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【利益相反（Conflict of Interest）の有無】
ない

【演題名】
# 日本人重症筋無力症患者におけるエフガルチギモドの長期有効性と安全性の検討

【演題名(英文)】
# Evaluation of the Long-Term Safety and Efficacy of Efgartigimod in Japanese Patients With gMG

【著者】
増田 眞之[1]，村井 弘之[2]，鈴木 靖士[3]，紺野 晋吾[4]，寒川 真[5]，杉本 太路[6]，山本 大輔[7]，Guglietta Antonio[8]，Ulrichts Peter[8]，T'joen Caroline[8]，今井 富裕[9]，高橋 正紀[10]，鵜沢 顕之[11]，槍沢 公明[12]

【著者(英文)】
Masayuki Masuda[1], Hiroyuki Murai[2], Yasushi Suzuki[3], Shingo Konno[4], Makoto Samukawa[5], Takamichi Sugimoto[6], Daisuke Yamamoto[7], Guglietta Antonio[8], Ulrichts Peter[8], Caroline T'joen[8], Tomohiro Imai[9], Masanori Takahashi[10], Akiyuki Uzawa[11], Kimiaki Utsugisawa[12]

【所属】
[1]東京医科大学 神経学分野，[2]国際医療福祉大学医学部脳神経内科学，[3]国立病院機構仙台医療センター神経内科，[4]東邦大学医療センター大橋病院脳神経内科，[5]近畿大学内科学講座神経内科部門，[6]広島大学病院脳神経内科，[7]札幌医科大学医学部神経内科学，[8]アルジェニクス，[9]国立病院機構箱根病院，[10]大阪大学医学部附属病院 神経内科・脳卒中科，[11]千葉大学大学院医学研究院脳神経内科学，[12]総合花巻病院神経内科

【所属(英文)】
[1]Department of Neurology, Tokyo Medical University，[2]Department of Neurology, School of Medicine, International University of Health and Welfare, Tokyo, Japan，[3]Department of Neurology, National Hospital Organization Sendai Medical Center，[4]Department of Neurology, Toho University Ohashi Hospital Medical Center，[5]Department of Medicine, Kindai University Hospital，[6]Department of Clinical Neuroscience and Therapeutics, Hiroshima University，[7]Department of Neurology, Sapporo Medical University Hospital, Sapporo, Japan，[8]argenx，[9]Department of Neurology, National Hospital Organization Hakone Hospital，[10]Department of Neurology, Osaka University Hospital, Suita, Japan，[11]Department of Neurology Graduate School of Medicine, Chiba University, Chiba, Japan，[12]Department of Neurology, Hanamaki General Hospital

Purpose:To evaluate the long-term tolerability and efficacy of efgartigimod (EFG), a human IgG1 antibody Fc fragment that blocks FcRn, in patients with generalized myasthenia gravis (gMG), including those of Japanese descent. Methods: Safety and efficacy of EFG in patients with gMG was previously shown in the 26-week placebo-controlled ADAPT study, which included Japanese ethnicity as a stratification criterion. EFG 10 mg/kg IV was administered in cycles of 4 weekly infusions with subsequent cycles initiated after ≥5 weeks based on clinical response. Patients who completed ADAPT were eligible to enroll in the ongoing open-label, 3-year extension study ADAPT+. Results: 91% of ADAPT patients (151/167) entered ADAPT+. As of February 2021,

106 AChR-Ab+ and 33 AChR-Ab- had received ≥1 dose of EFG, including 10 Japanese patients (7 AChR-Ab+; 3 AChR-Ab-). The mean (SD) study duration was 370.7 (110.5) days, resulting in 138 PYs of observation. The most common adverse events (AEs) observed during long-term follow up were headache (22.3%), nasopharyngitis (10.8%), and diarrhea (8.6%). The most common infections besides nasopharyngitis were urinary tract infections (7.2%) and COVID-19 (4.3%). Rates of AEs did not increase with additional cycles. Consistent improvements were observed in MG-ADL and QMG scores during each treatment cycle. No notable differences were observed between Japanese and non-Japanese populations. Conclusions: Favorable safety and efficacy profiles were observed with repeated treatment cycles of EFG in ADAPT+ for both non-Japanese and Japanese patients with gMG