

# Press Release



2017年7月14日

日本イーライリリー株式会社

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EL17-35

本資料は、米国イーライリリーが2017年7月12日(米国現地時間)に発表したニュースリリースを日本語に翻訳したもので、内容および解釈については原本である英語が優先されます。なお、日本の法規制などの観点から一部、削除、改変または追記している部分があります。

## イーライリリー社、Alzheimer's Association International Conference®2017 (AAIC®2017)において、40件以上の研究報告を発表予定

アルツハイマー病患者の適時・適切な診断と介入の必要性を強調する  
重要なヘルスアウトカムデータなどを発表

2017年7月12日インディアナポリスイーライリリー・アンド・カンパニー(以下「リリー」)(NYSE: LLY)は、7月16日~20日に英国ロンドンで開催予定のAlzheimer's Association International Conference®2017 (AAIC®2017)において、40件以上の調査・研究を報告します。報告を予定しているのは、アルツハイマー病の診断前の医療資源使用に関するヘルスアウトカムデータや、種々の臨床開発段階にある有望な治療薬や診断手法など、リリーの広範なアルツハイマー病パイプラインに関するデータです。

リリーのグローバル・アルツハイマー病・プラットフォーム副社長であるフィリス・フェレルは次のように述べています。「これまでの研究から、アルツハイマー病は、日常生活に影響を及ぼす症状が現れる数年前から発症しはじめることが示されています。この疾患と効率的に立ち向かうためには、アルツハイマー病を有する人々や、介護者、医師が、一刻も早く疾患を認識し診断することを目標として、より早く、より意義のある対話を行う必要があります。リリーは、依然としてアルツハイマー病の解決法を探し求めており、近い将来有望な新規の治療法が発見されると信じています。」

特に関心が高いと思われるのは、アルツハイマー病の今後のケアに役立つ情報であると考えられる、以下のオーラルプレゼンテーション(口頭発表)です:

- **Trends in Health Service Use and Potentially Avoidable Hospitalizations Prior to Alzheimer's Disease Diagnosis: A Matched, Retrospective Study of US Medicare Beneficiaries** Oral presentation, Thursday, July 20, 12:00PM – 12:15PM. Presenting author: JS Andrews

報告される予定のその他の研究は以下のとおりです(注意:日時は英国時間です)::

## ソラネズマブに関するデータ

- **Plasma Pharmacokinetics and Pharmacodynamics of Solanezumab in Mild and Moderate AD Patients** *Poster presentation, Sunday, July 16, 9:30AM- 4:15PM. Presenting author: B Willis*
- **The Basics of Fluid Biomarkers in Alzheimer's Disease: Standardization, Quality Control and Regulatory Issues for Fluid Biomarkers** *Educational workshop, Friday, July 14, 8:00AM – 5:00PM. Presenting author: RA Dean*
- **Solanezumab Central Target Engagement and Pharmacodynamic Activity in the EXPEDITION 3 Trial of Patients with Mild AD: Comparison to EXPEDITION/EXPEDITION 2** *Poster presentation, Sunday, July 16, 9:30AM – 4:15PM. Presenting author: J Raskin*
- **Deriving a Cut-Off for the Elecsys®  $\beta$ -Amyloid (1–42) Immunoassay for Use in Clinical Trials Supported by Eli Lilly for Patients with Clinically Defined Alzheimer's Disease** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: L. Shaw*
- **Effect of Solanezumab on Biomarkers of Neurodegeneration in the EXPEDITION3 Trial in Mild Alzheimer Disease** *Poster presentation, Saturday, July 15, 12:15 PM – 1:30 PM. Presenting author: AJ Schwarz*
- **Safety of Solanezumab in Phase 3 Studies in Individuals with Mild Alzheimer's Disease Dementia** *Poster presentation, Sunday, July 16, 9:30AM – 4:15PM. Presenting author: C Carlson*
- **Contemporary Issues in Clinical Trials Methods: Delayed Start Analysis in Phase 3 Solanezumab EXPEDITION3 Study in Mild Alzheimer's Disease** *Educational workshop, Friday, July 14, 8:00AM – 5:00PM. Presenting author: H Liu-Seifert*
- **Comparison of Baseline ARIA-H Prevalence at 1.5T and 3T MRI Field Strengths in a Multi-Site Global Clinical Trial with Cohort of 2137 AD Subjects** *Poster presentation, Sunday, July 16, 9:30AM – 4:15PM. Presenting author: A Schwarz*
- **The Integrated Alzheimer's Disease Rating Scale (iADRS) Findings from the EXPEDITION3 Trial** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: A Wessels*
- **The Patient Voice: Exploring Treatment Preferences in Participants with Mild Cognitive Concerns to Inform Regulatory Decision-Making** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: KE Bullok*
- **Big Pharma in VCID: What Will It Take?** *Featured research session, Wednesday, July 19, 5:15PM – 5:35PM. Presenting author: J Sims*

