

Research Coordinator: Camille Biggins (540-4723) or x1646

Data Coordinator (for Holter monitor): Nina Lee (314-2106) or x8250

BLU-667-1101 / C1D1 & C1D15 / Example of CTU Schedule

10:00	Holter monitor administered by research staff (must be done 30 min before pre-dose Holter observation)
10:15	Single EKG-B (must be done within 1 hour before pre-dose PK)
10:30 – 11:30	Patient supine (Pre-dose Holter observation)
11:15	Pre-Dose PK
11:30	***BLU-667 DOSING***
11:50-12:00	Patient supine (30MIN post-dose Holter observation)
12:00	30MIN post-dose PK (\pm 5 min)
12:20-12:30	Patient supine (1HR post-dose Holter observation)
12:30	1HR post-dose PK (\pm 5 min)
13:20-13:30	Patient supine (2HR post-dose Holter observation)
13:30	2HR post-dose PK (\pm 5 min)
14:30	4HR Single EKG-B (must be done within 1 hour before 4HR post-dose PK)
15:20-15:30	Patient supine (4HR post-dose Holter observation)
15:30	4HR post-dose PK (\pm 10 min)
17:20-17:30	Patient supine (6HR post-dose Holter observation)
17:30	6HR post-dose PK (\pm 10 min)
19:20-19:30	Patient supine (8HR post-dose Holter observation)
19:30	8HR post-dose PK (\pm 10 min)
20:00	Holter monitor discontinued by CTU staff (must be done 30 min after 8HR Holter observation)

Notes (Copied from Study Protocol):

- When the timing of a PK sample coincides with the timing of an EKG-B, the EKG-B will be completed within 1 hour prior to the collection of the PK.
- When the timing of a PK sample coincides with the timing of a Holter extraction, the Holter extraction will be completed within 15 minutes prior to the collection of the PK sample. PK samples should not be drawn until the Holter extraction period has passed.

Biggins, Camille P

From: Biggins, Camille P
Sent: Thursday, September 20, 2018 10:33 AM
To: [Redacted]
Subject: Schedule Overview of Cycle 1
Attachments: Pt Paper Diary App.pdf

Hello Mr. [Redacted],

I have attached a paper copy of your eDiary here, in case you encounter technical problems with the eDiary app. Below please find an overview of your appointment schedule here at the SCCA for **Cycle 1** of the [Redacted] investigational treatment.

Note: Unless otherwise indicated, please do not take your morning dose on the days you are scheduled for an SCCA visit. Instead, bring your SGN-2FF materials with you to the clinic. The CTU nurse will administer the study drug.

Cycle 1, Day 1: Thursday, 9/20

- **7:00 AM** Blood draw (1st floor, Alliance Lab)
- **8:00 AM** Provider visit w/ **Dr. Santana-Davila** to clear you for treatment (**4th Floor**)
- **9:40 AM** Infusion visit (**5th floor, Clinical Trials Unit**)
 - Be sure to check in with Pharmacy to pick up your SGN-2FF study drug
 - CTU nurse will administer SGN-2FF
 - Research blood draw
 - Pre-Dose
 - 30 Min Post-Dose
 - 1 Hour Post-Dose
 - 2 Hour Post-Dose
 - 4 Hour Post-Dose
 - 6 Hour Post-Dose
 - 8 Hour Post-Dose

Cycle 1, Day 2: Friday, 9/21

- **11:10 AM** Infusion visit (**5th floor Clinical Trials Unit**)
 - CTU nurse will administer SGN-2FF
 - Research blood draw
 - Pre-Dose
 - 30 Min Post-Dose

Cycle 1, Day 4: Monday, 9/24

- **Note: If appropriate, you may self-administer your morning dose at home on this day, but have the CTU nurse administer your evening dose in clinic.**
- **3:10 PM** Infusion visit (**5th floor Clinical Trials Unit**)
 - CTU nurse will administer SGN-2FF
 - Research blood draw
 - Pre-Dose
 - 30 Min Post-Dose

Cycle 1, Day 8: Thursday, 9/27

- **8:30 AM** Blood draw (**1st floor, Alliance Lab**)
- **2:20 PM** Infusion visit (**5th floor, Clinical Trials Unit**)
 - CTU nurse will administer SGN-2FF
 - Research blood draw
 - Pre-Dose
 - 30 Min Post-Dose

Cycle 1, Day 15: Thursday, 10/4

- **7:00 AM** Blood draw (**1st floor, Alliance Lab**)
- **8:00 AM** Provider visit w/ **Katie Weaver, ARNP** to clear you for treatment (**4th Floor**)
- **9:30 AM** Infusion visit (**5th floor, Clinical Trials Unit**)
 - Be sure to check in with Pharmacy to pick up your SGN-2FF study drug
 - CTU nurse will administer SGN-2FF
 - Research blood draw
 - Pre-Dose
 - 30 Min Post-Dose
 - 1 Hour Post-Dose
 - 2 Hour Post-Dose
 - 4 Hour Post-Dose
 - 6 Hour Post-Dose

Cycle 1, Day 22: Thursday, 10/11

- ***Note: You may self-administer your morning dose at home.***
- **9:00 AM** Blood draw (**1st floor, Alliance Lab**)

Cycles 2+, Day 1: (Schedule Not Available)

- Blood draw (**1st floor, Alliance Lab**)
- Provider visit to clear you for treatment
- Infusion visit
 - Be sure to check in with Pharmacy to pick up your SGN-2FF study drug
 - CTU nurse will administer SGN-2FF
 - Research blood draw
 - Pre-Dose
 - 30 Min Post-Dose

Cycles 2+, Day 15: (Schedule Not Available)

- Blood draw (**1st floor, Alliance Lab**)
- Provider visit to clear you for treatment
- Be sure to check in with Pharmacy to pick up your SGN-2FF study drug

Cycle 2, Day 22: (Schedule Not Available)

- Blood draw (**1st floor, Alliance Lab**)

Please don't hesitate to contact me should any additional questions arise.

Kind regards,
Camille

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Camille A. Biggins
Research Coordinator

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