Screening (Day -30 to 1)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

INFORMED CONSENT (Screening)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Date patient signed Informed Consent: _____
(DD/MMM/YYYY)

Protocol version:
- ◯ Original
- ◯ Amendment no: _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

DEMOGRAPHIC INFORMATION (Screening)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Gender ○ Male ○ Female

Date of Birth: _____ (DD/MMM/YYYY) Age: _____ (YEARS)

Ethnicity: ☐ Hispanic or Latino ☐ Not Reported ☐ Not Hispanic or Latino ☐ Unknown

Race : ☐ White ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ American Indian or Alaska Native ☐ Other, Specify: _____

Smoking Status: ☐ Current ☐ Former ☐ Never

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

ELIGIBILITY CRITERIA (Screening)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Does the patient meet all eligibility criteria?

☐ Yes

☐ No

If 'No', indicate one or more failed inclusion or exclusion criteria:

Inclusion Criterion # :_____ Exclusion Criterion # :_____

Inclusion Criterion # :_____ Exclusion Criterion # :_____

Inclusion Criterion # :_____ Exclusion Criterion # :_____

Was patient enrolled? ☐ No

☐ Yes

If patient was not enrolled, provide reason:

☐ Did not meet eligibility

☐ Withdrew consent

☐ Other, specify :_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Screening)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Screening)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Total number of lesions noted : _____

Were any other abnormalities seen?

- ◯ No
- ◯ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?

- ◯ No
- ◯ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

General Medical/Surgical History

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Check if there is no Medical/ Surgical History

Sequence: _____ Diagnosis or Procedure or therapies or current medication _____

(Please include the history of all relevant neoplastic disease, its symptoms, findings, previous therapy, and investigations as well as significant past and all co-existing diseases and current medications for the previous 5 years.)
(Record history of the neoplastic disease on the Bladder Cancer History page)

Body System Code * _____

Date of Onset/Procedure : _____ (DD/MMM/YYYY) Stop Date: _____ (DD/MMM/YYYY) ☐ Ongoing

Is there additional Medical History?: ☐ Yes

Body System Code1

01 HEENT	**05 Renal/ Genitourinary**	**09 Endocrine/Metabolic**	**13 Allergies**
02 Respiratory	**06 Reproductive**	**10 Hematologic/Lymphatic**	**S Other**
03 Cardiovascular	**07 Musculoskeletal**	**11 Neurological**	
04 Gastrointestinal	**08 Dermatologic**	**12 Psychiatric**	

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Previous Bladder Cancer History

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

TURBT History :

☐ No history of TURBT

Date (DD/MM/YYYY)	Highest Stage (T stage)	Highest Grade 1973 or 2004

1-T0	7- Papilloma	13- High Grade
2-Ta	8- G1	14- Analysis not performed
3-TIS(CIS)	9- G2	88- Information not available
4-T1	10- G3	
5- ≥T2	11- PUNLUMP	
6-Histology not consistent with urothelial malignancy	12- Low Grade	

Intravesical Bladder Cancer Therapy :

Was any prior Intravesical Bladder Cancer Therapy carried out? ◯ Yes ◯ No

Date (DD/MM/YYYY)	Agent Type*	Total # of Intravesical instillations	Indication

18- Apaziquone(EOquin)	21-Gemcitabine	24- Single Postoperative TURBT Instillation
19-Mitomycin C	22-BCG	25- Adjuvant Course of Intravesical instillation
20-Epirubicin	23-Other Agent	88-Information not available

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Current Bladder Tumor Status

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Is the current tumor primary or recurrent bladder cancer?

- ◯ **Primary**
- ◯ **Recurrent** (please also complete Bladder cancer history form)

Total Number of Recurrences : _____

Presentation :

Hematuria
- ◯ No
- ◯ Yes

If Yes,
- ◯ Gross
- ◯ Microscopic

Please provide the test(s) performed to exclude extravesical (upper tract) and metastatic disease. Check all that apply

- ☐ CTIVP Date_____
- ☐ MRU Date_____
- ☐ CT Date_____
- ☐ MRI Date_____
- ☐ Ultrasound Date_____
- ☐ Retrograde Pyelogram Date_____
- ☐ CXR Date_____
- ☐ Other, Specify_____ Date_____

Current presumed AUA risk category:

