TREAT-NMD Advisory Committee for Therapeutics is launched to guide best potential new therapies for the treatment of neuro-muscular diseases to clinical trials

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Press Release
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Applications invited for comprehensive appraisals of new therapies by 15 December 2009

TREAT-NMD has launched the TREAT-NMD Advisory Committee for Therapeutics (TACT) to provide free and transparent guidance and advice on the trial-readiness of potential new therapies for neuromuscular diseases. With perspective and experience over the overall drug development process, including a multidisciplinary group of experts and pragmatic approach, TACT can provide a unique and essential educational tool for the field.

Developers, clinicians and researchers working on therapies with promising preclinical results can contact TACT for advice on the steps to advance into clinical trials. These could include novel approaches, not yet tested in other conditions that require a greater level of clinical study-enabling data, and approved drugs with potential for repurposing. In both situations the goal of the advice is to position the potential therapy along a realistic pathway to eventual clinical trial and registration. It is expected that the expert and unbiased nature of the appraisal will influence funding organisations and therefore help developers of therapies secure funding.

Kate Bushby, TREAT-NDM coordinator explained, “Of the many promising research results presented at conferences, published in journals and hailed as the basis for possible future treatments and cures for neuromuscular disorders, only a very small number ever make it to the clinical trial stage. Evaluating which of them are actually ready for this step is a challenge not only for potential funders and sponsors, but often for the researchers themselves. This is where TACT can offer very real assistance.”

TACT review meetings will take place every 6 months, with interested parties invited to submit applications by 15 December for the first meeting which will beheld in Rome, 6 – 8 February 2010. The evaluation of the projects will be provided to applicants within approximately six weeks of the review meeting and a non-confidential summary will be published on the TREAT-NMD website within two months of the meeting.

The application process will focus the applicant on a number of important considerations including scientific rationale, the appropriateness and interpretation of preclinical studies performed, safety and toxicology issues, drug distribution and kinetics, feasibility and cost of drug manufacturing and supply, context of project in the clinical development plan and regulatory considerations critical to advancing a compound into the clinic.

Nick Catlin, CEO of Action Duchenne commented, “TACT is a great initiative by TREAT-NMD and will help fund raising charities like ourselves to identify which are the most likely compounds to yield a realistic treatment within the foreseeable future. We believe that the TACT initiative will help to speed the most appropriate therapies into clinical trials resulting in treatments for our children.”

Interested groups should contact Emma.Heslop@ncl.ac.uk as soon as possible. For additional information please visit the news item www.treat-nmd.eu/about/news/news/702/

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Notes to Editors

About TACT

TACT, the TREAT-NMD Advisory Committee for Therapeutics, is an expert body set up by TREAT-NMD to provide free and transparent guidance and advice on the trial-readiness of potential new therapies for neuromuscular diseases. The strength of TACT is in the calibre of its experts, and the rigour and independence of its review process. The committee is chaired by Cristina Csimma, Vice President, Drug Development at Virdante Pharmaceuticals. There is a core group of 8 leading specialists, with a broader committee consisting of 35 professionals with relevant expertise in specific areas including preclinical, clinical, regulatory, ethical, drug discover/medicinal chemistry and clinical trial coordination centre representation.

About TREAT-NMD

TREAT-NMD is a Network of Excellence, coordinated from Newcastle University UK, facilitating collaborative research in neuromuscular disease that aims to create the infrastructure to ensure that the most promising new therapies reach patients as quickly as possible. The network brings together the key players in the neuromuscular field and is a natural partner for biotech and pharmaceutical companies developing new therapeutics for neuromuscular conditions. Its tools and services and access to an unparalleled depth of expertise can support, simplify and accelerate the trial and approval process. Its suite of services includes defined and recruitable patient cohorts obtained through its global patient registries, experienced trial sites accessed through its care and trial sites registry, outcome measures validated for NMDs, regulatory advice, GCP training, clinical evaluator training, care standards generation, and advisory board setup.

For more information, please visit: www.treat-nmd.eu

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