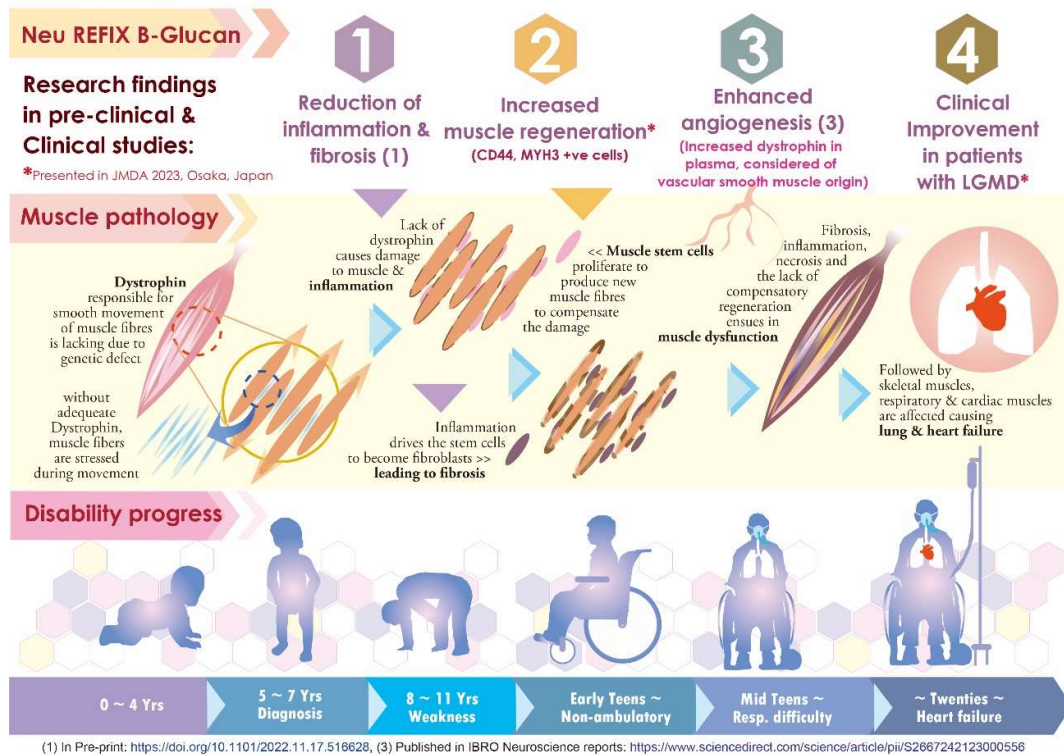


Press Release

Neu-REFIX: Japanese β -glucan proves clinically helpful in limb girdle muscular dystrophy, and improves muscle regeneration in MDX mice.

Duchenne awareness day webinar narrates the presentations made in the 10th Japanese Muscular Dystrophy Association Meeting held in Osaka, Japan.

Chennai, 10th September, 2023; Disease modifying effects of Neu-REFIX beta glucans in patients with Limb Girdle Muscular Dystrophy (LGMD) in a pilot clinical study were presented in the joint meeting of 9th Annual conference of Japan Muscle Research Society and 10th Annual conference of Japan Muscular Dystrophy Association. In the study conducted for sixty days, the markers of muscle function improved, which is considered a good sign of slowing down of the disease progress, said Dr. Raghavan, the principal investigator of the study, conducted in JAICARE Hospital, Madurai, India, during the **World Duchenne Awareness Day Webinar on the 10th September, 2023**. He also briefed on the pre-clinical evidence in MDX mice models, confirming the enhancement of muscle regeneration in disease affected mice, upon consumption of Neu REFIX beta glucans, that was also presented in Osaka, Japan by Dr. Koji Ichiyama. This evaluation was jointly undertaken with the research team lead by Prof. Shuji Sakamoto, Science Research Center, Kochi Medical School, Kochi University.



Muscular Dystrophies are rare genetic diseases in which the affected victims lack necessary components for smooth functioning of the muscles making their muscles become weaker gradually. Duchenne Muscular Dystrophy (DMD) is the commonest form of this rare disease entity affecting 1 in 3500~5000 male births, which usually shows signs of the disease before the age of six. LGMD is considered much rare, whose onset is usually at a later age than DMD. The research team, having earlier proven the safety and efficacy of the Neu-REFIX Beta glucans in DMD both in pre-clinical and

clinical studies of up to six months duration, undertook the study in LGMD, in which the grades of assessment of muscle function and ambulation were found to be improved after Neu-REFIX oral consumption as an adjuvant along with the standard of care medications. The increase in regenerating muscles which were proven in animal studies explains the reason why clinically, the muscle strength improvement is observed, commented the researchers. Prof. Dr. Stephen Abraham Sureshkumar (Former Professor of Pediatric Neurology, Government Stanley Medical College, Madras Medical College & Institute of Child Health, Chennai, India) and Prof. Dr. John Solomon (Pediatric Oncologist, Emeritus Professor, The Tamil Nadu Dr. M.G.R. Medical University & Balaji Medical college, Chennai, India.), who joined the webinar as panelists, said that they are very delighted to hear such encouraging outcome in these studies and insisted that the myocardial fibrosis and heart failure should also be looked into these patients and if the Neu-REFIX beta-glucans can control the same, that will be of much help to the DMD patients who are in their late 20's and likely to develop cardiac problems.

In the animal study in MDX mice models, which resemble DMD, the enhancement of muscle regeneration was presented in the meeting, which was reported after oral feeding with Neu-REFIX beta glucans alone, without any disease modifying medications that are used in clinical settings. The repetitive cycles of degeneration and regeneration of the skeletal muscles in muscular dystrophies is very complex, and the exact nature and mechanism of the inflammatory cascade needs in-depth evaluation. If the mechanism of the efficacy of the Neu-REFIX beta glucans is clearly understood, that may in future pave way for additional applications in auto-immune diseases as well, as a broad-spectrum immune modulator and therefore we are evaluating more biomarkers in those animal models, said Prof Naoki Yamamoto (Emeritus professor, Tokyo Medical and Dental University), a co-author of the study. Being a virologist, he appreciated the evaluation of gut microbiome in DMD patients in the studies conducted in the background of evolving data from other institutes which correlates to the clinical outcome in ours, making this approach, a multi-pronged one.

MediNippon Healthcare Pvt. Ltd in Chennai, India which undertook the clinical studies with support from GN Corporation Co Ltd, Japan, clinicians and scientists affiliated with hospitals and research institutes in India and Japan are also proposing to undertake more pre-clinical and clinical longer duration multi-centric studies to validate Neu REFIX efficacy to find ways to help improve the quality of life of patients affected by different forms of muscular dystrophies and to help prolong their life span.

Neu-REFIX, a Beta glucan, produced as an exopolysaccharide by the yeast Aureobasidium Pullulans, belongs to Beta-1,3-1,6 glucan group of food additives as per MHLW listing; Commercially available as a food supplement, without any therapeutic claims and is not a drug or remedy to any illness. Research findings should not be construed as medical advice. Not GRAS (USFDA), EFSA (EU) certified. Presentations and research publications are meant for academic and educational purposes.

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