

## An Open Letter

To:

Tanya Curry, Brian Dickie (MND Association)

Professor Nigel Leigh (Sussex)

Professor Ammar Al Chalabi (King's)

Professor Dame Pamela Shaw (Sheffield)

Professor Andrea Malaspina (Queen Mary)

April 2024

Dear all,

We are writing to you as UK members of the Mirocals Consortium who we have worked closely with over the past few years as fundraisers/awareness raisers/campaigners for the MND community.

With this message, we do not wish to go over old ground about the delay in publishing the results of the trial. What we would like to do, however, is to focus on the selection of commercial partner for Mirocals and the lack of transparency on how this choice came about.

As we have made clear on several occasions along with others, this is morally unacceptable for a trial funded by UK and EU taxpayers and charity donors. This is important not only for the current situation, but for the future of research involving repurposed drugs (in particular) going forward.

Sadly, because of the Consortium's (and Iltoo's) refusal to provide clarity on commercial arrangements and your responses indicating disclosure is not possible because of NDAs, the logical conclusion is that you are putting the interests of Iltoo, the charity and the Universities above those of patients and their families.

Perhaps you have a valid explanation for taking this stance. If so, could you please explain it to us?

We ask you to answer as fully as possible the following questions...

- Why are the full trial results not being released? Are there contractual reasons and/or are some members of the Consortium or the commercial partner blocking publication?
- Who is making money from the sale of the trial results and the creation of a new IL-2 product? How is income from the sale being distributed? What is the schedule for payment and distribution? Are members of the Consortium or the commercial partner delaying publication?
- Why was a deal done with a company, Iltoo, that does not have a commercial product which, when created, will have to highly likely go through further trial/studies/analysis and approval processes when an existing drug, easily re-compounded Proleukin (as used in the trial) is already available commercially around the world in plentiful supply?
- Can you describe the process that arrived at the choice of Iltoo as commercial partner? In respect of this, were all conflicts of interest properly disclosed as we presume would be necessary for the award of an EU Horizon grant, let alone the use of charitable funds?

- Why have two companies using the name Iltoo been established in the UK, each of them with the same principal, Pieter Klaassen, a person also named as having interest in the Mirocals trial since 2015 under the company name, WGK?
- Why isn't the Consortium showing support to the patient community NOW by publicly describing how it is preparing for patients to get rapid access to the trial drug, low-dose compounded Proleukin, through all available pathways (not just full authorisation) in the event of a positive outcome to the trial?

Clear and comprehensive answers to our questions are very important to us because of our strong public links with the charity and research into MND. By being transparent on the commercial dealings, you can help reassure us you have the best interests of patients and their families at heart.

We fully appreciate it is possible that the results may not be positive. However, these questions are still valid in the context of future trials.

It is those families, their friends and ourselves who have contributed significantly to the funding of the trial and who look to you for leadership, not only in science to discover meaningful treatments, but also to find the most rapid pathways to get them into patients' bodies.

We want to continue to work with you all on progress towards finding a cure. However, we cannot let this particular situation go on any longer without becoming more vocal on it and engaging with other high-profile supporters to bring it to public attention.

However, we are confident that you will be able to give us clear and comprehensive responses so that we can all move forward together.

Yours sincerely,

Stephen and Stephanie Darby

Rob and Lindsey Burrow

Geoff Burrow

Marcus and Louise Stewart

Ed and Jo Slater