Low risk

- ◯ PUNLMP (Patients with strongly-suspected PUNLMP at Screening or TURBT should not be enrolled in the study)
- ◯ Solitary, Low Grade Ta, <= 3cm, Primary or if Recurrent over a year of last resection

Intermediate risk

- ◯ Solitary, Low Grade Ta, <= 3 cm, Recurrent within a year of last resection
- ◯ Solitary, Low Grade Ta, > 3 cm
- ◯ Solitary, High Grade Ta, <= 3 cm, Primary
- ◯ Multiple , all Low Grade Ta

(According to AUA Guidelines 2016)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Vital Signs (Screening)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not Done If not done, please specify reason

Date of Assessment
(DD/MMM/YYYY)

Height
(cm)

Body Temperature
(°C)

Body Weight
(kg)

Blood Pressure
(mmHg)
Systolic / Diastolic

Heart Rate
(beats/minute)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

PHYSICAL EXAMINATION (Screening)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Check if Physical Examination was not done.

If not done, please specify reason _____

Date of Examination _____
(DD/MMM/YYYY)

Were there any clinically significant abnormal findings?

☐ No
☐ Yes*

*** (Please record all clinically abnormal findings on the General Medical/Surgical History page)**

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Complete Blood Count (Screening)

Panel Collection date _____ (DD/MMM/YYYY)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not Done Panel Lab ID _____ If not done,please provide reason _____ Panel Time Drawn _____ (00:00-23:59)

Test Name:	Not Done	Result	Unit	Clinical Significance		
WBC _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hemoglobin _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hematocrit _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Platelets _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Blood Chemistry (Screening)

Protocol No.: SPI-QAP-306 Site No.: Patient No.: Panel Time Drawn (00:00-23:59) Panel Collection date (DD/MMM/YYYY) Panel Lab ID

☐ Not Done If not done,please provide reason

Test Name:	Not Done	Result	Unit	Clinical Significance		
Glucose	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Blood Urea Nitrogen	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Creatinine	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Sodium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Potassium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Chloride	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Carbon Dioxide	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Albumin	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Alk Phosphatase	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
AST	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
ALT	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Pregnancy Test (Screening)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not Applicable

Reason if Pregnancy Test Not Applicable:

- ◯ Patient is male.
- ◯ Patient is post-menopausal (≥1 year since last menses) and/or surgically non-reproductive female.

Collection Date _____
(DD/MMM/YYYY)

RESULT:

- ◯ Negative
- ◯ Positive*

Note:-

(* **Pregnancies involving a study patient or a patient's partner, that occur from the first dose of study treatment through 35 days after the last dose of study treatment, must be reported within 24 hours after the Investigator has gained knowledge of the event via fax or e-mail. Follow-up information regarding the outcome of the pregnancy will be requested by the Spectrum Pharmacovigilance Department.**

All patients who become pregnant during participation in this study are to be withdrawn from the study.)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Screening)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Ketones	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Specific Gravity	◯ Not Done		☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
pH	◯ Not Done		☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Treatment(Visit 1 Day 1)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Vital Signs (Visit 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not Done

Date of Assessment

(DD/MMM/YYYY)

Body Temperature

(°C)

Blood Pressure

(mmHg)
Systolic / Diastolic

Heart Rate

(beats/minute)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Complete Blood Count (Visit 1 Day 1)

Panel Collection date _____ (DD/MMM/YYYY)

Protocol No.: SPI-QAP-306

Site No.: _____ Patient No.: _____

☐ Not Done

Panel Lab ID _____

Panel Time Drawn _____ (00:00-23:59)

☐ Not Applicable as Screening assessment was done less than 72 hours ago

If not done,please provide reason _____

Test Name:	Not Done	Result	Unit	Clinical Significance		
WBC _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hemoglobin _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hematocrit _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Platelets _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.
For rest of the Visits, please list the Abnormal and Clinically Significant abnormality in Adverse Event form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Blood Chemistry (Vist 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.: Patient No.: Panel Time Drawn (00:00-23:59) Panel Collection date (DD/MMM/YYYY) Panel Lab ID

☐ Not Done If not done,please provide reason

☐ Not Applicable as Screening assessment was done less than 72 hours ago

Test Name:	Not Done	Result	Unit	Clinical Significance		
Glucose	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Blood Urea Nitrogen	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Creatinine	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Sodium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Potassium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Chloride	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Carbon Dioxide	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Albumin	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Alk Phosphatase	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
AST	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
ALT	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 1 Day 1) just Prior to instillation

