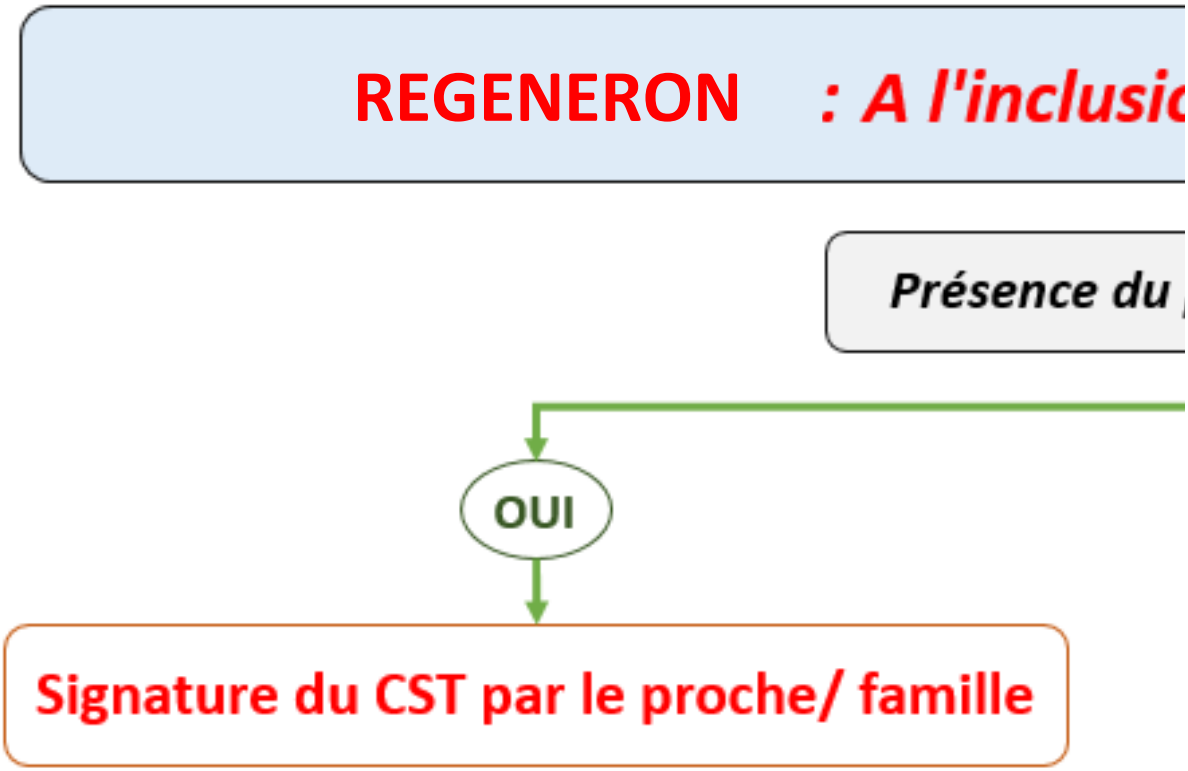
REGENERON : Phase 2, multicenter, randomi
group, POC study of a single IV dose of RE
hypotension who are



CRITERES D'INCLUSION

1. Patients entre 18 et 85 ans.
2. Infection prouvée ou suspectée, définie par l'administration ou la p
3. Hypotension induite par le sepsis ne répondant pas aux fluides IV (≥
à une dose d'au moins 0,2 µg/kg/min NAD, avec une PAM ≥ 65 mmH
randomisation.
4. Critères à remplir pendant 2 heures consécutives avant la randomi
   - PAM ≥ 65 mmHg, cible 65-75 mmHg
   - 1 ou 2 vasopresseurs, dose combinée entre 0,1 et 1,0 µg

- 1 ou 2 vasopresseurs, dose combinée entre 0,1 et 1,0 µg
- Pas de changement du nombre de vasopresseurs

