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)

Clinical Study No.:
ABCDEFG

ETCD=SCRN

ELEMENT=SCREENING

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

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
❑ Surgically sterilized RPORRES=N

SUPPRP.QVAL when SUPPRP.QNAM=NCPREAS, 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
❑ A sterile sexual partner
❑ Abstinence
❑ Other, specify: _____

RPTESTCD=CONTMET
RPTEST=Contraception Method
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: _____

(if more than 1 race selected, RACE=MULTIPLE and add one SUPPDM.QNAM=RACEx for each race selected)
SUPPDM.QVAL when QNAM=RACEOTH

VSTEST = Height
Height (cm) |___|___|___| VSORRES VSORRESU=cm VSORRESU=cm

VSTEST = Weight
Body weight (kg) |___|___|___|.|___| VSORRES 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.