ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: December 13, 2017

ClinicalTrials.gov ID: NCT01469221

Study Identification

Unique Protocol ID:	SPI-1012
Brief Title:	Efficacy and Safety Study of Apaziquone vs. Placebo in Patients With Non-Muscle Invasive Bladder Cancer (NMIBC)
Official Title:	A Phase 3 International, Double-Bind Trial Evaluating Efficacy and Safety of Multiple Instillations of Intravesical Apaziquone vs. Placebo in Patients With Low-Intermediate Risk Non-Muscle Invasive Bladder Cancer (NMIBC)
Secondary IDs:	2011-003517-42 [EudraCT Number]

Study Status

Record Verification:	October 2017
Overall Status:	Terminated [Business reason]
Study Start:	January 2012 [Actual]
Primary Completion:	April 2013 [Actual]
Study Completion:	April 2013 [Actual]

Sponsor/Collaborators

Sponsor:	Spectrum Pharmaceuticals, Inc
Responsible Party:	Sponsor
Collaborators:	Allergan

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	

Unapproved/Uncleared Device:	No
U.S. FDA IND/IDE:	Yes
IND/IDE Information:	FDA Center: CDER IND/IDE Number: 73572 Serial Number: 0095 Has Expanded Access: No
Human Subjects Review:	Board Status: Approved Board Name: NEIRB Board Affiliation: Phone: 617-243-3924 Email: info@neirb.com Address:
Data Monitoring:	Yes
FDA Regulated Intervention:	Yes
Section 801 Clinical Trial:	Yes

Study Description

Brief Summary:	This is an international, multicenter, double-blind, placebo-controlled, randomized study. All eligible patients entering the open label phase of the study will receive a single immediate instillation of apaziquone (4 mg in 40 mL diluent), post transurethral resection-bladder tumor (TURBT). Following Central Pathology review of histology and Double Blind Phase qualification, patients with confirmed eligibility will be randomized to receive either 6 weekly intravesical instillations of apaziquone or matching placebo and undergo cystoscopic and safety assessments every 3 months for 24 months. Patients with histologic evidence of recurrent disease during the study will be treated according to current treatment guidelines or local standard of care. Safety and efficacy assessments will be performed at 3 month intervals for all randomized patients throughout the study. Patients who receive single dose of apaziquone immediately following TURBT and are not eligible for randomization will be followed for 3 months by cystoscopic exam and safety assessments.
Detailed Description:	

Conditions

Conditions:	Bladder Cancer
Keywords:	Bladder Cancer Non-Muscle Invasive Bladder Cancer NMIBC Apaziquone

EOquin
GU Cancer
TURBT

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Interventional Study Model:	Parallel Assignment
Number of Arms:	2
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)
Allocation:	Randomized
Enrollment:	47 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Apaziquone Apaziquone (4 mg in 40 mL)	Drug: Apaziquone 6 weekly multi-instillation of Apaziquone 4 mg in 40 mL Other Names: • EoQuin • EO9
Placebo Comparator: Placebo Matching placebo (40 mL)	Drug: Placebo 6 weekly multi-instillation of matching placebo in 40mL

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Sex:	All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria (for Open Label):

1. Has the patient given written informed consent and is the patient willing and able to abide by the protocol?
2. Is the patient 18 years old or above?
3. If the patient is a female of childbearing potential, is she using an acceptable/effective method of contraception?
4. Does the female patient of childbearing potential have a negative serum pregnancy test at screening?
5. Does the patient with clinically apparent primary or recurrent low grade Ta NMIBC have :

   - multiple tumors (2-7)
   - No single Tumor > 3 cm
   - No history / evidence of Tis

   Or does the patient with clinically apparent primary or recurrent high grade Ta NMIBC have:

   - A single tumor that is ≤ 3 cm
   - No history / evidence of Tis
6. Is the patient able to retain bladder instillations for a minimum of 60 minutes (± 6 minutes)?
7. Did the patient have upper urinary tract evaluation to exclude urothelial carcinoma, hydronephrosis or renal cell carcinoma or other renal cancers in the 6 months prior to study screening?
8. Is patient's urethra (including prostatic urethra in men) endoscopically free of any visible TCC?
9. For patients with recurrent tumor, did the patient have at least a 6-month cystoscopically-confirmed tumor-free interval between the last tumor recurrence and the time of screening?
10. Has the male patient with a prostate specific antigen (PSA) between 4 and 10 ng/mL had a diagnostic evaluation that reasonably excludes the diagnosis of prostate cancer in the opinion of the Investigator?

