

ELI LILLY AND COMPANY – CITATIONS

In this section, you will find citations to select publications regarding investigational assets and investigational uses for approved products that may be of interest to our investors. For a more complete listing of Lilly sponsored clinical trials and available study results, please visit the [ClinicalTrials.gov](https://www.clinicaltrials.gov) website.

Biomedicines

Baricitinib (LY3009104) – Atopic Dermatitis

- Guttman-Yassky E, Silverberg JI, Nemoto O, Forman SB, Wilke A, Prescilla R, de la Peña A, Nunes FP, Janes J, Gamalo M, Donley D, Paik J, DeLozier AM, Nickoloff BJ, Simpson EL. Baricitinib in adult patients with moderate-to-severe atopic dermatitis: a phase 2 parallel, double-blinded, randomized placebo-controlled multiple-dose study. *J Am Acad Dermatol.* 2018;pii: S0190-9622(18):30129-4;epub Feb 1.

Baricitinib (LY3009104) – Systemic Lupus Erythematosus

- Wallace DJ, Furie RA, Tanaka Y, Kalunian KC, Mosca M, Petri MA, Dörner T, Cardiel MH, Bruce IN, Gomez E, Carmack T, DeLozier AM, Janes JM, Linnik MD, de Bono S, Silk MT, Hoffman RW. Baricitinib for systemic lupus erythematosus: a double-blind, randomised, placebo-controlled, phase 2 trial. *The Lancet*, 392 (10143), 222 – 231.

Galcanezumab (LY2951742) – Migraine Prevention

- Dodick D, Goadsby P, Spierings E, Scherer J, Sweeney S, Grayzel D. CGRP Monoclonal Antibody LY2951742 for the Prevention of Migraine: A Phase 2, Randomized, Double-Blind, Placebo Controlled Study. *Lancet Neurology.* 2014;13(9):885-92.
- Oakes TM, Zhang Q, Ferguson MB, Skljarevski V, Martinez JM, Johnson KW, Schacht AL, Due MR, Goadsby PJ, Dodick DW. Efficacy and safety of LY2951742 in a randomized, double-blind, placebo-controlled, dose-ranging study in patients with migraine. Presented at American Headache Society- 58th Annual Meeting. 2016;56(S1):68.
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- Ford J, Jackson J, Milligan G, Cotton S, Ahl J, Aurora S. A real-world analysis of migraine: a cross-sectional study of disease burden and treatment patterns. *Headache.* 2017;57(10):1532-1544.
- Skljarevski V, Stauffer VL, Zhang Q, Detke HC, Millen BA, Yang J, Selzler KJ, Conley R, Aurora SK. Phase 3 Studies (EVOLVE-1 & EVOLVE-2) of Galcanezumab in Episodic Migraine: Results of 6-Month Treatment Phase. Presented at International Headache Society - 18th International Headache Congress. Sept 6, 2017, Vancouver, CA.
- Stauffer VL, Sides R, Camporeale A, Skljarevski V, Ahl J, Aurora SK. A Phase 3, Long-Term, Open-Label Safety Study of Self-Administered Galcanezumab Injections in Patients with Migraine. Presented at International Headache Society - 18th International Headache Congress. Sept 6, 2017, Vancouver CA.
- Skljarevski V, Oakes TM, Zhang Q, Ferguson MB, Martinez J, Camporeale A, Johnson KW, Shan Q, Carter J, Schacht A, Goadsby PJ, Dodick DW. Effect of Different Doses of Galcanezumab vs

Placebo for Episodic Migraine Prevention: A randomized clinical trial. *JAMA Neurol.*

2018;75(2):187-193. Doi:10.1001/jamaneurol.2017.3859

- Skljarevski V, Matharu M, Millen B, Ossipov M, Kim Y, Yang J. Efficacy and Safety of Galcanezumab for the Prevention of Episodic Migraine: Results of the EVOLVE-2 Phase 3 Clinical Trial. *Cephalalgia.* 2018;38(8):1442-1454.
- Stauffer VL, Dodick DW, Zhang Q, Carter JN, Ailani J, Conley RR. Evaluation of galcanezumab for the prevention of episodic migraine: The EVOLVE-1 randomized clinical trial. *JAMA Neurol.* Doi:10.1001/jamaneurol.2018.1212 Published online May 29, 2018.