CRITERES D'EXCLUSION

1. Unable to obtain informed consent by participant or LAR (according to country- and IRB/E
2. Unwilling or unable to comply with clinic visits and study-related procedures.
3. Clinical status requires vasopressor and/or BP management inconsistent with the study pr
4. Anticipated to discontinue vasopressors within 48 hours of randomization in the opinion c
5. **Planned procedure (eg, surgery) within 24 hours of randomization.**
6. **Receiving continuous neuromuscular blockade** during the screening period.
7. Primary cause of hypotension suspected to be due to non-sepsis cause (eg, hemorrhage, b
8. **Ejection fraction <20%** in the most recent known echocardiogram.
9. **Acute coronary syndrome based on clinical symptoms and/or ECG during hospitalization**
10. History of hospitalization due to heart failure, myocardial infarction, stroke, clinically sign transient ischemic attack, or unstable angina within the preceding 3 months
11. Any prior diagnosis of severe pulmonary hypertension meeting one or more of the follow
    a. Echocardiographic evidence of more than moderate pulmonary hypertensi echocardiogram prior to or during the screening period, or
    b. Severe right ventricular dilation/hypertrophy or flattening of the interventr prior to or during the screening period, or
    c. Mean pulmonary artery pressure >40 mm Hg by right heart catheterization
12. Receiving 3 or more vasopressors, during the screening period or at the time of study dru
13. Combined vasopressor dose exceeds 2 µg/kg/min NED during the screening period or at
14. **Cirrhosis with Child-Pugh Score ≥10** or acute hepatic failure with MELD score of ≥30.
15. **On ECMO** or other extracorporeal therapy during the screening period or at the time of s
16. **Expected death within 24 hours.**
17. **Chronic mechanical ventilation for any reason** or severe chronic obstructive pulmonary exacerbation of COPD) prior to hospital admission.
18. Received bone marrow transplant during the preceding 6 months or chemotherapy durir
19. Known allergy or hypersensitivity to components of the study drug.
20. Prior enrollment in this study.
21. **Decision to limit full care taken before obtaining informed consent** (eg, do not resuscita
22. Members of the clinical site study team and/or their immediate family unless prior appro
23. Pregnant or breastfeeding women.
24. Women of childbearing potential (WOCBP)* who are unwilling to practice highly effectiv contraceptive measures include:

a. Stable use of combined (estrogen and progestogen containing) hormonal c
injectable, implantable) associated with inhibition of ovulation initiated 2 or more menstrual

b. Intrauterine device; intrauterine hormone-releasing system;

c. Bilateral tubal occlusion/ligation;

d. Vasectomized partner (provided that the male vasectomized partner is the
obtained partner of the WOCBP study participant and that the vasectomized partner has obt

e. sexual abstinence†, ‡.