Exclusion Criteria (for Open Label):

1. Has the patient received any previous pelvic radiotherapy (includes external beam and/or brachytherapy)?
2. Has the patient ever received apaziquone?
3. Has the patient received an induction course (completed 5 of 6 scheduled weekly instillations) of intravesical BCG (± interferon) with the last dose given less than 12 months ago?
4. Has the patient had any prior intravesical chemotherapy, exclusive of single-dose adjuvant intravesical chemotherapy immediately post-TURBT?
5. Does the patient have a history of urinary retention or a post void residual ≥ 250 cc by bladder scan or ultrasound (post void residual test may be repeated up to 3 times)?
6. Does the patient have or has the patient had any bladder tumor with histology other than transitional cell carcinoma?
7. Does the patient have or has the patient had micro-papillary transitional cell carcinoma?
8. If the patient has recurrent papillary disease of the bladder, has the pathology been anything other than pTa in the past?
9. Does the patient have an active urinary tract infection confirmed by culture or a documented history of recurrent UTI (≥ 6 for females and ≥2 for males per year) in the prior 2 years?
10. Does the patient have a bleeding disorder or a screening platelet count < 50 x 109/L?
11. Does the patient have a screening hemoglobin < 10 g/dL?
12. Does the male patient have a screening serum PSA > 10 ng/mL?
13. Does the patient have a history of Acquired Immunodeficiency Syndrome or HIV positive?

14. Does the patient have a condition or a concurrent severe and/or uncontrolled medical or psychiatric disease (e.g., uncontrolled diabetes, decompensated congestive heart failure, myocardial infarction within 6 months of study, unstable and uncontrolled hypertension, or an active uncontrolled infection), which could compromise participation, compliance with scheduled visits and/or completion of the study?
15. Has the patient participated in an investigational protocol within the past 90 days?
16. Is the patient pregnant or breast feeding?
17. Does the patient have a life expectancy of <3 years?
18. Has the patient had any other malignancy or received therapy for any malignancy in the last five years except
    - non-melanoma skin tumors
    - stage 0 (in situ) cervical carcinoma
    - undetectable PSA for ≥1 year following definitive therapy for localized prostate cancer?
19. Does the patient have documented vesicoureteral reflux or an indwelling ureteral stent?
20. Does the patient have tumor in a bladder diverticulum?
21. Does the patient have a known allergy to red color food dye?

Double-Blind Phase Inclusion Criteria

1. Was all visible tumor resected at the initial TURBT?
2. Does Central Pathology review of the patient's bladder tumor confirm:
    - Low grade Ta disease for multiple tumors (2 - 7) or
    - High Grade Ta disease for single tumor
    - No microscopic evidence of lymphovascular invasion and/or evidence of tumor thromboemboli

Contacts/Locations

Central Contact Person: Dustin Wright
Telephone: 310-717-1355
Email: dustin.wright@sppirx.com

Central Contact Backup:

Study Officials: Show-Li Sun, MD
Study Director
Spectrum Pharmaceuticals, Inc

Locations: **United States, California**
Tower Research Institute
Los Angeles, California, United States, 90048
Contact: Maria Reyes 310-854-9898 Ext. x 141 reyesm@TOWERUROLOGY.COM
Principal Investigator: Edward Uchio, MD

United States, Florida
Department of Urology, University of Miami Miller School of Medicine
Miami, Florida, United States, 33136

