

**Clinical Study No.:**  
**ABCDEFG**

Patient Identification Number |\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_|

*Phase 2, proof-of-concept, randomized, double-blinded,  
placebo-controlled, multicenter study to assess efficacy  
and safety of jklmn as add-on therapy to standard of care  
in adult patients with AAAA (aaa)*

## **Case Report Form**

**DM (Demographics)****DS (Disposition)****SE (Subject Elements)**

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ETCD=SCRN

ELEMENT=SCREENING

**REGISTRATION / INFORMED CONSENT**

SITEID

Patient Identification Number (derived)

|\_\_\_\_\_|

SUBJID

Is the patient able to provide written informed consent  
signature?

 Yes    No

SUPPDS.QVAL where QNAM=CONSPAT

If Yes, date of written informed consent signature from patient  
(dd-MMM-yyyy) [DSTERM = Informed Consent Obtained from Patient]

RFICDTC

DSSDTC

SESTDTC

If No, date of written informed consent signature from legally  
authorized representative (dd-MMM-yyyy) [DSTERM = Informed Consent Obtained from Guardian]

DSCAT = PROTOCOL MILESTONE

**DM (Demographics)****RP (Reproductive System Findings)**

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**SV (Subject Visits)****VS (Vital Signs)**

Patient Identification Number \_\_\_\_\_

**Screening day -1 or 1****VISIT = Screening****SVSTDTC****SVENDTC**

Visit Date/Time (dd-MMM-yyyy HH:mm)

\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|  
\_\_\_\_\_|:\_\_\_\_|**DEMOGRAPHY**

Date of Birth (dd-MMM-yyyy)

\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|**BRTHDTC***Please record at least the year in case the law in your country does not allow to insert the complete date of birth (i.e., UN-UNK-YYYY)***AGEU=YEARS**

Age (years)

\_\_\_\_\_|**AGE**

Age (years) (derived)

\_\_\_\_\_|

Sex

 Male     Female **SEX****RPTESTCD = CHILDPOT****RPORRES=Y**

If female, childbearing potential status:

 Childbearing potential    **RPORRES=Y**  
 Postmenopausal with no menstrual bleeding for at least one year prior to study start    **RPORRES=N** Surgically sterilized    **RPORRES=N**

**SUPPRP.QVAL when QNAM=NCPREAS,  
RPORRES=N**

Contraception method  
(check all that apply)**RPTESTCD=CONTMET****RPTEST=Contraception Method** None  
 Hormonal contraception, systemic, implantable, transdermal, or injectable contraceptives from at least 2 months before the screening visit until 30 days after the last IMP dose A sterile sexual partner Abstinence Other, specify: \_\_\_\_\_**RPORRES**  
(one row for each option checked)**SUPPRP.QVAL when QNAM=OTHCM  
QLABEL=Other contraception method**Self-reported race/ethnicity  
(check all that apply)**RACE** White  
 Black or African American  
 Asian  
 Hispanic / Latino  
 Other, specify: \_\_\_\_\_**SUPPDMD.QVAL when QNAM=RACEOTH****VSORRES**    **VSORRESU=cm**    **VSORRESU=kg****VSTEST = Height**

Height (cm)

\_\_\_\_\_|**VSORRES****VSTEST = Weight**

Body weight (kg)

\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|\_\_\_\_\_|**VSORRES****VSORRESU=cm****VSORRESU=kg****VSSTRESU=kg***Note for programmer: Date of Birth will be a partial date to the Year. Age will be derived if full DOB is recorded, age won't be derived and manually entered by the clinical site if full DOB is not recorded.*