

Basic information	
Title of the study	Phase I multiple dose study of T-4288 in healthy adult subjects
Public title of the study	-
Primary sponsor	Toyama Chemical Co., Ltd.
Secondary sponsor	-
Study Type	interventional (treatment)
Summary	To evaluate the pharmacokinetic profile, safety and tolerability

Details of the study									
Disease or condition	Japanese healthy adult male subjects								
Intervention	<table border="1"> <tr> <td>Intervention name</td> <td>T-4288</td> </tr> <tr> <td>INN of the intervention</td> <td>Solithromycin</td> </tr> <tr> <td>Classification name(code) of the intervention</td> <td>614</td> </tr> <tr> <td>Dosage And administration of the intervention</td> <td>Oral Multiple Dose</td> </tr> </table>	Intervention name	T-4288	INN of the intervention	Solithromycin	Classification name(code) of the intervention	614	Dosage And administration of the intervention	Oral Multiple Dose
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Objectives of the study	To evaluate the pharmacokinetic profile, safety and tolerability								
Study phase	Phase I								
Study design	Randomized, Double-Blind, Placebo-Controlled study								
Target sample size									
Inclusion Criteria Age: Sex:	<ol style="list-style-type: none"> 1. Japanese healthy male subjects between 20 and 55 years of age 2. BMI between 18.0 and 30.0 kg/ m² 3. Understand the requirements of the study and voluntarily consent to participate in the study 4. Others 								
Exclusion Criteria	<ol style="list-style-type: none"> 1. Have a history or presence of clinically significant cardiovascular, dermatologic, endocrine, gastrointestinal, hematologic, hepatic, immunologic, neurologic, oncologic, psychiatric, pulmonary, or renal disease or any other condition, which, in the opinion of the PI, would jeopardize the safety of the subject or impact the validity of the study results 2. Have a history of allergy to macrolide antibiotics 3. Others 								
Outcome	<table border="1"> <tr> <td>Primary Outcome</td> <td>pharmacokinetic profile, safety and tolerability</td> </tr> <tr> <td>Timepoints</td> <td>-</td> </tr> <tr> <td>Secondary Outcome</td> <td>-</td> </tr> <tr> <td>Timepoints</td> <td>-</td> </tr> </table>	Primary Outcome	pharmacokinetic profile, safety and tolerability	Timepoints	-	Secondary Outcome	-	Timepoints	-
	Primary Outcome	pharmacokinetic profile, safety and tolerability							
	Timepoints	-							
	Secondary Outcome	-							
Timepoints	-								
Study status	Completed								
recruitment status	Study Completed								
Region	Japan								
Contact information									
Organization	富山化学工業株式会社 Toyama Chemical Co., Ltd.								
Division	開発管理部 Data Science and Administration Department								
Contact person or e-mail address etc.	https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn								
Organization	Toyama Chemical Co., Ltd								

(Scientific)	
Division (Scientific)	Data Science and Administration Department
Contact person or e-mail address etc. (Scientific)	https://www.toyama-chemical.co.jp/en/form/general/input.php?id=TCClinicalEn