

# JY231 Injection for the Treatment of Relapsed/Refractory Neurologic Immune Disorders

NCT06797024

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Tongji Hospital
Enrollment	20 participants

## Key Eligibility Criteria

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### Inclusion (19)

- Male or female subjects (both 18 and 75 years of age) aged 18 to 75 years who have signed an informed consent (ICF) that none of the available treatment options have been effective; and
- Previously diagnosed relapsed/refractory neuroimmune disorders for which there are currently no effective treatments, as determined by the specified diagnostic criteria, including:
- Patients with AQP4 antibody-positive optic neuromyelitis optica (NMOSD) who meet the 2015 IPND NMOSD diagnostic criteria and meet one of the following requirements:
- Treatment with at least one immunosuppressive agent for at least one year, or intolerance of immunosuppressive therapy with suboptimal symptom control; At least 2 relapses in the last 12 months or 3 relapses in the last 24 months and at least 1 relapse in the 12 months prior to screening.
- Patients with myasthenia gravis (MG) who meet the 2020 MGFA diagnostic criteria for a total MG-ADL score of e6 with a relevant antibody-positive MGFA classification II-IV and meet one of the following requirements:

... and 14 more (see full listing online)

### Exclusion (14)

- have a contraindication or hypersensitivity to fludarabine, cyclophosphamide, and any component of the test drug;
- have received intravenous immunoglobulin or plasma exchange therapy or immunosorbent therapy within 4 weeks prior to retrieval;
- have used tacrolimus, cyclosporine, azathioprine, morphine, mycophenolate mofetil, methotrexate, or methotrexate within 1 week prior to mono-harvesting;
- Treatment with neonatal Fc receptor (FcRn) antagonists (e.g., Efgartigimod, etc.) within 1 week prior to single-take;
- have used complement inhibitory therapy (e.g., eculizumab, etc.) within 1 week prior to single-take;

... and 9 more (see full listing online)

## Locations (1 total)

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Tongji Hospital affiliated to Tongji Medical College of Huazhong University of Science and Technology, Wuhan, Hubei, China

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<https://clinicaltrials.gov/study/NCT06797024>

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