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not done Collection Date _____ (DD/MMM/YYYY)

If not done, please provide reason: _____ Collection Time _____ (00:00 to 23:59)

Test		Result	Clinical Significance
Appearance (Color)	◯ Not Done	◯ colorless ◯ Pale Yellow ◯ Dark Yellow ◯ Amber ◯ Blue Green ◯ Pink ◯ Red ◯ Maroon	
Appearance (Clarity)	◯ Not Done	◯ clear ◯ hazy ◯ cloudy ◯ turbid ◯ Milky ◯ Small clots ◯ Medium clots ◯ Large clots	
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Ketones	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Specific Gravity	◯ Not Done	_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
pH	◯ Not Done	_____	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Please enter value/grading per dipstick report/kit

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Transurethral Resection of Bladder Tumor (Visit 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Date of TURBT _____
(DD/MMM/YYYY)

TURBT Start Time _____
(00:00 to 23:59)

TURBT Stop Time _____
(00:00 to 23:59)

Total Number of Lesions _____

Visualization Equipment
◯ White Light ◯ Blue Light with Optiview
◯ Narrow Band Imaging

Post resection Irrigation
◯ No irrigation ◯ Syringe Irrigation /flush till clear ◯ Continuous Bladder Irrigation

Lesion Site #	Location Code#	Size(cm)
1		
2		
3		
4		
5		
6		
7		
8		

OP Report uploaded to eCaselink:
◯ Yes
◯ No

Comments : _____

(Note:- All Histology specimens should be sent to local pathology laboratory, each lesion in separate specimen container identified by site & lesion number).

(If sending multiple specimens from same lesion please mark consistently as A. Lesion 1, left wall papillary tumor: B. Lesion 1 left wall, base of tumor and so on.)

 # Tumor Location Code:
T= Trigone R= Right Lateral Wall L=Left Lateral Wall
A= Anterior Wall P= Posterior Wall
D= Dome O= Other,Specify N= Not Specified B= Bladder Neck

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

RANDOMIZATION (Visit 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

Will patient be Randomized?

☐ No
☐ Yes

If no, provide reason

Randomization Date

(DD/MMM/YYYY)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Study Drug Instillation (Visit 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

Kit Number assigned:

Was instillation done ?

- ◯ Yes
- ◯ Not done due to significant bleeding ***(please record Hematuria on AE Page)***
- ◯ Not done due to non-target population
- ◯ Not done due to PUNLMP histology
- ◯ Not done due to bladder wall integrity/safety concern
- ◯ Not done due to Other reason, Specify _____

Was visual assessment of urine & urinalysis dip strip test carried out right before drug instillation ?

- ◯ Yes
- ◯ No

Any observations? _____

Was the bladder completely drained prior to drug instillation ?

- ◯ Yes
- ◯ No

Instillation Date

(DD/MMM/YYYY)

Time Study Drug Instillation Began:

(00:00-23:59)

Time Study Drug Drained from Bladder:

(00:00-23:59)

Please provide the clinical setting where instillation was performed?

- ◯ OR (Operation Room)
- ◯ RR (Recovery Room)
- ◯ Outpatient Office
- ◯ Other, Specify_____

Was the start of instillation at 60 minutes (+/-30 minutes) from end of TURBT?

- ◯ Yes
- ◯ No

If No, please give reason: _____

Volume of Instillate?

- ◯ 50 mL
- ◯ Other, Specify _____

If Other than 50 mL, give reason: _____

Was the study drug retained in bladder for 60 minutes (+/-5 minutes) ?

- ◯ Yes
- ◯ No

If No, please give reason: _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Pathology (Visit 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not Done

Report Date _____ (DD/MMM/YYYY)

Please provide the location codes*

WHO 2004

Lesion Site #	Location Code#	pT Staging*	Grade**	Muscularis Propria Presence
1				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
2				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
3				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
4				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
5				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
6				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
7				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
8				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist

Will patient receive additional intravesical therapy (e.g. BCG,Mitomycin) for bladder cancer based on this report?

◯ Yes *(If received report therapy on Concomitant Medication page)*

◯ No

Report uploaded to eCaselink?

