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SMP-028/ketoconazole drug: drug interaction study

Submission date	Recruitment status	[ ] Prospectively registered
19/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/07/2016	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
D4050156

Study information

Scientific Title
An exploratory, randomised, open-label, two-period, crossover study in healthy subjects to evaluate the effect of ketoconazole on the pharmacokinetics of SMP-028

Study objectives

Primary aim:
To assess the effects of administration of the CYP3A4 inhibitor, ketoconazole, on the single dose pharmacokinetic (PK) profile of SMP-028 in healthy subjects.

Secondary aim:
To assess the safety and tolerability of SMP-028 when co-administered with the CYP3A4 inhibitor, ketoconazole.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Capenhurst Independent Research Ethics Committee, 16/03/2010

Primary study design
Interventional

Study design
Randomised open-label two-period crossover study in healthy subjects

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Asthma

Interventions
Subjects will be randomised (in a 1:1 ratio) into one of two treatment sequences (Treatment A followed by Treatment B or Treatment B followed by Treatment A):
Treatment A consists of Ketoconazole 400 mg daily, administered orally twice a day on Days 1 to 7 followed by a single oral dose of SMP-028 20 mg on the morning of Day 5.
Treatment B consists of a single dose of SMP-028 20 mg on Day 1.
Subjects will be followed up for 8 days after dosing in Treatment A and 4 days in Treatment B.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ketoconazole, SMP-028

Primary outcome(s)
Pharmacokinetics:
1. Primary endpoints:
Comparative SMP-028 exposure between treatment periods (AUC[0-∞] and C[max]) over 72 hours
2. Secondary endpoints:
Comparative SMP-028 exposure between treatment periods (other pharmacokinetic parameters), and exposure levels of the metabolites of SMP-028 over 72 hours

Key secondary outcome(s)
Safety endpoints:
1. The proportion of subjects with adverse events (AEs)
2. Changes in standard laboratory safety tests
2.1. haematology
2.2. clinical chemistry
2.3. urinalysis
3. Concomitant medication review
4. Vital signs
5. Complete physical examinations
6. 12-lead ECG

Completion date
30/06/2010

Eligibility

Key inclusion criteria
Healthy subjects aged 18 to 55 years who are in good health as determined by past medical history, physical examination, electrocardiogram, clinical safety laboratory tests and urinalysis

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
Standard exclusion criteria for a healthy volunteer study

Date of first enrolment
18/03/2010

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Dainippon Sumitomo Pharma Europe Ltd
London
United Kingdom
SW1E 6QT

Sponsor information

Organisation
Dainippon Sumitomo Pharma Europe Ltd (UK)

ROR
https://ror.org/03sh4z743

Funder(s)

Funder type
Industry

Funder Name
Dainippon Sumitomo Pharma Co. Ltd (Japan)

Alternative Name(s)
Dainippon Sumitomo Pharma Co., Ltd.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Japan

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes