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

Clinical Study No.:
ABCDEFG

Patient Identification Number |___|___|___|___|___|___|

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

SV = Subject Visits

VS = Vital Signs

Clinical Study No.:
ABCDEFG

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

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
SUPPRP.QVAL when SUPPRP.QNAM=NCPREAS, RPORRES=N   ❑ Surgically sterilized   RPORRES=N

Contraception method (check all that apply)   ❑ 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
RPTESTCD=CONTMET
RPTEST=Contraception Method   ❑ A sterile sexual partner   RPORRES (one row for each option checked)
❑ Abstinence
❑ Other, specify: _____   SUPPRP.QVAL when QNAM=OTHCM QLABEL=Other contraception method

Self-reported race/ethnicity (check all that apply) RACE   ❑ White
❑ Black or African American   (if more than 1 race selected, RACE=MULTIPLE and add one SUPPDM.QNAM=RACEx for each race selected)
❑ Asian
❑ Hispanic / Latino
❑ Other, specify: _____   SUPPDM.QVAL where QNAM=RACEOTH

VSTEST = Height
Height (cm) |___|___|___| VSORRES   VSORRESU, VSSTRESU=cm
VSTEST = Weight
Body weight (kg) |___|___|___|.|___| VSORRES   VSORRESU, 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.