◯ Yes

◯ No

Comments:

 # Tumor Site:
T= Trigone R= Right Lateral Wall L=Left Lateral Wall
A= Anterior Wall P= Posterior Wall
D= Dome O= Other,Specify N= Not Specified B= Bladder Neck

*** pT Stage Codes:**

pTX: Primary tumor cannot be assessed
pT0: No evidence of primary tumor
pTa: Noninvasive papillary carcinoma
pTis: Carcinoma in situ: "flat tumor"
pT1: Tumor invades lamina propria (subepithelial connective tissue)
pT2: Tumor invades muscularis propria (detrusor muscle)
pT2a: Tumor invades superficial muscularis propria (inner half)
pT2b: Tumor invades deep muscularis propria (outer half)
pT3: Tumor invades perivesical tissue
pT3a: Microscopically
pT3b: Macroscopically (extravesicular mass)
pT4: Tumor invades any of the following: prostatic stroma, seminal vesicles, uterus, vagina, pelvic wall, abdominal wall
pT4a: Extravesical tumor invades directly into prostatic stroma, uterus, or vagina
pT4b: Extravesical tumor invades pelvic wall, or abdominal wall

2004 WHO / ISUP Consensus Classification for Urothelial Lesions

Urothelial carcinoma in situ

Papillary urothelial carcinoma, low grade

Papillary urothelial carcinoma, high grade

Papillary urothelial neoplasm of low malignant potential

Urothelial papilloma

Inverted urothelial papilloma

Other

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Risk Assessment based on pathology review (Visit 1 Day 1)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Please choose based on the Highest Stage/Grade :

Target Population - Low Risk

- **PUNLMP*** ○
- **Solitary, Low Grade Ta, <= 3cm, Primary or if Recurrent over a year of last resection** ○

Target Population - Intermediate Risk

- **Solitary, Low Grade Ta, <=3cm , Recurrent within a year of last resection** ○
- **Solitary, Low Grade Ta ,> 3cm** ○
- **Solitary, High Grade Ta, <= 3cm, Primary** ○
- **Multiple, all Low Grade Ta** ○

Non-Target Population

- **Solitary, High Grade Ta, >3cm or Recurrent** ○
- **Multiple, High Grade Ta** ○
- **Low Grade T1** ○
- **High Grade T1** ○
- **CIS** ○
- **T2 or above** ○
- **With any variant histology, or any lymphovascular invasion, or any high-grade prostatic urethral involvement** ○
- **No Malignant tumor present** ○

(According to AUA Guidelines 2016)

Safety Follow Up/
Visit 2 Day 35

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Vital Signs (Visit 2 Day 35)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not Done

Date of Assessment _____
(DD/MMM/YYYY)

Body Temperature _____
(°C)

Blood Pressure _____
(mmHg)
Systolic / Diastolic

Heart Rate _____
(beats/minute)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

PHYSICAL EXAMINATION (Visit 2 Day 35)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Check if Physical Examination was not done.

If not done, please specify reason _____

Date of Examination _____
(DD/MMM/YYYY)

Were there any clinically significant abnormal findings?

☐ No
☐ Yes*

*** (Please record all clinically abnormal findings on the Adverse Events page.**

SAE and AE Reporting Guidelines

For all Consented patients during the screening process and TURBT.
Only Serious Adverse Events related to study procedures.

For patients who do not receive drug instillation at time of Day 1 TURBT
Only Serious Adverse Events related to study procedures, (screening and TURBT)

For all non-Target population patients, (received agent and discontinued after final pathology)
All AEs and SAEs from the time of study drug administration until Day 35 (±5 days) post-TURBT will be recorded and followed until resolution.

For Target population patients continuing the trial
All AEs and SAEs will be recorded from the time of study drug administration until the 3-month Follow-up Visit.
Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-Study.
Adverse events will be followed until resolution or back to baseline.)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Complete Blood Count (Visit 2 Day 35)

Panel Collection date _____ (DD/MMM/YYYY)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not Done Panel Lab ID _____ If not done,please provide reason _____ Panel Time Drawn _____ (00:00-23:59)

Test Name:	Not Done	Result	Unit	Clinical Significance		
WBC _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hemoglobin _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hematocrit _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Platelets _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form. For rest of the Visits, please list the Abnormal and Clinically Significant abnormality in Adverse Event form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Blood Chemistry (Visit 2 Day 35)

Protocol No.: SPI-QAP-306 Site No.: Patient No.: Panel Time Drawn (00:00-23:59) Panel Collection date (DD/MMM/YYYY) Panel Lab ID

