INCLUSION AND EXCLUSION FORM

Protocol Title: A multi-center, randomized, double-blind, phase IV clinical trial on the diuretic effects of Acetazolamide (Diamox ®) in patients with Decompensated heart failure and Volume OveRload.

Protocol Version / Date: version 2.0 / 03 January 2019

Inclusion criteria	***YES***	***NO***
• Signed written informed consent must be obtained before any study assessment is performed	☐	☐
• Male or female patient of 18 years of age or older	☐	☐
• An elective or emergency hospital admission with clinical diagnosis of decompensated HF with at least one clinical sign of volume overload. Sign of volume overload: OEDEMA/PLEURAL EFFUSION/ASCITES (delete as appropriate) Chest X-ray or ultrasound (if pleural effusion is used as inclusion criteria): ☐ Not applicable ☐ ___ : ___ (24 hour clock) Abdominal ultrasound (if ascites is used as inclusion criteria) ☐ Not applicable ☐ ___ : ___ (24 hour clock)	☐	☐
• Maintenance therapy with oral loop diuretics at a dose of at least 1 mg bumetanide or an equivalent dose for at least 1 month before hospital admission *(Conversion: 1 mg bumetanide = 40 mg furosemide = 20 mg torsemide)* Name oral diuretic: BUMETANIDE/FUROSEMIDE/TORSEMIDE (delete as appropriate) Start date: ……/……../……. Daily dose: ……..mg	☐	☐
• Plasma NT-proBNP levels >1000 ng/L or BNP levels >250 ng/L at the time of screening. Plasma NT-proBNP levels: …….. ng/L or BNP levels: …….. ng/L	☐	☐
• Assessed LVEF imaging within 12 months of inclusion: Assessment by ECHOCARDIOGRAPHY/CATHETERIZATION/NUCLEAR SCAN/MAGNETIC RESONANCE (delete as appropriate) Date of the assessment: ……/……../……. LVEF ……..%	☐	☐
If "NO" is ticked for one of the inclusion criteria above the patient should <u>not be included!</u>		

Exclusion criteria	***YES***	***NO***
• Concurrent diagnosis of an acute coronary syndrome defined as typical chest pain in addition to a troponin rise above the 99th percentile and electrocardiographic changes suggestive of cardiac ischemia	☐	☐
• History of congenital heart disease requiring surgical correction	☐	☐
• History of a CARDIAC TRANSPLANTATION / VENTRICULAR ASSIST DEVICE (delete as appropriate)	☐	☐
• Systolic blood pressure <90 mmHg or mean arterial pressure <65 mmHg at screening BP: ……/……mmHg (systolic / diastolic)	☐	☐
• Expected use of INTRAVENOUS INOTROPES/VASOPRESSORS/NITROPRUSSIDE during the study (delete as appropriate). *The use of nitrates and/or molsidomine is allowed at the discretion of the treating physician.*	☐	☐
• Estimated glomerular filtration rate <20 mL/min/1.73m² at screening: eGFR:…… mL/min/1.73m²	☐	☐
• Use OF RENAL REPLACEMENT THERAPY/ULTRAFILTRATION at any time before study inclusion (delete as appropriate)	☐	☐
• Treatment with intravenous loop diuretics > 2 mg bumetanide or > 80 mg furosemide during the index hospitalization and prior to randomization: Type: BUMETANIDE / FUROSEMIDE / NO TREATMENT prior to randomisation (delete as appropriate) Dose: ……mg	☐	☐
• Treatment with acetazolamide within 1 month prior to randomization	☐	☐
• Exposure to nephrotoxic agents (i.e. contrast dye) anticipated within the next 3 days	☐	☐
• Use of any non-protocol defined diuretic agent with the exception of mineralocorticoid receptor antagonists during the treatment phase of the study. Thiazides, metolazone, indapamide and amiloride should be stopped upon study inclusion. If patient is taking a combination drug including a thiazide-type diuretic, the thiazide-type diuretic should be stopped	☐	☐
• Current use of sodium-glucose transporter-2 inhibitors If yes: ☐ Canagliflozine , ☐ Dapagliflozine, ☐ Empagliflozine	☐	☐
• Subjects who are pregnant or breastfeeding MEN / PRE-MENOPAUSAL WOMEN / POST MENOPAUSAL WOMEN (delete as appropriate) If pre-menopausal: surgically sterile YES/NO (delete as appropriate) If NO -> perform pregnancy test: POSITIVE/NEGATIVE (delete as appropriate)	☐	☐
• Subjects with urinary incontinence who are not willing to receive a bladder catheter	☐	☐
If "YES" is ticked for one of the exclusion criteria above the patient should <u>not be included!</u>		

<u>Declaration of Investigator</u>

I, _____ (Principal/Sub- Investigator), confirm that the patient _____ (full name) born on ____/_____/_____ fulfils all the eligibility criteria and is suitable for the above mentioned study.

Principal/Sub- Investigator Signature: _____

Study Site Number: _____ Date: _____