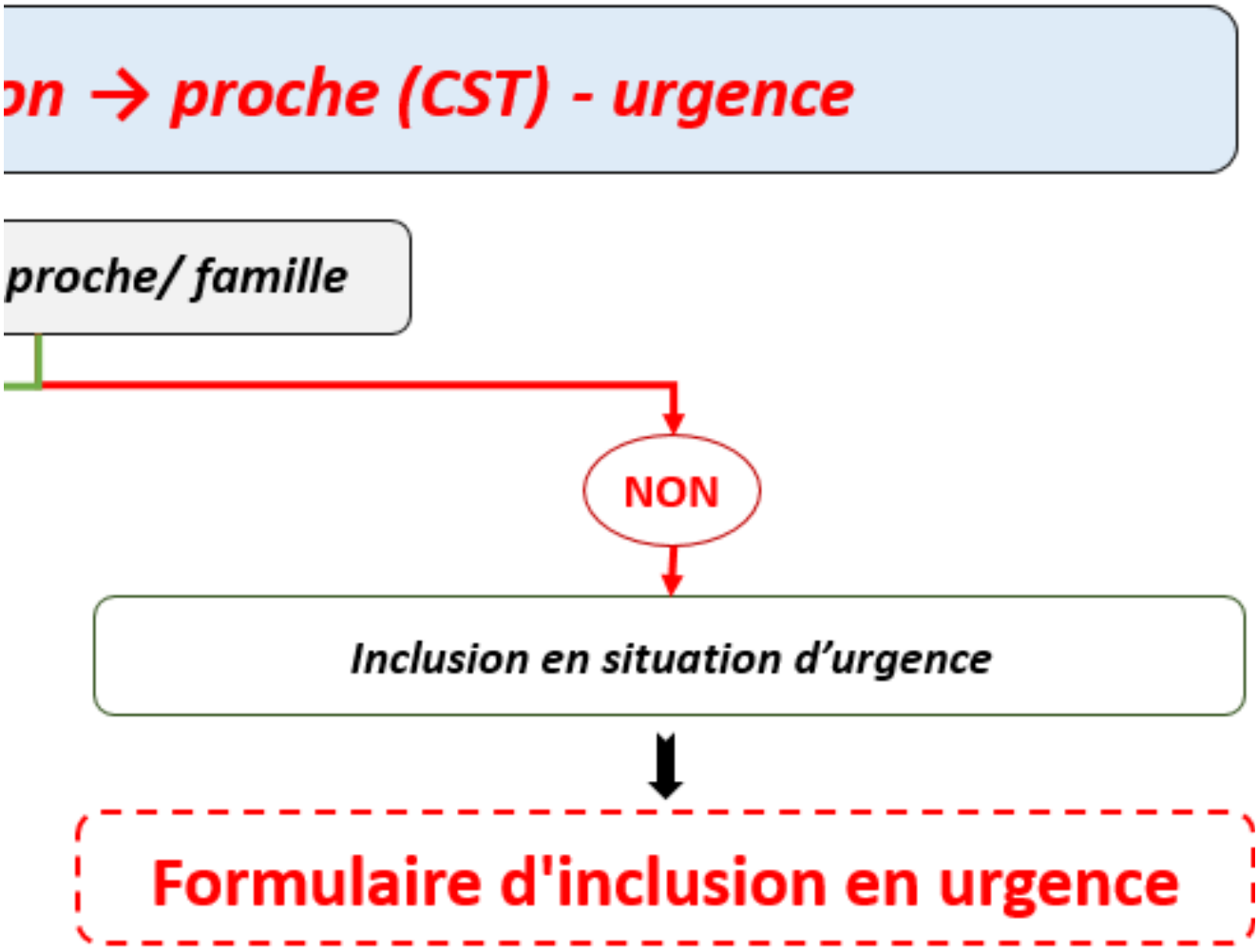
25. Sexually active adult men who are unwilling to use the following forms of medically acce
success, for at least 90 days following study drug administration.

26. Is committed to an institution by virtue of an order issued either by the judicial or the ad

27. Presents any concern to the study investigator that might confound the results of the stu

28. Participated in any clinical research study evaluating another investigational drug includi
(whichever is longer) of an investigational biologic drug, or within at least 4 weeks for other

ized, double-blind, placebo-controlled, parallel
:GN7544 in participants with sepsis-induced
: receiving SOC therapy.



olanification d'une antibiothérapie pendant la période de screening.
≥ 20 ml/kg de cristalloïdes), sous 1 ou 2 vasopresseurs
Hg (cible : 65-75 mmHg) pendant au moins 2 heures consécutives avant la

isation :

g/kg/min NED

g/kg/min NED

C-specific regulations).

rotocol

of the investigator

burns, or cardiogenic shock), including shock after cardiac arrest.

n (eg, ST elevation myocardial infarction).
nificant ventricular arrhythmia (eg, sustained VT requiring medication adjustments or cardioversion),

ving criteria:
on, defined as an estimated right ventricular systolic pressure ≥55 mm Hg on the most recent

ricular septum consistent with severe pulmonary hypertension on the most recent echocardiogram

within the past year, if available.

ug administration

the time of study drug infusion

study drug adminiastration

disease (COPD) requiring either continuous daily oxygen use or mechanical ventilation (for acute

ng the preceding 30 days for lymphoma or leukemia.

ate, do not intubate)

oval granted by the sponsor.

e contraception for at least 90 days following study drug administration. Highly effective

ontraception (oral, intravaginal, transdermal) or progestogen-only hormonal contraception (oral,
l cycles prior to screening;

sole sexual partner of the WOCBP study participant and that the vasectomized partner has
tained medical assessment of surgical success for the procedure); and/or

ptable birth control: consistent use of a condom OR vasectomy with medical assessment of surgical

ministrative authorities.
udy or poses an additional risk to the participant by their participation in the study.
ng biologics or therapy, including specific immunotherapy, within 90 days or at least 5 halflives
investigational drug, prior to the screening visit.