

A Study on Efficacy, Safety and Immunogenicity of 9MW0311 in Postmenopausal Women With Osteoporosis

NCT06804590

Status	RECRUITING
Phase	Phase 3
Sponsor	Mabwell (Shanghai) Bioscience Co., Ltd.
Enrollment	278 participants

Key Eligibility Criteria

Inclusion (4)

- Women who can walk freely (e50 and d80 years);
- As measured by DXA, the absolute value of BMD at lumbar spine, femoral neck or total hip was $-4.0 \leq T \text{ value} \leq -2.5$;
- Subjects must have at least one of the following other risk factors: 1) history of previous fragility fractures; 2) Either or both parents have a history of hip fragility fracture; 3) Increased bone turnover rate during screening; 4) Low body weight; 5) Old age (e70); 6) Currently smoking.
- The duration of spontaneous amenorrhea was ≥ 2 years or ≥ 2 years after bilateral oophorectomy. If the status of bilateral oophorectomy is unknown or if the ovaries are preserved after hysterectomy, follicle stimulating hormone (FSH) levels ≥ 40 mIU/mL may be used to confirm the status of postoperative menopause.

Exclusion (25)

- Bone/metabolic disease
- Hyperparathyroidism or hypoparathyroidism
- Thyroid condition: Hyperthyroidism or hypothyroidism
- Rheumatoid arthritis
- Malignant tumors
- ... and 20 more (see full listing online)

Locations (1 total)

Mabwell (Shanghai) Bioscience Co., Ltd., Beijing, China