☐ Not Done If not done,please provide reason

Test Name:	Not Done	Result	Unit	Clinical Significance		
Glucose	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Blood Urea Nitrogen	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Creatinine	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Sodium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Potassium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Chloride	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Carbon Dioxide	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Albumin	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Alk Phosphatase	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
AST	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
ALT	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 2 Day 35)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not done If not done, please provide reason: _____ Collection Date _____ (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Ketones	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Specific Gravity	◯ Not Done	_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
pH	◯ Not Done	_____	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 3 (Month 3)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date _____
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Vital Signs (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not Done If not done, please specify reason

Date of Assessment
(DD/MMM/YYYY)

Body Temperature
(°C)

Blood Pressure
(mmHg)
Systolic / Diastolic

Heart Rate
(beats/minute)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

PHYSICAL EXAMINATION (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Check if Physical Examination was not done.

If not done, please specify reason _____

Date of Examination _____

(DD/MMM/YYYY)

Were there any clinically significant abnormal findings?

☐ No

☐ Yes*

*** (Please record all clinically abnormal findings on the Adverse Events page.**

SAE and AE Reporting Guidelines

For all Consented patients during the screening process and TURBT.
Only Serious Adverse Events related to study procedures.

For patients who do not receive drug instillation at time of Day 1 TURBT
Only Serious Adverse Events related to study procedures, (screening and TURBT)

For all non-Target population patients, (received agent and discontinued after final pathology)
All AEs and SAEs from the time of study drug administration until Day 35 (±5 days) post-TURBT will be recorded and followed until resolution.

For Target population patients continuing the trial
All AEs and SAEs will be recorded from the time of study drug administration until the 3-month Follow-up Visit.
Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-Study.
Adverse events will be followed until resolution or back to baseline.)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Complete Blood Count (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: Patient No.: Panel Collection date (DD/MMM/YYYY)

☐ Not Done Panel Lab ID If not done,please provide reason Panel Time Drawn (00:00-23:59)

Test Name:	Not Done	Result	Unit	Clinical Significance		
WBC	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Hemoglobin	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Hematocrit	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Platelets	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.
For rest of the Visits, please list the Abnormal and Clinically Significant abnormality in Adverse Event form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Blood Chemistry (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: Patient No.: Panel Time Drawn (00:00-23:59) Panel Collection date (DD/MMM/YYYY) Panel Lab ID

☐ Not Done If not done,please provide reason

Test Name:	Not Done	Result	Unit	Clinical Significance		
Glucose	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Blood Urea Nitrogen	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Creatinine	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Sodium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Potassium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Chloride	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Carbon Dioxide	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Albumin	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Alk Phosphatase	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
AST	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
ALT	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 3 Month 3)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Ketones	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Specific Gravity	◯ Not Done		☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
pH	◯ Not Done		☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 4 (Month 6)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 4 Month 6)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 4 Month 6)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 4 Month 6)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 5 (Month 9)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 5 Month 9)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 5 Month 9)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 5 Month 9)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 6 (Month 12)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 6 Month 12)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 6 Month 12)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date _____
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 6 Month 12)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not don If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 7 (Month 15)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 7 Month 15)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 7 Month 15)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date _____
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 7 Month 15)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 8 (Month 18)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 8 Month 18)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 8 Month 18)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date _____
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 8 Month 18)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 9 (Month 21)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 9 Month 21)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 9 Month 21)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date _____
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 9 Month 21)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 10 (Month 24)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 10 Month 24)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 10 Month 24)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date _____
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 10 Month 24)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 11 (Month 30)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 11 Month 30)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 11 Month 30)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 11 Month 30)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 12 (Month 36)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 12 Month 36)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ◯ No
- ◯ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ◯ No
- ◯ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 12 Month 36)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 12 Month 36)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 13 (Month 42)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 13 Month 42)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 13 Month 42)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 13 Month 42)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 14 (Month 48)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 14 Month 48)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 14 Month 48)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 14 Month 48)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 15 (Month 54)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 15 Month 54)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 15 Month 54)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 15 Month 54)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Visit 16 (Month 60)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Visit 16 Month 60)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Visit 16 Month 60)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Mark if not done

If not done, please specify reason:

Collection Date
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Visit 16 Month 60)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

End of Study

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

End of Study

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Date patient completed/ withdrew from study: _____

(DD/MMM/YYYY)

Did patient complete protocol-specified treatment and all follow-up visits ?

