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China approves Phase II clinical trial of InnoCare's cancer drug

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InnoCare announces approval of Phase II clinical trial using Orelabrutinib for the treatment of NMOSD in China

InnoCare Pharma, a leading biopharmaceutical company, has announced the Investigational New Drug (IND) approval of its Bruton's tyrosine kinase (BTK) inhibitor orelabrutinib by China National Medical Products Administration (NMPA) to start phase II clinical trial in Neuromyelitis Optica Spectrum Disorder (NMOSD) in China.

This is a randomized, double-blind, placebo-controlled phase II clinical study evaluating the efficacy and safety of orelabrutinib in NMOSD patients.

Neuromyelitis optica spectrum disorder (NMOSD) is a chronic inflammatory demyelinating autoimmune disease of the central nervous system mainly involving the optic nerve and spinal cord, which are mediated by antigen-antibodies related to humoral immunity. Clinically, it is characterized by attacks of predominantly optic neuritis and longitudinally extensive transverse myelitis. One Chinese latest epidemiological study based on inpatients shows that the peak age-incidence of the disease is 45-65 years old, the incidence rate is 0.445/100,000 people per year, and the ratio of female to male is 4.71:1.

NMOSD is a highly relapsing, severely disabling disease. More than 90% of patients have relapses, about 60% within 1 year, 90% within 3 years. Most patients are left with severe visual impairment (blindness), limb dysfunction (paraplegia), and bowl and bladder dysfunction. Studies have shown that there is a clear correlation between functional disability and relapse in NMOSD patients, so it is necessary to seek new treatments to reduce relapse in patients.