A Phase Ib, open-label, randomized study to assess safety and preliminary efficacy of tafasitamab in addition to R-CHOP or tafasitamab plus lenalidomide in addition to R-CHOP in patients with newly diagnosed diffuse large B-cell lymphoma (DLBCL): First-MIND

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Background
• R-CHOP (rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, prednisolone) remains the standard of care for newly diagnosed diffuse large B-cell lymphoma (DLBCL), with cure rates of 60-70%.
• However, more effective front-line options are needed to further improve outcomes, particularly in high-risk patients.

Preclinical
Approximately 15-20% of treatment-naive patients with DLBCL have CD19 low-expressing tumors, while CD19 high-expression tumors show lower response to R-CHOP. CD19低表达的DLBCL患者约为15-20%，而CD19高表达的DLBCL患者对R-CHOP的应答率较低。

R-CHOP (rituximab, cyclophosphamide, doxorubicin hydrochloride, vincristine, prednisolone)

ADCC, antibody-dependent cellular cytotoxicity; ADCP, antibody-dependent cellular phagocytosis; DLBCL, diffuse large B-cell lymphoma; iNHL, indolent non-Hodgkin lymphoma.

Study design
This is a Phase Ib, open-label, randomized study of tafasitamab given in addition to R-CHOP or R-CHOP + lenalidomide in addition to R-CHOP in patients with newly diagnosed DLBCL (NCT04134936; Figure 2).

Study endpoints
• The primary endpoint is the incidence and severity of treatment-emergent adverse events.
• The key secondary endpoints are ORR and post-treatment tomography-negative CR rate at the end of treatment.

Other secondary endpoints include the long-term safety and efficacy, pharmacokinetics, and immunogenicity (Table 2).