Contact: Vee Mungal 305-243-7207 vmungal@med.miami.edu
Principal Investigator: Mark Soloway, MD

United States, New Jersey
Somerset Urological Associates, PA
Somerville, New Jersey, United States, 08876
Contact: Basia Dzierzek 908-359-2099 Ext. 206 basia.dzierzek@pharmatrials.info
Principal Investigator: Joel M Fischer, MD
Sub-Investigator: Keith A Harmon, MD
Sub-Investigator: Arthur D Feldman, MD
Sub-Investigator: Dhiren S Dave, MD

United States, New York
Associated Medical Professionals of New York, PLLC
Oneida, New York, United States, 13421
Contact: Melissa Clark 315-363-8862 MClark@ampofny.com
Principal Investigator: Bashar Omarbasha, MD

Male and Female Urology
Staten Island, New York, United States, 10314
Contact: Basia Dzierzek 908-359-2099 Ext. 206 basia.dzierzek@pharmatrials.info
Principal Investigator: Richard Maggio, MD
Sub-Investigator: Joseph Motta, MD
Sub-Investigator: Jay Basillote, MD

Associated Medical Professionals of New York, PLLC
Syracuse, New York, United States, 13210
Contact: Tonya Godfrey tgodfrey@ampofny.com
Principal Investigator: Joel Bass

United States, North Carolina
Alliance Urology Specialists
Greensboro, North Carolina, United States, 27403
Contact: Pattie Edwards 336-274-1114 Ext. 5328
Contact: Karen Michael, RN 336-274-1114 Ext. 5328
Principal Investigator: John J. Wrenn, MD

Poland
Szpital Miejski im. Prof. E. Michałowskiego
Katowice, Poland, 40-073
Contact: Wiesław Duda, Dr n. med. +48 032 251 54 36
Principal Investigator: Wiesław Duda, Dr n. med.

CenterMed Kraków sp z o.o.
Kraków, Poland, 31-530
Contact: Piotr Maciukiewicz maciukiewicz@krak.pl

Principal Investigator: Piotr Maciukiewicz

Wojewódzki Szpital Specjalistyczny im. Stefana Kardynała Wyszyńskiego Samodzielny Publiczny Zakład Opieki Zdrowotnej w Lublinie, Oddział Urologii i Onkologii Urologicznej
Lublin, Poland, 20-718
Contact: Paweł Malik, MD, PhD +48 81 537 46 36 pmalik@o2.pl
Principal Investigator: Jacek Niezabitowski, MD

Nieubliczny Zakład Opieki Zdrowotnej Europejskie Centrum Zdrowia Otwock im. Fryderyka Chopina Nieubliczny Zakład Opieki Zdrowotnej
Otwock, Poland, 05-400
Contact: Anna Belka '+48 22 710 30 49 anna.belka@ecz-otwock.pl
Principal Investigator: Jakub Dobruch, MD

Niepubliczny Zakład Opieki Zdrowotnej Pabianickie Centrum Medyczne
Pabianice, Poland, 95-200
Contact: Grzegorz Krzyżanowski, Dr n. med. grzegorz.krzyzanowski@yahoo.pl
Principal Investigator: Grzegorz Krzyżanowski, Dr n. med.

Niepubliczny Zakład Opieki Zdrowotnej Pabianickie Centrum Medyczne
Pabianice, Poland, 95-200
Contact: Grzegorz Krzyżanowski, Dr n. med. grzegorz.krzyzanowski@yahoo.pl
Principal Investigator: Grzegorz Krzyżanowski, Dr n. med.

Samodzielny Publiczny Zakład Opieki Zdrowotnej, Wojewódzki Szpital Specjalistyczny nr 3
Rybnik, Poland, 44-200
Contact: Jacek Węglorz, Dr n. med. +48 032 429 15 79
Principal Investigator: Jacek Węglorz, Dr n. med.

