Orelabrutinib Combined With Zuberitamab in the Initial Treatment of MZL

NCT06985472

Status	RECRUITING
Phase	Phase 2
Sponsor	Li Zhiming
Enrollment	33 participants

Key Eligibility Criteria

Inclusion (10)

• \. Age 18 years or older; 2. ECOG performance status (PS) level 0\~2; 3. The expected survival is not less than 12 weeks; 4. CD20-positive marginal area lymphoma confirmed according to WHO2008 lymphoma classification standard, including splenic MZL, lymph node MZL and extranodal MZL subtypes; 5. MZL with stage III/IV disease and stage I/II disease recurrence or progression after local treatment can also be included, and patients who have received BTKi inhibitor therapy for more than 6 months can also be included; 6. Enhanced computerized tomography/magnetic resonance imaging (CT/MRI) to detect measurable lesions; 7. Indications for MZL treatment that meet NCCN guidelines and have not received systematic treatment for MZL in the past (anti-infective treatment such as anti-HP and HCV is not systemic treatment); 8. The main organ function is normal and meet the following criteria :

• blood routine examination standards must meet:

• ANC\>1.0×109/L;

• PLT\>75×109/L (e50×109/L for patients with confirmed bone marrow infiltration);

• Hb\>80g/dL;

... and 5 more (see full listing online)

Exclusion (15)

• Patients with central nervous system invasion;

• Previous or co-existing uncured malignancies, except cured skin basal cell MZL clinical trial protocol cancer, cervical carcinoma in situ and superficial bladder cancer;

• Patients with the following cardiovascular diseases: Grade II or above myocardial ischemia or myocardial infarction, poorly controlled arrhythmias (including QTc interval 2450 ms for men and 2470 ms for women); According to NYHA standards, patients with grade III to V cardiac insufficiency or left ventricular ejection fraction (LVEF) \<50% indicated by cardiac color ultrasound;

• Abnormal coagulation function (INR\>1.5 or prothrombin time (PT) \>ULN+4 seconds or APTT \>1.5 ULN), have a tendency to hemorrhage or are receiving thrombolytic or anticoagulant therapy;

• Arteriovenous thrombosis events occurring in the 12 months prior to enrollment, such as cerebrovascular accidents (including temporary ischemic attack, cerebral hemorrhage, cerebral infarction), deep vein thrombosis, and pulmonary embolism;

... and 10 more (see full listing online)

Locations (2 total)

Sun Yat-sen University Cancer Center, Guangzhou, Guangdong, China
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