INTERNATIONAL
CELLULAR MEDICINE
SOCIETY

March 19, 2017

ICMS STATEMENT REGARDING TREATMENT PROTOCOL FOR AGE RELATED MACULAR DEGENERATION UTILIZED BY US STEM CELL / BIOHEART

The International Cellular Medicine Society (ICMS) Institutional Review Board (IRB) did not approve the bilateral treatment techniques or practitioners utilized by US Stem Cell / Bioheart that resulted in the three cases of blinding complications that was described in the New England Journal of Medicine, Brief Report, published March 16, 2017. This conclusion is based upon a review of internal IRB documentation and publically available information.

The Institutional Review Board did approve a single eye treatment study protocol with BCVA worse than 20/200. Shareen Greenbaum, M.D., a board certified Ophthalmologist, was presented as the principal investigator. Dr. Greenbaum was the physician expected to treat patients in accordance with criteria established in the approved version of the protocol.

Per written communications and representations from Bioheart / US Stem Cell to ICMS and posted on clinicaltrials.gov, no patients were enrolled in the study protocol and the study was discontinued without having ever performed a single procedure.

As detailed below, the patients referenced in the New England Journal of Medicine (NEJM), Brief Report, were not treated under the ICMS IRB approved protocol:

1. The patients that were treated were not treated according to the ICMS protocol. As the recent NEJM article recognized, the ICMS protocol (NCT02024269) was withdrawn: “A fourth trial (NCT02024269), which was withdrawn on September 15, 2015, before enrollment had begun, focused on the use of intravitreal autologous adipose tissue–derived stem cells in patients with non-neovascular AMD.” http://www.nejm.org/doi/full/10.1056/NEJMoa1609583

2. The patients described in the NEJM article would have been excluded under the protocol ICMS reviewed. The BCVA in these patients was not 20/200 or worse (legally blind).

3. According to the complaints filed by the two patients, the primary clinical investigator approved by the ICMS was not the clinician who performed the injections. Expectations are that standards of care are followed. The primary clinical investigator, with appropriate credentials, is expected to be the one who would perform the procedures. Apparently, a staff member, an ARNP, performed the injections.

4. The protocol approved by the ICMS requires BCVA worse than 20/200. It also contemplates single eye treatment. There is no mention of bilateral injections. Throughout the protocol, the treated eye is consistently referred to in the singular and the protocol does not contemplate, much less condone, bilateral treatment. If the protocol had mentioned bilateral treatments, it would not have received approval from the ICMS IRB.

Reed Davis
Executive Director
International Cellular Medicine Society