Ixekizumab (LY2439821)- Axial Spondyloarthritis

- van der Heijde D, Cheng-Chung Wei J, Dougados M, Mease P, Deodhar A, Maksymowych WP, Van den Bosch F, Sieper J, Tomita T, Landewé R, Zhao F, Krishnan E, Adams DH, Pangallo B, and Carlier H. Ixekizumab, an Interleukin-17A antagonist in the treatment of Ankylosing Spondylitis/Radiographic Axial Spondyloarthritis: 16 Week Results of a Phase 3 Randomized, Double-Blind, Double-Dummy, Active and Placebo Controlled Trial in Biologic Disease Modifying Anti-Rheumatic Drug-naïve patients (COAST -V). *The Lancet.* Published online Oct 22, 2018.
- Deodhar A, Poddubnyy D, Pacheco-Tena C, Salvarani C, Lespessailles E, Rahman P, Järvinen P, Sanchez Burson J, Gaffney K, Bong Lee E, Krishnan E, Santisteban S, Li X, Zhao F, Carlier H, Reveille JD, on behalf of the COAST-W study group. Efficacy and safety of Ixekizumab in the Treatment of Radiographic Axial Spondyloarthritis: 16 Week Results of a Phase 3 Randomized, Double-Blind, Placebo Controlled Trial in Patients with Prior Inadequate Response or Intolerance to Tumor Necrosis Factor Inhibitors. *Arthritis Rheumatol.* Published online Oct 22, 2018.
- Kiltz U, van der Heijde D, Boonen A, Gensler LS, Hunter T, Zhao F, Carlier H, Braun J. Ixekizumab Significantly Improves Self-Reported Overall Functioning and Health in Patients with Active AS/Radiographic Axial SpA Naive to Biologic DMARD Therapy: 16 Week Results of a Phase 3 Randomized, Active and Placebo-Controlled Trial. *Arthritis Rheumatol.* 2018;70(suppl 10).

Lasmiditan (LY2951742) – Acute Migraine

- Färkkilä M, Diener HC, Géraud G, Láinez M, Schoenen J, Harner N, Pilgrim A, Reuter U; COL MIG-202 study group. Efficacy and tolerability of lasmiditan, an oral 5-HT_{1F} receptor agonist, for the acute treatment of migraine: a phase 2 randomised, placebo-controlled, parallel-group, dose-ranging study. *Lancet Neurol.* 2012;11(5):405-13.
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- Kuca B, Berg P, Wietecha L, Aurora S. Lasmiditan (200 mg and 100 mg) Compared to Placebo for Acute Treatment of Migraine. Presented at American Headache Society - 59th Annual Scientific Meeting. June 8, 2017, Boston MA.
- Wietecha LA, Kuca B, Case MG, Selzler KJ, Aurora SK. Phase 3 Study (SPARTAN) of Lasmiditan Compared to Placebo for Acute Treatment of Migraine. Presented at International Headache Society - 18th International Headache Congress. Sept 9, 2017, Vancouver, CA.

Mirikizumab (LY3074828)- Psoriasis

- Reich K, Bissonnette R, Menter A, Klekotka P, Patel D, Li J, Tuttle J, Papp K. Efficacy and Safety of mirikizumab (LY3074828) in the treatment of moderate-to-severe plaque psoriasis: Results from a Phase 2 study. Presented at Psoriasis: Gene to Clinic. Dec 1, 2017, London, UK.
- Rich P, Maari C, Leonardi C, Klekotka P, Patel D, Li J, Tuttle J, Papp K. Efficacy, safety, and quality of life in patients with moderate-to-severe plaque psoriasis treated with mirikizumab (LY3074828) in a Phase 2 study. Presented at American Academy of Dermatology - 76th Annual Meeting. Feb 16, 2018, San Diego, CA.
- Gooderham M, Bagel J, Heredia EE, Li J, Zhu B, Guo J, Klekotka P. Mirikizumab Significantly Improves Self-Reported Disease Severity and General Health Status in Patients with Moderate-to-Severe Psoriasis. International Federation of Psoriasis Associations - 5th Psoriasis & Psoriatic Arthritis Conference. Jun 27, 2018, Stockholm, Sweden.

