#### THE 6-MINUTE WALK TEST AND OTHER CLINICAL ENDPOINTS IN DUCHENNE MUSCULAR DYSTROPHY: RELIABILITY, CONCURRENT VALIDITY, AND MINIMAL CLINICALLY IMPORTANT DIFFERENCES FROM A MULTICENTER STUDY

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ABSTRACT: Introduction: An international clinical trial enrolled 174 ambulatory males ≥5 years old with nonsense mutation Duchenne muscular dystrophy (nmDMD). Pretreatment data provide insight into reliability, concurrent validity, and minimal clinically important differences (MCIDs) of the 6-minute walk test (SMWT) and other endpoints. Methods: Screening and baseline

Abbreviations: 6MWD, 6-minute walk distance; 6MWT, 6-minute walk test; ATS, American Thoracic Society; CRRG, Cooperative International Neuronuscular Research Group, CK, creative limite: DMD, Ducherve. muscular dystrophy: EEL energy expenditure index; FPQL, health-related quality of the MOD, minimal directly important differences; MPS, mucopolyspocharidosis; nmDMD, nonsense mutation DMD; NSAA, North Star Arrikulatory Assessment: PedsGL, Pediatric Quality of Life Inventory; TFT, terrend Nursellion heat

Key words: 6-minute walk test ambulgion; Duchernie muscular dystrophy, energy expenditure index, musicular dysfrophy; myometry, natural history: PedeGL; timed function test.

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Disclosures: G.M.M is a member of the Cooperative Neuromuscular Research Group (CRIFIG) Executive Committee and has served on advisory committees for PTC Thirapeutics, Inc., Sarepts Thirapeutics, Inc., GascolinithiOne, Processes, Halo Thirapeutics, Shire HGT, Cardino Thirapeutics, and North AG. E.K.H. is a member of the CRIFIG Executive Committee and has served as a consultant for Genzyme Corsignation and PTC Therapeutics, Inc. R.T.A. has served as a consultant for PTC Therapoutca, inc., and Sarepta Therapeutica, J.M.F. serves on a scentific actisory board for Propersia, on the editorial board of Neuromuscular Disorders, and serves/has served as a member of the CRIPG Executive Contentine and as a consultant for Propersia, GascoSmithkline, Genyyme Corporation, PTC Therapelutics, Inc., and Acceleron Pharms, M.E. riss. served as a circuit evaluator trainer for FTG Therapeutics, and as a consubant for Prosense and DissoSmithKline. E.G. has served as a clinical evaluator trainer for PTC Therapeutics, A.M.G. has served as a clinical evaluator trainer for PTC Therapeutics, PLS, is the Ohel Medical Officer for PTC Transpection. J.B. is the Vice President for Clinical Development at PSC Therapeutics, G.E. is the Executive Director of Biostatistics at PTC Therapeutics, A.R. is the Director of Clinical Development at PTC Therapeutics, S.W.P. is the Chief Executive Officer and founding scientist, PTC

Additional Supporting Information may be lound in the online yeason of

Collaborating authors are leted in Appendix 1, Other members of the PTC124-GD-007-DMD Study Group are listed in Appendix 2 in the Supporting information.

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evaluations included the 6-minute walk distance (6MWD), timed function tests (TFTs), quantitative strength by myometry, the PedsQL, heart rate-determined energy expenditure index, and other exploratory endpoints. Results: The 6MWT proved feasible and reliable in a multicenter context. Concurrent validity with other endpoints was excellent. The MCID for 6MWD was 28.5 and 31.7 meters based on 2 statistical distribution methods. Conclusions: The ratio of MCID to baseline mean is lower for 6MWD. than for other endpoints. The 6MMD is an optimal primary endpoint for Duchenne muscular dystrophy (DMD) clinical trials that are focused therapeutically on preservation of ambulation and slowing of disease progression.

Advanced Advanced Bills (1992) - 1988. (1991).

Duchenne muscular dystrophy (DMD) is a disabling and life-threatening X-linked genetic disorder caused by defects in the gene for dystrophin, a protein that stabilizes muscle cell membranes.1 DMD is characterized by complete loss of dystrophin and is the most common neuromuscular disease of childhood. It affects 1 in 3800-6300 males, and there are an estimated 15,000 patients with the disease in the USA. 2.3 There is no approved therapy that addresses the underlying cause of DMD.45 In ~13% of boys with nonsense mutation DMD (nmDMD, which represents ~1700 boys in the USA and ~2400 boys in Europe), the causative defect in the dystrophin gene is a nonsense mutation that truncates dystrophinprotein production by introducing a premature stopcodon into dystrophin mRNA.6-8

#### THE NEED FOR CLINICALLY MEANINGFUL EMPPOINTS IN DMD

Given that several novel approaches to treatment of DMD have shown promise in preclinical and/or proof-of-concept clinical studies, 5-12 the research community has faced the need to identify and develop clinically meaningful outcome measures for use in pivotal therapeutic trials. In boys with DMD, walking abnormalities are a major disease manifestation that has great importance to patients and

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