Wojewódzki Szpital Specjalistyczny W Siedlcach
Siedlce, Poland, 08-110
Contact: Tadeusz Dmowski, Dr n. med. 48 025 640 32 98
Principal Investigator: Tadeusz Dmowski, Dr n. med.

Pomorska Akademia Medyczna
Szczecin, Poland, 70-111
Contact: Andrzej Sikorski, MD +48 091 466 11 00
Principal Investigator: Andrzej Sikorski, MD

Wojewódzki Szpital Specjalistyczny im Janusza Korczaka
Słupsk, Poland, 76-200
Contact: Jacek Ołubiec, Dr n. med. +48 059 841 34 15
Principal Investigator: Jacek Ołubiec, Dr n. med.

Szpital Kliniczny Dzieciątka Jezus - Centrum Leczenia Obrażeń
Warszawa, Poland, 02-005

Contact: Andrzej Borkowski, MD +48 022 502 21 48
Principal Investigator: Andrzej Borkowski, MD

Wojskowy Instytut Medyczny, Centralny Szpital Kliniczny MON
Warszawa, Poland, 00-909
Contact: Henryk Zieliński, MD +48 022 681 63 19
Principal Investigator: Henryk Zieliński, MD

Międzyleski Szpital Specjalistyczny w Warszawie Oddział Urologii
Warszawa, Poland, 04-749
Contact: Artur Antoniewicz, MD
Contact: aaa@urologia.waw.pl
Principal Investigator: Artur Antoniewicz, MD

Centrum Medycznego Kształcenia Podyplomowego, Samodzielny Publiczny Szpital Kliniczny im. Prof. W. Orłowskiego
Warszawa, Poland, 00-416
Contact: Wojciech Pypno, MD 48 022 621 71 78 wpypno@wp.pl
Principal Investigator: Wojciech Pypno, MD

Szpital Bielański im. ks. J. Popiełuszki Samodzielny Publiczny Zakład Opieki Zdrowotnej
Warszawa, Poland, 01-809
Contact: Anna Bonder-Nowicka, MD +48 22 569 01 48 ambonder@interia.pl
Principal Investigator: Piotr Kryst, MD

Wojewódzki Szpital Specjalistyczny we Wrocławiu, Ośrodek Badawczo Rozwojowy
Wrocław, Poland, 51-124
Contact: Jerzy Sokołowski, Dr n. med. +48 071 327 03 15
Principal Investigator: Jerzy Sokołowski, Dr n. med.

Niepubliczny Zakład Opieki Zdrowotnej-Centrum Medyczne Szpital Świętej Rodziny sp z o.o.
Łódź, Poland, 90-302
Contact: Antoni Majek mantonim@interia.pl
Principal Investigator: Antoni Majek

Slovakia
Univerzitná nemocnica L. Pasteura Košice Univerzitná nemocnica L. Pasteura Košice
Košice, Slovakia, 041 66
Contact: Miroslav Iláš +421 556 403 590 miroslav55@centrum.sk
Principal Investigator: Ladislav Valanský, MD

Univerzitná nemocnica Martin Urologická klinika
Martin, Slovakia, 036 59
Contact: Olga Žňavová +421 43 4203 896 znavova@mfn.sk
Principal Investigator: Jan Kliment, MD

Fakultná nemocnica s poliklinikou J. A. Reimana Prešov Urologická klinika

Prešov, Slovakia, 081 81
Contact: Mária Minčíková +421 908 448 630 maria.mincikova@gmail.com
Principal Investigator: Ivan Minčík, MD

Fakultná nemocnica s poliklinikou Žilina Urologické oddelenie
Žilina, Slovakia, 012 07
Contact: Edita Soláriková + 421 41 5110 782 edita.solarikova@gmail.com
Principal Investigator: Juraj Mikuláš, MD

Czechia
Nemocnice Jablonec nad Nisou, Urologické oddělení
Jablonec nad Nisou, Czechia, 466 60
Contact: Filip Rapp, MD 420483345705 rapp@nemjbc.cz
Principal Investigator: Jaroslav Všetička, MD

