

Inclusion criteria

Patients meeting the following criteria will be considered for inclusion into the trial:

1. Age ≥ 18 years
2. Planned for one of the following types of open chest cardiovascular surgery with the use of CPB:
 - a. 1) combined valve and CABG surgery 2) aortic valve plus aortic root and/or ascending aorta (excluding aortic arch)
 - b. CABG with 3 or more distal anastomoses
3. Screening eGFR ≥ 25 mL/min/1.73m² and ≤ 65 mL/min/1.73m² (calculated at Screening using sCreat which can be maximally 28 days old and the 2021 CKD-EPI formula [1] without race correction ($\text{eGFR} = 142 \times \text{Min}(\text{Scr}/\kappa, 1)^{\alpha} \times \text{Max}(\text{Scr}/\kappa, 1)^{-1.200} \times 0.9938^{\text{Age}}$ [$\times 1.012$ if female]))
4. Female patients of childbearing potential agreeing to use one of the following effective contraception methods within IP treatment and 14 days thereafter:
 - a. combined (oestrogen and progestogen containing) hormonal contraception associated with inhibition of ovulation (oral, intravaginal, transdermal)
 - b. progestogen-only hormonal contraception associated with inhibition of ovulation (oral, injectable, implantable)
 - c. intrauterine device
 - d. intrauterine hormone-releasing system
 - e. bilateral tubal occlusion
 - f. vasectomized partner (with medical assessment of the surgical success)
 - g. sexual abstinence

Abstinence is only accepted as true abstinence when this is in line with the preferred and usual lifestyle of the patient. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods and withdrawal) is not an acceptable method of contraception.

Post-menopausal females (i.e., >60 years of age or no menses for 12 consecutive months without an alternative medical cause with confirmatory follicle-stimulating hormone (FSH) level of ≥ 40 mIU/mL) do not require contraception during the trial.
5. Male patients agreeing to refrain from donating sperm, use a male condom when having sexual intercourse and in case their partner is of childbearing potential they must agree to use adequate and effective contraception method (see inclusion criterion 4) within IP treatment and 14 days thereafter

Exclusion criteria

A patient will not be eligible for inclusion if any of the following criteria applies:

1. Body weight ≤ 55 kg
2. Known or suspected glomerulonephritis (other than diabetic kidney disease) or other systemic vasculitis
3. Confirmed or treated endocarditis requiring antimicrobial or antiviral treatment within 30 days prior to surgery or other current active infection requiring antimicrobial or antiviral treatment within 14 days prior to surgery
4. Known chronic liver disorder with Child-Pugh C classification

5. Current planned (or scheduled) surgical intervention under conditions of circulatory arrest, including planned deep hypothermic circulatory arrest
6. Planned surgery for aortic dissection
7. Use of left ventricular assist device (LVAD), or intra-aortic balloon pump or other cardiac devices, within 7 days prior to surgery
8. Received any investigational drug within 30 days or 5 half-lives (whichever is longer) prior to Day 1 or planned or current participation in another interventional study until the EoT visit has been completed
9. Previous receipt of ilofotase alfa
10. Not willing and able to understand the information on the nature, the scope, and the relevance of the trial and to provide voluntary, written informed consent to participate in the trial before any trial related procedures
11. Pregnant or nursing women
12. Known or suspected hypersensitivity to ilofotase alfa or any components of the formulation used
13. Any previous organ transplantation
14. Congenital heart disease
15. Diagnosed with AKI (as defined by KDIGO criteria) within 3 months prior to surgery
16. History of RRT
17. Cardiogenic shock or hemodynamic instability which require inotropes or vasopressors or other mechanical devices such as intra-aortic balloon counter-pulsation (IABP) within 24 hours prior to surgery
18. A requirement for any of the following within one week prior to surgery: implantation of a defibrillator or permanent pacemaker, mechanical ventilation, IABP, LVAD, other forms of mechanical circulatory support
19. Required cardiopulmonary resuscitation within 14 days prior to cardiac surgery
20. Ongoing sepsis (as defined by SEPSIS-3, the Third International Consensus Definitions for Sepsis and Septic Shock) within the past 2 weeks or, in the opinion of the investigator, an untreated diagnosed clinically significant infection (viral or bacterial) prior to or at Screening and before randomization
21. Medical condition which requires active immunosuppressive treatment (daily steroid doses of ≤ 10 mg are allowed)
22. Employees or relatives of the sponsor or the investigator