

**EMBARGOED UNTIL 10AM ON 15<sup>th</sup> MAY 2025**

The UK MND Clinical Studies Group, having reviewed the MIROCALS clinical trial results published in The [Lancet](#), has agreed the following statement:

Low-dose interleukin-2 (IL-2<sub>LD</sub>) did not show a significant survival benefit in the overall study population over a 21-month period. Further analysis of the data showed IL-2<sub>LD</sub> might improve life expectancy in a group of people with lower or more moderate baseline neurofilament levels which correlate with slower rates of disease progression. The researchers conducting the study have indicated that a further study is needed to confirm this finding. Based on the results from the MIROCALS clinical trial we know that IL-2<sub>LD</sub> is not a cure for MND. However, the trial is an important step forward in the search for effective treatment for MND. It is clear that IL-2<sub>LD</sub> is safe and well tolerated.

We understand the urgency voiced by patient communities to make IL-2<sub>LD</sub> immediately available to people living with MND. At the moment there is no mechanism for this to happen within the NHS outside of a formal early access programme. Individual clinicians cannot currently prescribe IL-2<sub>LD</sub> for patients with MND without local NHS Hospital Trust approvals. NHS Trusts have previously refused off-label use of IL-2<sub>LD</sub> and we do not anticipate that the publication of the MIROCALS paper is likely to change this position.

More data are urgently required to give a definitive answer on the potential therapeutic benefits of IL-2<sub>LD</sub> and how it could be used in clinical practice. The most thorough route to gather these data is a comprehensive phase 3 trial, which would likely be led by the pharmaceutical industry. An alternative or complementary approach would be an early access scheme. Such a scheme would need to be fully funded and include a robust framework for collecting sufficient efficacy and safety data that would allow a clear conclusion regarding the overall benefits of IL-2<sub>LD</sub>. We are strongly supportive of whichever of these approaches can bring us the definitive answers sooner and are urgently exploring both now.

UK MND Clinical Studies Group

15th May 2025