Fakultní Thomayerova nemocnice s poliklinikou Urologické oddělení
Prague, Czechia, 14059
Contact: Roman Zachoval roman.zachoval@ftn.cz
Principal Investigator: Roman Zachoval

IPDSharing

Plan to Share IPD:

References

Citations:

Links:

Available IPD/Information:

Study Results

Participant Flow

Pre-assignment Details	Patients 1) meeting Open Label Phase and Double Blind Phase inclusion and exclusion criteria, including confirmed histology based on Central Pathology Review, and 2) has eligibility packet approved by Sponsor, are randomized in a 1:1 fashion to receive 6 weekly instillations of apaziquone or matching placebo.

Reporting Groups

	Description
Apaziquone	6 weekly multi-instillation of Apaziquone 4 mg in 40 mL
Placebo	6 weekly multi-instillation of matching placebo in 40 mL
Open Label-Apaziquone	Single dose of Apaziquone 4 mg in 40 mL

Open Label Phase

	Apaziquone	Placebo	Open Label-Apaziquone
Started	0	0	47
Completed	0	0	44
Not Completed	0	0	3

Double Blind Phase

	Apaziquone	Placebo	Open Label-Apaziquone
Started	14	17	0
Completed	0	0	0
Not Completed	14	17	0
Protocol Violation	1	0	0
Physician Decision	1	1	0
Sponsor Terminate Study	12	16	0

Baseline Characteristics

Reporting Groups

	Description
Apaziquone	Apaziquone (4 mg in 40 mL) Apaziquone: 6 weekly multi-instillation of Apaziquone 4 mg in 40 mL
Placebo	Matching placebo (40 mL) Placebo: 6 weekly multi-instillation of matching placebo in 40mL

Baseline Measures

		Apaziquone	Placebo	Total
Overall Number of Participants		14	17	31
Age, Categorical Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	14 participants	17 participants	31 participants
	<=18 years	0 0%	0 0%	0 0%
	Between 18 and 65 years	5 35.71%	9 52.94%	14 45.16%
	>=65 years	9 64.29%	8 47.06%	17 54.84%
Age, Continuous Mean (Standard Deviation) Unit of measure: years	Number Analyzed	14 participants	17 participants	31 participants
		68.4 (9.9)	63.6 (9.2)	65.7 (9.7)
Sex: Female, Male Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	14 participants	17 participants	31 participants
	Female	6 42.86%	6 35.29%	12 38.71%
	Male	8 57.14%	11 64.71%	19 61.29%
Ethnicity (NIH/ OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	14 participants	17 participants	31 participants
	Hispanic or Latino	0 0%	0 0%	0 0%
	Not Hispanic or Latino	14 100%	17 100%	31 100%
	Unknown or Not Reported	0 0%	0 0%	0 0%

		Apaziquone	Placebo	Total
Race (NIH/OMB) Measure Type: Count of Participants Unit of measure: participants	Number Analyzed	14 participants	17 participants	31 participants
	American Indian or Alaska Native	0 0%	0 0%	0 0%
	Asian	1 7.14%	0 0%	1 3.23%
	Native Hawaiian or Other Pacific Islander	0 0%	0 0%	0 0%
	Black or African American	0 0%	0 0%	0 0%
	White	13 92.86%	17 100%	30 96.77%
	More than one race	0 0%	0 0%	0 0%
	Unknown or Not Reported	0 0%	0 0%	0 0%

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Time to Recurrence
Measure Description	Time from randomization to the date of first histologically confirmed recurrence of bladder cancer
Time Frame	24 Months

Analysis Population Description

Patients who were in the Double Blind Phase

Reporting Groups

	Description
Apaziquone	Apaziquone (4 mg in 40 mL) Apaziquone: 6 weekly multi-instillation of Apaziquone 4 mg in 40 mL
Placebo	Matching placebo (40 mL) Placebo: 6 weekly multi-instillation of matching placebo in 40mL