## 神経変性に関するデータ

- **Establishing Microfluidic Devices As an in Vitro Neuronal Model for Studying Molecular and Functional Aspects of Transneuronal Tau Propagation** *Poster presentation, Tuesday, July 18, 9:30AM – 4:15PM. Presenting author: A Katsikoudi*
- **Investigating Glymphatic Function during Early Tau Pathology Using Dynamic Contrast-Enhanced MRI** *Poster presentation, Saturday, July 15, 12:15PM – 1:30PM. Presenting author: O Ismail*

- **The Coalition Against Major Diseases: Towards U.S. FDA Qualification of Hippocampal Volume As a Biomarker for Enrichment in Clinical Trials for Pre-Dementia Stages of Alzheimer's Disease** *Poster presentation, Wednesday, July 19, 9:30 AM – 4:15PM. Presenting author: D Conrado*
- **Regulated Release of HYPER-Phosphorylated, Aggregated and Seeding Competent Tau from BRAIN Rodent and Human Synaptosomes** *Oral presentation, Sunday, July 16, 3:00PM-3:15PM. Presenting author: E Sher*
- **Plasma Total Tau, Cognitive Decline, and Risk of Mild Cognitive Impairment in the Mayo Clinic Study on Aging** *Poster presentation, Tuesday, July 18, 9:30AM – 4:15PM. Presenting author: M Mielke*
- **Characterisation of Molecular Mechanisms That Are Triggered and Contribute to Tau Pathology in a Cell Model of Tau Aggregation** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: J Wolak*
- **fMRI of Visual Stimuli in a Tau Model of Alzheimer's Disease** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: I Harrison*
- **In Vivo Two-Photon Imaging of the Effects of Tauopathy and Amyloidopathy on Synapses** *Poster presentation, Tuesday, July 18, 9:30AM – 4:15PM. Presenting author: J Jackson*
- **Developing In Vivo models of Tau Propagation Which Are Relevant to Human Disease Pathogenesis and Applicable to Pre-Clinical Drug Discovery** *Oral presentation, Tuesday, July 18, 2:15PM – 2:30PM. Presenting author: Z Ahmed*
- **An Academic-Private Partnership for the Validation of New Models to Understand Tau-Related Hyperexcitability & Aggregation Using Human Induced Pluripotent Stem Cells** *Poster presentation, Tuesday, July 18, 9:30AM – 4:15PM. Presenting author: AC Socorro*
- **Characterization of Biofluid sTREM2 Using a Novel sTREM2 Assay** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: H Wang*
- **Assessing TREM2 Function in Alzheimer's Disease with RNA-Seq** *Oral presentation, Monday, July 17, 5:30PM – 5:45PM. Presenting author: G Carbajosa*

#### 抗タウ抗体に関するデータ

- **Aggregate-Selective Anti-Tau Antibody MC-1 Demonstrated Robust in Vitro and In Vivo Activity to Neutralize Transmissible Tau and Reduce Tau Pathology** *Oral presentation, Monday, July 17, 5:00PM – 5:15PM. Presenting author: M Hayashi*
- **Preclinical Characterization of an Antibody [LY3303560] Targeting Aggregated Tau** *Oral presentation, Monday, July 17, 5:15PM – 5:30PM. Presenting author: R Alam*
- **Preclinical in Vitro and In Vivo Characterization of Tau Antibodies to Block Tau Propagation** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: S Wu*

### FabPEG(アミロイドβ抗体)に関するデータ

- **Tolerability, Pharmacokinetics and Pharmacodynamics in Healthy Subjects of Single Doses of LY2599666, an Antigen Binding Fragment (Fab) of a Monoclonal Antibody That Targets Soluble Monomer Aβ Linked to a Poly(ethylene glycol) Molecule** *Poster presentation, Sunday, July 16, 9:30AM – 4:15PM. Presenting author: AM Hake*

### Flortaucipir(タウ PET)に関するデータ

- **A Robust, Simplified Braak-Type Classification Scheme for Flortaucipir F 18 Tau PET Images** *Oral presentation, Saturday, July 15, 9:45AM – 10:00AM. Presenting author: AJ Schwarz*
- **The Association of Tau Burden in Cerebral Lobes and Functional Brain Networks with Performance in Different Cognitive Domains** *Poster presentation, Wednesday, July 19, 9:30AM – 4:15PM. Presenting author: A Charil*
- **Comparison of Regional Flortaucipir PET to Quantitative Tau and Amyloid Immunoassay in Patients with Alzheimer's Disease Pathology: A Pilot Clinico-Pathological Study** *Poster presentation, Monday, July 17, 9:30AM – 4:15PM. Presenting author: AD Siderowf*
- **An Update on the Binding Profile of Flortaucipir in AD Versus Normal CNS Proteins and Normal Brain** *Oral presentation, Sunday, July 16, 3:15PM – 3:30PM. Presenting author: G Attardo*
- **Parametric Imaging of Tau Load in Alzheimer's Patients and Controls Using Flortaucipir** *Poster presentation, Saturday, July 15, 12:15PM – 1:30PM. Presenting author: EE Wolters*
- **Pathology in the Early Alzheimer's Prodrome: Self and Informant Cognitive Concerns Show Different Patterns of Association with Tau Deposition on [18f]Flortaucipir PET in Amyloid Positive Older Adults** *Poster presentation, Saturday, July 15, 12:15PM - 1:30PM. Presenting author: S Risacher*
- **PET Biomarkers in the EXPEDITION 3 Trial of Patients with Mild AD** *Oral presentation, Thursday, July 20, 8:30AM – 8:45AM. Presenting author: MA Mintun*
- **Modeling of Tau Trajectories across the Alzheimer's Disease Spectrum Using [18F]-Flortaucipir PET Imaging** *Poster presentation, Wednesday, July 19, 9:30AM - 4:15PM. Presenting author: S Shcherbinin*

