Clinical trial results:
Multicenter, open-label, dose escalation study to evaluate safety, tolerability and pharmacokinetics of RLX030 in addition to standard of care in pediatric patients from birth to <18 years of age, hospitalized with acute heart failure

Summary

Results information

Trial information

Trial identification

Additional study identifiers

Sponsors

Paediatric regulatory details

Results analysis stage

General information about the trial

Population of trial subjects

Subjects enrolled per country

Subjects enrolled per age group

Subject disposition

Recruitment

Pre-assignment

Period 1	

Arms	
Arm title	

Arm title	

Arm title	

Number of subjects in period 1			

Baseline characteristics

Reporting groups	

Reporting group values			

Statistical analyses

Primary: Pharmacokinetic parameter: Css (steady state concentration)

End point values				

Statistical analyses

Primary: Pharmacokinetic parameter: CL (clearance)

End point values				

Statistical analyses

Secondary: Change from baseline of arterial blood pressure

End point values				

Statistical analyses

Secondary: Change from baseline of central venous pressure (CVP)

End point values				

Statistical analyses

Secondary: Change from baseline of left atrial pressure (LAP)

End point values				

Statistical analyses

Secondary: Change from baseline of pulmonary artery pressure (PAP– systolic and diastolic)

End point values				

Statistical analyses

Secondary: Change from baseline of central venous and arterial oxygen saturation

End point values				

Statistical analyses

Secondary: Change from baseline of urine output

End point values				

Statistical analyses

Secondary: Change from baseline of blood lactate levels

End point values				

Statistical analyses

Adverse events

Adverse events information	
Dictionary used	
Reporting groups	

Serious adverse events			

Non-serious adverse events			

More information

Substantial protocol amendments (globally)

Date	Amendment

Interruptions (globally)

Limitations and caveats
