedness was felt which lasted about 10 minutes. Within 15 minutes she was able without any observable tremor to write normally and her sciatic pain disappeared.

Within 60 minutes, her voice and intention tremor was estimated to have improved by at least 80% and her gait was steadier but the left hemiparesis was only marginally improved.

At 5 days post treatment her left hemi-paretic walking has been partially corrected and her gait using a cane, became almost normal. At 6 days her walking continued to improve and the circumduction of the left leg had completely gone.

Within 10 minutes, of her second treatment, her left leg improved and her ambulatory function continued to become more positive and her getting up from a chair was greatly improved.

Following her third treatment she was able to walk with an almost normal gait and the continued use of a cane-the tremor and ataxia had not returned. 5 days later she was able to walk in therapy without a short leg brace on the left leg.

Following her 4th treatment she again saw an improvement in her ambulatory abilities and her handwriting abilities remain stable plus.

She continues with weekly treatment to become stronger and is currently able to walk with an almost normal hip flexion and extension rather than circumduction.

CBC, SMA 23. Laboratory data base normal before and after

PATIENT NUMBER – AG1706

The patient is a 72 year old white female who has lived with chronic progressive multiple sclerosis (MS) for 30 years. She has recurrent leg spasms needs daily urinary catheterization, hand tremors and has been wheelchair dependent for the past ten years. In addition a recent fall caused a lower leg fracture which required surgical intervention.

The patient was placed upon a 7 day treatment cycle and experienced no light headedness or vertigo following her first dose, however 15 minutes post injection she noticed that both left and right hands seemed stronger, the right hand was less distorted, the tremor abated gradually over a few days and her hand writing and trunk strength was much improved.

Following a second treatment her hand writing improved so that she can write with her right hand now for the first time in months. Balance has improved and she is able to stand erect with minimal help for dressing. A recent X-ray of the fractured leg has revealed that the damage has healed more speedily than expected.

Weekly treatments continue to show a general improvement in strength and stability so that ADL are readily accomplished.

After 10 treatments the osteoporosis index has improved +4.7% in the spine and +2.9% in left femur. She continues to improve in the strength of standing and walking.

CBC, SMA 23 Laboratory data base normal before and after.

DIABETIC ULCERATION AND WOUND HEALING:

A small number of patients suffering from Chronic Diabetic Ulceration and other open wounds have been treated very successfully with SF1019 and it is interesting to note that angiogenesis occurred in most cases within a few days and that insulin levels also dropped. In every case following a four to six week cycle leg ulcers completely disappeared and normal circulation was restored.

We are currently planning to undertake a wound healing trial at the University of Wales (wound healing unit).

CHRONIC IMMUNE DEMYELINATING POLYNEUROPATHY (CIDP):

PATIENT NUMBER – AG 1702

The patient was a 55 Year old white female with an 18 month history of Chronic Immune Demyelinating Polyneuropathy (CIDP) who was wheel chair dependent with some limited use of her hands.

The patient was placed on a twice weekly regime. Following her first treatment she reported an immediate light headedness with no vertigo. Within 10 minutes she could raise her legs from her hips. The following day she succeeded in walking with a walker for about 60 feet. The second treatment 3 days after the first accelerated the increased strength in the hips and legs and the

patient reported walking 60 or more yards with her walker. During exercise she reported a tingling of her hands, fingers, feet and toes and reported that her skin felt more normal to the touch.

The third injection improved the strength and rehab is progressing very well. The patient reports that the muscles of her legs are tight and twice weekly injections of SF-1019 caused continuation of increased strength while she rehabs daily. She is able to walk around easily with her walker and is beginning to transfer to higher surfaces. After the third injection she began to be able to move her toes and dorsiflex her left ankles. After the 5th injection she was able to move the toes on both feet-more on the left than the right.

At three weeks her assisted walking with a walker continued to improve. Toe movement is improved (left better than right) and her legs have filled out with muscles. She is able to stand 3-4 minutes in an upright position and is working on increasing her hip girdle stamina. For about three to four days following each injection she experiences a significant increase in leg and hip girdle strength, which gradually reduces to a lower but improving overall base line over the next 3-4 days.

At five weeks she was walking with a walker for a distance of about 300-400 yards her pelvic girdle was still weak. After 3 more days, the walker assisted walking has increased to 600-700 yards.

At seven weeks her walking has doubled and standing her tolerance has increased so that she can ambulate only with her walker. After 3 months of therapy with SF-1019 she was discharged using a walker only to ambulate. After 3 months without any injections the patient continues to improve and walks now with a cane and is moving into independent living facilities.

CBC, SMA 23 Laboratory battery performed pre and post treatment all tests were normal.

PATIENT NUMBER – AG 1703

The patient was a 65 year old white female with a 10 year history of Chronic Immune Demyelinating Polyneuropathy (CIDP) contracted apparently following a silicone breast implant.

Nerve biopsy and laboratory data confirmed the diagnosis. She was explanted and had severe hip girdle weakness, sicca syndrome and could not rise from a chair or get up from a squatting position without help. During periods of stress she invariably developed chest wall pain and general chest pain requiring narcotics.