Mirikizumab (LY3074828)- Ulcerative Colitis

- Sandborn WJ, Ferrante M, Bhandari BR, D'Haens GR, Berliba E, Feagan BG, Laskowski J, Friedrich S, Durante M, Tuttle J. Efficacy and safety of anti-interleukin-23 therapy with mirikizumab (LY3074828) in patients with moderate-to-severe ulcerative colitis in a Phase 2 study. Presented at Digestive Disease Week – Jun 5, 2018, Washington, DC.

Solanezumab (LY2062430) – Alzheimer’s Disease

- Doody RS, Thomas RG, Siemers E, Lui-Seifert H, Mohs R, for the Solanezumab Study Group, Farlow M, Iwatsubo T, Vellas B, Joffe S, Kieburtz K, Raman R, Sun X, and Aisen PS for the Alzheimer’s Disease Cooperative Study Steering Committee. Phase 3 Trials of Solanezumab for Mild-to-Moderate Alzheimer’s Disease. *New England Journal of Medicine*. 2014;370(4):311-21.
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Tanezumab – Cancer Pain, Chronic Low Back Pain, Osteoarthritis

- Sopata M, Katz N, Carey W, Smith MD, Keller D, Verburg KM, West CR, Wolfram G, Brown MT. Efficacy and Safety of Tanezumab in the Treatment of Pain from Bone Metastases. *Pain*. 2015;156(9):1703-1713.
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- Hochberg MC, Abramson SB, Vignon EP, Verburg KM, West CR, Smith MD, Tive L, Hungerford D. When is Osteonecrosis Not Osteonecrosis? Adjudication of Reported Serious Adverse Joint Events in the Tanezumab Clinical Development Program. *Arthritis Rheumatology*. 2016;68:382-91.

Tau PET Tracer

- Devous MD Sr, Joshi AD, Navitsky M, Southekal S, Pontecorvo MJ, Shen H, Lu M, Shankle WR, Seibyl JP, Marek K, Mintun MA. Test-Retest Reproducibility for the Tau PET Imaging Agent Flortaucipir F 18. *Journal of Nuclear Medicine*. 2017;doi: 10.2967/jnumed.117.200691. [Epub ahead of print].
- Southekal S, Devous MD Sr, Kennedy I, Navitsky M, Lu M, Joshi AD, Pontecorvo MJ, Mintun MA. Flortaucipir F 18 Quantitation using a Parametric Estimate of Reference Signal Intensity (PERSI). *Journal of Nuclear Medicine*. 2017;doi: 10.2967/jnumed.117.200006. [Epub ahead of print].
- Pontecorvo MJ, Siderowf A, Dubois B, Doraiswamy PM, Frisoni GB, Grundman M, Nobili F, Sadowsky CH, Salloway S, Arora AK, Chevrette A, Deberdt W, Dell'Agnello G, Flitter M, Galante N, Lowrey MJ, Lu M, McGeehan A, Devous MD Sr, Mintun MA. Effectiveness of Flortaucipir PET Imaging in Changing Patient Management. *Dementia and Geriatric Cognitive Disorders*. 2017;44:129-143.
- Swinford CG, Risacher SL, Charil A, Schwarz AJ. Memory concerns in the early Alzheimer's disease prodrome: Regional association with tau deposition. *Alzheimers Dementia*. 2018;2(10):322-331; doi: 10.1016/j.dadm.2018.03.001.
- Pontecorvo MJ, Devous MD Sr, Navitsky M, Lu M, Salloway S, Schaerf FW, Jennings D, Arora AK, McGeehan A, Lim NC, Xiong H, Joshi AD, Siderowf A, Mintun MA, 18F-AV-1451-A05 investigators. Relationships between flortaucipir PET tau binding and amyloid burden, clinical diagnosis, age and cognition. *Brain*. 2017;140(3):748-763.