☐ No

☐ Yes

If No, discontinued due to *(check one box)*:

◯ It is determined by Day 1 pathology review that the patient has histology other than low- to intermediate- risk NMIBC

◯ Development of an adverse event (AE) (**Please enter in AE CRF**)

◯ Withdrawal of consent

◯ Investigator decision, Specify_____

◯ Sponsor decision

◯ The patient refuses further follow-up study procedures, including cystoscopy

◯ The patient is lost to follow-up (missed at least two consecutive follow-up cystoscopies)

◯ Patient has a cystectomy

◯ Patient has a histologically confirmed recurrence

◯ Death (please complete death form)

◯ Pregnancy

◯ The study drug was not instilled on Day 1, Specify reason_____

◯ Other, specify_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Death

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Date of Death _____
(DD/MMM/YYYY)

Cause of Death:

- ◯ Disease Progression
- ◯ Adverse Event* (***Please enter in AE CRF***)
- ◯ Other, specify:_____

*** (Please record all clinically abnormal findings on the Adverse Events page. Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-Study.)**

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Investigator Verification

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

◯ Yes ◯ No

I have reviewed laboratory and imaging data as well as documentation of data changes. I approve the completed CRFs.

Principle Investigator's Signature _____ Date: _____
(DD/MMM/YYYY)

Print Name: _____

Adverse Events & Concomitant Medications

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Adverse Events

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Check if No AEs occurred

Row: _____ Adverse Event Term*: _____ SAE[5] ☐ No ☐ Yes

Start Date: _____ (DD/MMM/YYYY) Stop Date: _____ (DD/MMM/YYYY) ☐ Ongoing

SAE Category[5]:
- ◯ Fatal
- ◯ Life-threatening
- ◯ Initial or prolonged Hospitalization
- ◯ Disability or Permanent Damage
- ◯ Congenital Anomaly/Birth Defect
- ◯ Other Important Medical Events

Dose Related Action(s) Taken:[1] _____ Severity [2] _____

Outcome:[3] _____ Relationship to Study Drug[4] _____ Was Treatment Given?[6] ☐ No ☐ Yes

Are there additional Adverse Events: ☐ Yes

[1]Dose Related Action Taken Codes:	[2]Event Grade Codes CTCAE (4.03):	[3]Outcome Codes:	[4]Relationship Codes:
0 = Dose Not Changed 1 = Dose Reduced 2 = Drug Interrupted 3 = Drug Withdrawn 7 = Dose Delayed	1 = Mild 2 = Moderate 3 = Severe 4 = Life-threatening/Disabling 5 = Fatal	1 = Recovered/Resolved 2 =Recovered/ Resolved with sequelae 3 = Not Resolved 4 = Fatal 5 = Unknown	0 = Not Related 1 = Unlikely Related 2 = Possibly Related 3 = Probably Related 4 = Definitely Related

[5]SAEs (regardless of their relationship to study treatment) are to be reported and the serious adverse event report (SAER) faxed or e-mailed within 24 hours of knowledge of the event to:**Spectrum Pharmaceuticals, Inc.Primary Contact: Pharmacovigilance Department Fax: +1 (949) 861-6599 E-mail: drugsafety@sppirx.com**

[6]If treatment was given, enter on Concomitant Medication CRF page

(*SAE and AE Reporting Guidelines

For all Consented patients during the screening process and TURBT.
Only Serious Adverse Events related to study procedures.

For patients who do not receive drug instillation at time of Day 1 TURBT
Only Serious Adverse Events related to study procedures, (screening and TURBT)

For all non-Target population patients, (received agent and discontinued after final pathology)
All AEs and SAEs from the time of study drug administration until Day 35 (±5 days) post-TURBT will be recorded and followed until resolution.