Measured Values

	Apaziquone	Placebo
Overall Number of Participants Analyzed	14	17
Time to Recurrence Median (Full Range) Unit of measure: months	NA (1.5 to 1.5) [1]	8.5 (2.5 to 8.5)

[1] only 1 patient recurred, median time to recurrence not reached

2. Secondary Outcome Measure:

Measure Title	2-Year Recurrence Rate
Measure Description	Proportion of patients with recurrence at or before 24 months
Time Frame	24 Months

Analysis Population Description

Patients who were in the Double Blind Phase

Reporting Groups

	Description
Apaziquone	Apaziquone (4 mg in 40 mL) Apaziquone: 6 weekly multi-instillation of Apaziquone 4 mg in 40 mL
Placebo	Matching placebo (40 mL) Placebo: 6 weekly multi-instillation of matching placebo in 40mL

Measured Values

	Apaziquone	Placebo
Overall Number of Participants Analyzed	14	17
2-Year Recurrence Rate Measure Type: Count of Participants Unit of measure: participants	1 7.14%	6 35.29%

Reported Adverse Events

Time Frame	[Not specified]
Adverse Event Reporting Description	[Not specified]

Reporting Groups

	Description
Apaziquone	6 weekly multi-instillation of Apaziquone 4 mg in 40 mL
Placebo	6 weekly multi-instillation of matching placebo in 40 mL
Open Label-Apaziquone	Single dose of Apaziquone 4 mg in 40 mL

All-Cause Mortality

	Apaziquone	Placebo	Open Label-Apaziquone
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total All-Cause Mortality	0/14 (0%)	0/17 (0%)	0/47 (0%)

Serious Adverse Events

	Apaziquone	Placebo	Open Label-Apaziquone
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	1/14 (7.14%)	0/17 (0%)	2/47 (4.26%)
Cardiac disorders			
Cardiac failure congestive †	1/14 (7.14%)	0/17 (0%)	1/47 (2.13%)
Renal and urinary disorders			

	Apaziquone	Placebo	Open Label-Apaziquone
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Urinary retention †	0/14 (0%)	0/17 (0%)	1/47 (2.13%)

† Indicates events were collected by systematic assessment.

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Apaziquone	Placebo	Open Label-Apaziquone
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	6/14 (42.86%)	11/17 (64.71%)	23/47 (48.94%)
Gastrointestinal disorders			
Diarrhoea †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Hepatobiliary disorders			
Hepatic cirrhosis †	1/14 (7.14%)	0/17 (0%)	1/47 (2.13%)
Infections and infestations			
Bronchitis †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Cystitis †	0/14 (0%)	3/17 (17.65%)	3/47 (6.38%)
Pharyngitis †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Skin infection †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Tooth infection †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Urinary tract infection †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Metabolism and nutrition disorders			
Hypercholesterolaemia †	2/14 (14.29%)	0/17 (0%)	2/47 (4.26%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Nervous system disorders			
Paraesthesia †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Renal and urinary disorders			
Calculus bladder †	0/14 (0%)	1/17 (5.88%)	1/47 (2.13%)
Cystitis noninfective †	0/14 (0%)	1/17 (5.88%)	2/47 (4.26%)

	Apaziquone	Placebo	Open Label-Apaziquone
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Haematuria †	1/14 (7.14%)	2/17 (11.76%)	4/47 (8.51%)
Nephrolithiasis †	1/14 (7.14%)	0/17 (0%)	1/47 (2.13%)
Pollakiuria †	1/14 (7.14%)	0/17 (0%)	2/47 (4.26%)
Urinary retention †	0/14 (0%)	1/17 (5.88%)	2/47 (4.26%)
Vascular disorders			
Peripheral ischaemia †	1/14 (7.14%)	0/17 (0%)	1/47 (2.13%)

† Indicates events were collected by systematic assessment.

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Official Title: Gajanan Bhat, PhD
Organization: Spectrum Pharmaceuticals
Phone: 949-743-9219
Email: Gajanan.Bhat@sppirx.com