

## Clinical trial information

Registration Item	Details of registration Item	Contents
Title of the study	Title of the study	A Phase III, multi-center, open-label study of Solithromycin in patients with respiratory tract infection
	Primary sponsor	Toyama Chemical Co., Ltd.
	Study Type	interventional (drug)
	Summary	To evaluate the efficacy, safety and pharmacokinetics of Solithromycin in patients with secondary infection of chronic respiratory diseases or acute bronchitis
Details of study	Interventional drug name	T-4288 (Solithromycin)
	Target illness	Secondary infection of chronic respiratory diseases or acute bronchitis
	Classification name (code) of the investigational drug	614 Acting mainly on gram-positive bacteria and mycoplasma
	Administration route	Oral Multiple Dose
	Control drug name(code/td)	-
	Classification name (code) of the investigational drug	-
	Administration route	-
	Objectives of the study	To evaluate the clinical efficacy and safety of Solithromycin in patients with secondary infection of chronic respiratory diseases or acute bronchitis
	Study phase	Phase III
	Study design	Open-label, Multi-center study
	Inclusion Criteria	<p>&lt;All participants&gt;</p> <ol style="list-style-type: none"> <li>1. Age: 20 years of age and older (at the time of obtaining informed consents)</li> <li>2. Gender : Both</li> <li>3. Inpatient/Outpatient status: Either</li> <li>4. Signed the informed consent form by patients or patients' legal representatives</li> </ol> <p>&lt;Secondary infection of chronic respiratory diseases&gt;</p> <ol style="list-style-type: none"> <li>1. Emerged cough or sputum, or increased sputum volume or purulence</li> <li>2. Others</li> </ol> <p>&lt;Acute bronchitis&gt;</p> <ol style="list-style-type: none"> <li>1. Confirmed sputum production or positive in antigen test of Mycoplasma</li> <li>2. Others</li> </ol>
	Outcome	fficacy, safety and pharmacokinetic profile
	Study status	On going
Duration of the study	-	
Region	Japan	
Contact information	Organization	Toyama Chemical Co., Ltd.
	Division	Data Science and Administration Department
	Contact	Form for Inquiry <a href="https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn">https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn</a>