For Target population patients continuing the trial
All AEs and SAEs will be recorded from the time of study drug administration until the 3-month Follow-up Visit.
Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-Study.
Adverse events will be followed until resolution or back to baseline.)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Concomitant Medications

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Check if No Medications were given

Row: _____ Medication: _____ Dose _____ Unit: _____ Dosing Frequency _____

Prophylaxis ☐ Indication for Use: _____

Route: ☐ Oral ☐ Subcutaneous ☐ Intravenous ☐ Intramuscular ☐ Inhalation

☐ Topical ☐ Nasal ☐ Intraocular ☐ OTHER: Specify: _____

Start Date: _____ (DD/MMM/YYYY) Stop Date: _____ (DD/MMM/YYYY) ☐ Continuing

Are there additional Concomitant Medications? ☐ Yes

Unscheduled forms

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Vital Signs (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not Done If not done, please specify reason

Date of Assessment
(DD/MMM/YYYY)

Body Temperature
(°C)

Blood Pressure
(mmHg)
Systolic / Diastolic

Heart Rate
(beats/minute)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

PHYSICAL EXAMINATION (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Check if Physical Examination was not done.

If not done, please specify reason _____

Date of Examination _____

(DD/MMM/YYYY)

Were there any clinically significant abnormal findings?

☐ No

☐ Yes*

*** (Please record all clinically abnormal findings on the Adverse Events page.**

SAE and AE Reporting Guidelines

For all Consented patients during the screening process and TURBT.
Only Serious Adverse Events related to study procedures.

For patients who do not receive drug instillation at time of Day 1 TURBT
Only Serious Adverse Events related to study procedures, (screening and TURBT)

For all non-Target population patients, (received agent and discontinued after final pathology)
All AEs and SAEs from the time of study drug administration until Day 35 (±5 days) post-TURBT will be recorded and followed until resolution.

For Target population patients continuing the trial
All AEs and SAEs will be recorded from the time of study drug administration until the 3-month Follow-up Visit.
Only deaths and AEs related to study procedures will be recorded from the 3 month visit until the End-of-Study.
Adverse events will be followed until resolution or back to baseline.)

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Complete Blood Count (Unscheduled)

Panel Collection date _____ (DD/MMM/YYYY)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not Done Panel Lab ID _____ If not done,please provide reason _____ Panel Time Drawn _____ (00:00-23:59)

Test Name:	Not Done	Result	Unit	Clinical Significance (where NCS-Abnormal, Not Clinically Significant & CS- Abnormal &Clinically Significant)		
WBC _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hemoglobin _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Hematocrit _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS
Platelets _____	☐ Not Done	Result: _____	Unit: _____	◯ Normal	◯ NCS	◯ CS

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Blood Chemistry (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: Patient No.: Panel Time Drawn (00:00-23:59) Panel Collection date (DD/MMM/YYYY) Panel Lab ID

☐ Not Done If not done,please provide reason

Test Name:	Not Done	Result	Unit	Clinical Significance		
Glucose	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Blood Urea Nitrogen	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Creatinine	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Sodium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Potassium	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Chloride	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Carbon Dioxide	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Albumin	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
Alk Phosphatase	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
AST	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS
ALT	☐ Not Done	Result:	Unit:	◯ Normal	◯ NCS	◯ CS

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

Note: At Screening visit, please list the Abnormal and Clinically Significant abnormality in Medical History form.

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Cystoscopy (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Exam Date _____
(DD/MMM/YYYY)

Were any lesions seen?
- ☐ Yes
- ☐ No

Total number of lesions noted : _____

Were any other abnormalities seen?
- ○ No
- ○ Yes

If Yes, explain:_____

OP Report uploaded to eCaselink?
- ○ No
- ○ Yes

Comments:_____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Cytology (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Mark if not done

If not done, please specify reason: _____

Collection Date _____
(DD/MMM/YYYY)

Urine Cytology Results?

- ◯ Positive or suspicious for High Grade Malignancy *
- ◯ Negative, No evidence of Malignancy
- ◯ Other, Specify_____

If Cystoscopy negative & Cytology marked as positive *

Were any enhanced imaging techniques used to determine source?

- ◯ Yes
- ◯ No, Please specify reason_____

If Yes

Collection Date _____
(DD/MMM/YYYY)

Was the source determined by enhanced imaging techniques per Institute Standard of Care ?

