NCT#: 04228445

To: PVP-19IC01 Principal Investigators

From: Provepharm PVP-19IC01 Study Team

RE: Removal of Pharmacokinetic sub study from protocol PVP-19IC01 amendment #2: An Open-Label, Randomized, Multicenter Study to Evaluate the Safety, Efficacy, Pharmacokinetics and Physician Satisfaction of Two Different Doses of 3,3'-Dioxo-2,2'-bisindolylidene-5,5'-disulfonate disodium 0.8% Solution When Used as an Aid in the Determination of Ureteral Patency.

This Clarification Letter is to remove the pharmacokinetic (PK) sub-study from the PVP-19IC01 protocol, Amendment # 2 dated 02 September 2020.

This protocol specifies that PK samples of plasma, urine and stool will be collected from a subset of approximately 16 subjects from 2 participating PK sites.

Zero patients have been enrolled into the PK sub study due to the difficulty in recruiting patients for the clinical trial during the COVID-19 emergency. Additionally, the logistical complexity involved with conducting the PK portion has made it challenging for the 2 sites to recruit consenting subjects. Therefore, the recruitment of patients for the PK sub study of the trial will be discontinued. A separate PK study will be conducted to obtain the necessary PK data.

Additionally, it was noted that the header of the approved protocol amendment 2, starting at page 19 through the end of the protocol, references the year 2019. The correct year should be 2020.

Please sign and date in the acknowledgment section below, return a copy of the signed document to Provepharm, Inc. and file the original in the current protocol section of your investigational site file.

Approvals:

Sponsor

[redacted]
Director, Clinical Operations
[redacted]

[redacted]
Signature and Date

Medical Monitor

[redacted]

[redacted]
Signature and Date

Acknowledged:

Principal Investigator:

Printed Name Signature and Date