### アルツハイマー病に関する一般的なデータ

- **Intermediate Changes in Cognition Predict Long Term Outcomes in Mild Alzheimer's Disease Dementia** *Poster presentation, Monday, July 17, 9:30AM – 4:15PM. Presenting author: C Reed*
- **Is the Annual Wellness Visit Adequate to Impact Cognitive Care?** *Poster presentation, Tuesday, July 18, 9:30AM – 4:15PM. Presenting author: N Fowler*

## 選択的アミロイドβ1-42抗体に関するデータ

- **Preclinical Discovery and Development of MEDI1814, a Monoclonal Antibody Selectively Targeting Beta-Amyloid 42 (Aβ42)** *Poster presentation, Sunday, July 16, 9:30AM – 4:15PM. Presenting author: A Billinton*
- **MEDI1814, a High-Affinity Antibody Directed to the C-Terminus of Aβx-42, Abrogates Synaptic Plasticity Disruption Caused By Synthetic or AD Brain-Derived Aβ Soluble Assemblies In Vivo** *Poster presentation, Tuesday, July 18, 9:30AM – 4:15PM. Presenting author: T Ondrejcek*
- **Evaluation of Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of MEDI1814, a beta-Amyloid 42 (ab42)-Specific Antibody, in Patients with Mild-Moderate Alzheimer's Disease** *Oral presentation, Monday, July 17, 2:15PM – 2:30PM. Presenting author: T Ostefeld*

## アルツハイマー病について

アルツハイマー病は、記憶などの認知機能に進行性の機能低下をもたらす致死的な疾患です。アルツハイマー病型認知症は、認知症の最も頻度の高い形態であり、認知症症例の60～80%を占めています<sup>1,2</sup>。現在、認知症を抱えて生活している人は世界中で約4,700万人いると推計されています<sup>1</sup>。患者数は2030年にはおよそ7,500万人、2050年には1億3,200万人に達すると推測されています<sup>1</sup>。世界中で、年間約1,000万人が認知症と新たに診断されており、これは、3.2秒ごとに1人が診断されていることを意味しています<sup>1</sup>。現在の年間の社会的および経済的損失は8,000億ドルを上回ると推計されており、2018年には1兆ドルに達すると推測されています<sup>3</sup>。

## イーライリリー・アンド・カンパニーについて

リリーは、世界中の人々のより豊かな人生のために、革新的な製品に思いやりを込めてお届けすることを目指すグローバルヘルスケアリーダーです。当社は、真のニーズを満たすべく高品質の医薬品の創造に献身した1人の男性により100年以上前に創立され、現在も当社のすべての事業においてそのミッションに忠実であり続けています。世界中で、イーライリリー社の従業員は人々の人生にインパクトを与えるような医薬品を発見し、それを必要とする人々に提供し、疾患についての理解や管理を向上させ、慈善活動やボランティア活動を通じて地域社会へ還元しています。リリーの詳細については [www.lilly.com](http://www.lilly.com) 及び <http://newsroom.lilly.com/social-channels> をご覧ください。

## 日本イーライリリーについて

日本イーライリリー株式会社は、米国イーライリリー・アンド・カンパニーの日本法人です。人々がより長く、より健康で、充実した生活を実現できるよう、革新的な医薬品の開発・製造・輸入・販売を通じ、がん、糖尿病、筋骨格系疾患、中枢神経系疾患、自己免疫疾患、成長障害、疼痛、などの領域で日本の医療に貢献しています。詳細はウェブサイトをご覧ください。 <http://www.lilly.co.jp>

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about investigational treatments and diagnostics for Alzheimer's disease and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that these investigational compounds or diagnostics will achieve primary study endpoints or receive regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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1. Alzheimer's Disease International. Dementia statistics. <http://www.alz.co.uk/research/statistics>. Accessed March 2017.

2. Alzheimer's Association. What Is Dementia? <http://www.alz.org/what-is-dementia.asp>. Published January 2016. Accessed March 2017.

3. Alzheimer's Disease International. World Alzheimer Report 2015 The Global Impact of Dementia. <https://www.alz.co.uk/research/WorldAlzheimerReport2015.pdf>. Accessed March 2017.

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