

A Study to Evaluate the Safety of Increasing Doses of DF5112 in Healthy Adults

NCT07232121

Status	RECRUITING
Phase	Phase 1
Sponsor	Dragonfly Therapeutics
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (4)

- Male or female participants aged 18 to 55 years (inclusive) at the time of informed consent.
- Body mass index (BMI) between e 18.0 and d 32.0 kg/m² and body weight e 45 kg.
- At the discretion of the Principal Investigator (PI) or designee, in good general health, with no significant medical history, and have no clinically significant abnormalities on physical examination at Screening and/or before the first administration of IP.
- Clinical laboratory values within normal range as specified by the testing laboratory, unless deemed not clinically significant by the PI or designee.

Exclusion (11)

- History or presence of cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrinological, hematological, or neurological disorders that, in the opinion of the PI or designee, are capable of significantly altering the absorption, metabolism, or elimination of drugs; constituting a risk when taking the study intervention; or interfering with the interpretation of data.
- History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system treated or untreated within the past 5 years, regardless of whether there is evidence of local recurrence or metastases (except for squamous and basal cell carcinoma of the skin or actinic keratoses that have been treated with no evidence of recurrence in the past 12 weeks; carcinoma in situ of the cervix or non-invasive malignant colon polyps that have been removed).
- History of or evidence of recurrent or chronic bacterial or fungal infections including those of the skin, vagina, oral cavity, etc., or systemic fungal infection.
- History of unexplained, recurrent infection, or infection requiring treatment with systemic antibiotics within 90 days prior to dosing on Day 1.
- Active oral infection.

... and 6 more (see full listing online)

Locations (1 total)

Scientia Clinical Research Ltd, Sydney, New South Wales, Australia