She was placed on a weekly treatment cycle, following the first treatment she experienced a brief (10 minute) period of light headedness without vertigo. Within 15 minutes she could rise from a chair and from a squatting position without help. In addition she was able without assistance to sit and stand using a conventional surgery chair. Her chest pain was immediately relieved and recurred slightly on the sixth day.

There has been no recurrence of chest pain since the second treatment was administered. Shoulder and hip girdle strength has improved remarkably as well as some observable improvement in the SICCA complex.

She has been unable to work for 5 years and after two months of treatment, she was able to return to her job.

CBC, SMA 23. Laboratory data base normal before and after

PATIENT NUMBER – AG 1705

The patient was a 27 year old white female diagnosed with Reflex Sympathetic Dystrophy Syndrome (RSD or RSDS) which is a multi-symptom, multi-system syndrome typically affecting one or more extremities (hands, feet), but may affect any part of the body. The condition affects the sympathetic nervous system (SNS) and the central nervous system (CNS).

The patient has an injury to the right brachial plexus and the subsequent development of right upper extremity RSD which is classified as grade 2-3. She further suffers from severe anxiety and depression and has proved to be unresponsive to all available other forms of therapy.

Normal laboratory battery and MRI performed.

The patient was placed upon a seven day treatment schedule and following the first treatment reported a light headedness after about 5 minutes and then over the next 15-20 minutes noticed that the permanent pain in her right arm and neck which was scored at 9 on a 1 to 10 scale seemed to be floating away into space. She was noted at that time by her mother to have a calm smile that she had never had before. Her general colour with capillary dilatation increased in both upper extremities for the first time (the right arm was cold and constricted blood vessels prior to treatment).

She noted some tingling over the right brachial plexus distribution and could freely move the right fingers and hand. 24 hours later the pain returned but at a much more tolerable level.

Within 10 minutes of her second treatment the right arm and neck pain that had previously been at a more tolerable 3 on a 1 to 10 scale was reduced to 0.75 and within 15 minutes was completely gone. In 24 hours the pain and movement restriction was gone.

Prior to the third treatment she reported an absence of pain and we observed only slightly restricted movement. Three to four days post treatment, the pain recurred but to a score of 5-6.

Within 15 minutes of her fourth treatment again pain was relieved to a more tolerable level and increased mobility improved. Her depression was treated with Dilantin 100mg which caused a rash in that cleared within 5 days.

Weekly treatments appear to have much improved her quality of life and she is now trying to enter an occupational rehabilitation program.

CBC, SMA 23 Laboratory data base normal before and after.

Summary of lab blood work across a cohort of 12 patients:

SF-1019

Summary of lab data

30th April 2007

Ref: US/AH/GM/001

Test	Mean		Mean		Lab Norms	Error %
	Pre Treatment		Post-3-4 wks			
	12 Patients	Range	12 patients	Range		
RBC	4.79	4.1-4.8	4.96	4.2-4.9	4.2- 5.50	
WBC	7.91	4.7-7.8	8.26	5.0-9.5	4.5-11	
Hgb	14.33	11.8-14.0	14.69	12-15.2	12-16.0	
Ht	42.48	37-45	44.15	39-46	37-47	
MCV	89.74	88-100	89.67	85-97	82-100	
MCH	30.99	27.5-33	31.5	28-34	27-34	
PLt	247	188-326	280	200-388	150-400	
PMN	57.4	40-64	42.8	39-62	39-69	
Lymph	27	25-32	41	33-45	25-45	
Baso	0.4	0-0.8	0.5	0-0.9	0-1.0	
Eosin	0.8	0-2	0.9	0.1-3	0-5.0	
FBS	87.8	67-102	90.6	72-100	65-100	0.55
Na	142	136-145	143	140-147	135-148	0.95
K	3.7	3.5-4.2	3.9	3.6-4.5	3.5-5	1.5
CO2	26	23-29	25	23-30	24-31	7.9
BUN	15.07	8-16.0	26.7	9-21.0	8-24.0	1.9
Creatinine	1.01	0.5-1.2	0.97	1.0-1.4	0.5-1.5	1.75
Uric Acid	5.73	3.5-7.0	5.46	5.7-8.6	3.5-8.5	
Cholesterol						
Triglycerides						
Ca	9.03	8.5-9.7	9.14	9.1-10.3	8.6-10.6	0.8
TP	7.13	5.0-7.2	7.48	6.4-8.1	6.3-8.2	1.95
Alb	4.59	3.6-4.9	4.73	4.0-4.8	3.9-5.0	2.75
Alk Phos	68.07	64-114	83.16	74-112	30-115	4.55
ALT	30.15	7.0-55	34.5	18-55.0	10-55.0	2.45
AST	23.5	10-16.2	24.6	18-40.6	10-42.0	1.95
T Bili	0.62	0.1-0.5	0.69	0.2-0.75	0.2-1.2	3.25