

Clinical Study No.:
ABCDEFGH

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

Clinical Study No.:
ABCDEFGH

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

Clinical Study No.:
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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)

____-____-____

BIRTHDTC

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

RPTSTCD = 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)

RPTSTCD=CONTMET

RPTST=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

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

☐ 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 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.