- ◯ Yes, Source is Upper Tract or Urethra
- ◯ Yes, Source is Bladder
- ◯ Source could not be determined

Any other findings _____

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Urine Dipstick (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: Patient No.:

☐ Not done If not done, please provide reason: Collection Date (DD/MMM/YYYY)

Test		Result	Clinical Significance
Glucose	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Ketones	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Specific Gravity	◯ Not Done		☐ CS ☐ NCS ☐ Normal
Blood	◯ Not Done	◯ Negative ◯ Trace ◯ Moderate ◯ Trace ◯ Value*_____ Non-Hemolyzed Hemolyzed	☐ CS ☐ NCS ☐ Normal
pH	◯ Not Done		☐ CS ☐ NCS ☐ Normal
Protein	◯ Not Done	◯ Negative ◯ Trace ◯ Value*_____	☐ CS ☐ NCS ☐ Normal
Nitrite	◯ Not Done	◯ Negative ◯ Positive	☐ CS ☐ NCS ☐ Normal
Leukocytes	◯ Not Done	◯ Negative ◯ Value*_____	☐ CS ☐ NCS ☐ Normal

Where, NCS - Abnormal, Not Clinically Significant and CS - Abnormal &Clinically Significant

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Transurethral Resection of Bladder Tumor (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

Date of TURBT _____
(DD/MMM/YYYY)

TURBT Start Time _____
(00:00 to 23:59)

TURBT Stop Time _____
(00:00 to 23:59)

Total Number of Lesions _____

Visualization Equipment
◯ White Light ◯ Blue Light with Optiview
◯ Narrow Band Imaging

Post resection Irrigation
◯ No irrigation ◯ Syringe Irrigation /flush till clear ◯ Continuous Bladder Irrigation

Lesion Site #	Location Code#	Size(cm)
1		
2		
3		
4		
5		
6		
7		
8		

OP Report uploaded to eCaselink:
◯ Yes
◯ No

Comments : _____

(Note:- All Histology specimens should be sent to local pathology laboratory, each lesion in separate specimen container identified by site & lesion number).

(If sending multiple specimens from same lesion please mark consistently as A. Lesion 1, left wall papillary tumor: B. Lesion 1 left wall, base of tumor and so on.)

 # Tumor Location Code:
T= Trigone R= Right Lateral Wall L=Left Lateral Wall
A= Anterior Wall P= Posterior Wall
D= Dome O= Other,Specify N= Not Specified B= Bladder Neck

SPECTRUM PHARMACEUTICALS
Redefining Cancer Care

Pathology (Unscheduled)

Protocol No.: SPI-QAP-306 Site No.: _____ Patient No.: _____

☐ Not Done

Date of sample collection _____ (DD/MMM/YYYY)

Report Date _____ (DD/MMM/YYYY)

Please provide the location codes*

WHO 2004

Lesion Site #	Location Code#	pT Staging*	Grade**	Muscularis Propria Presence
1				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
2				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
3				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
4				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
5				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
6				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
7				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist
8				◯ Muscle Present ◯ Muscle Absent ◯ Cannot be determined (explain)_____ ◯ Muscle not commented upon by pathologist

Will patient receive additional intravesical therapy (e.g. BCG,Mitomycin) for bladder cancer based on this report?

◯ Yes *(If received report therapy on Concomitant Medication page)*

◯ No

Report uploaded to eCaselink?

◯ Yes

◯ No

Comments:

 # Tumor Site:
T= Trigone R= Right Lateral Wall L=Left Lateral Wall
A= Anterior Wall P= Posterior Wall
D= Dome O= Other,Specify N= Not Specified B= Bladder Neck

*** pT Stage Codes:**

pTX: Primary tumor cannot be assessed
pT0: No evidence of primary tumor
pTa: Noninvasive papillary carcinoma
pTis: Carcinoma in situ: "flat tumor"
pT1: Tumor invades lamina propria (subepithelial connective tissue)
pT2: Tumor invades muscularis propria (detrusor muscle)
pT2a: Tumor invades superficial muscularis propria (inner half)
pT2b: Tumor invades deep muscularis propria (outer half)
pT3: Tumor invades perivesical tissue
pT3a: Microscopically
pT3b: Macroscopically (extravesicular mass)
pT4: Tumor invades any of the following: prostatic stroma, seminal vesicles, uterus, vagina, pelvic wall, abdominal wall
pT4a: Extravesical tumor invades directly into prostatic stroma, uterus, or vagina
pT4b: Extravesical tumor invades pelvic wall, or abdominal wall

2004 WHO / ISUP Consensus Classification for Urothelial Lesions

Urothelial carcinoma in situ

Papillary urothelial carcinoma, low grade

Papillary urothelial carcinoma, high grade

Papillary urothelial neoplasm of low malignant potential

Urothelial papilloma

Inverted urothelial papilloma

Other