Diabetes

GIP/GLP-1 Co-agonist Peptide (LY3298176)

- Frias JP, Nauck MA, Van J, Kutner ME, Cui X, Benson C, Urva S, Gimeno RE, Milicevic Z, Robins D, Haupt A. Efficacy and safety of LY3298176, a novel dual GIP and GLP-1 receptor agonist, in patients with type 2 diabetes: a randomised, placebo-controlled and active comparator-controlled phase 2 trial. *Lancet*. 2018;ePub ahead of print.

Jardiance - Type 1 Diabetes Mellitus, Heart Failure

- Perkins BA, Cherney DZ, Partridge H, Soleymanlou N, Tschirhart H, Zinman B, Fagan NM, Kaspers S, Woerle HJ, Broedl UC, Johansen OE. Sodium-glucose cotransporter 2 inhibition and glycemic control in type 1 diabetes: results of an 8-week open-label proof-of-concept trial. *Diabetes Care*. 2014;37(5):1480-3. doi: 10.2337/dc13-2338
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- Fitchett D, Zinman B, Wanner C, Lachin JM, Hantel S, Salsali A, Johansen OE, Woerle HJ, Broedl UC, Inzucchi SE; EMPA-REG OUTCOME trial investigators. Heart failure outcomes with empagliflozin in patients with type 2 diabetes at high cardiovascular risk: results of the EMPA-REG OUTCOME trial. *European Heart Journal*. 2016;37(19):1526-34. doi: 10.1093/eurheartj/ehv728

Nasal Glucagon – Severe Hypoglycemia Rescue

- Guzman CB, Dulude H, Piché C, Rufiange M, Sadoune AA, Rampakakis E, Carballo D, Triest M, Zhang MX, Zhang S, Tafreshi M, Sicard E. Effects of common cold and concomitant administration of nasal decongestant on the pharmacokinetics and pharmacodynamics of nasal glucagon in otherwise healthy participants: A randomized clinical trial. *Diabetes Obes Metab*. 2017 Oct 20. doi:10.1111/dom.13134. [Epub ahead of print]
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- Seaquist ER, Dulude H, Zhang XM, Rabasa-Lhoret R, Tsoukas GM, Conway RJ, Weisnagel SJ, Gerety G, Woo VC, Zhang S, Carballo D, Pradhan S, Piché CA, Guzman CB. Prospective study evaluating the use of nasal glucagon for the treatment of moderate to severe hypoglycaemia in adults with type 1 diabetes in a real-world setting. *Diabetes Obes Metab.* 2018;20(5):1316-1320.
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Trulicity - Type 2 Diabetes Mellitus

- Frias JP, Wynne AG, Matyjaszek-Matuszek B, Bartaskova D, Cox D, Woodward B, Li G, Milicevic Z. Efficacy and Safety of an Expanded Dulaglutide Dose Range—A Phase 2, Placebo-Controlled Trial in T2D Patients on Metformin. *Diabetes.* 2018;67(Suppl 1):126-OR.

Ultra Rapid Insulin Lispro - Type 1&2 Diabetes Mellitus

- Michael MD, Zhang C, Siesky AM, Cox AL, Sperry AE, Hansen RJ, Christe ME, Farmen MW, Wu H, Paavola CD, Moyers JS. Exploration of the Mechanism of Accelerated Absorption for a Novel Insulin Lispro Formulation. Poster presented at American Diabetes Association; June 9, 2017; San Diego, CA.
- Pratt E, Leohr J, Heilmann C, Johnson J, Landschulz W. Treprostinil Causes Local Vasodilation, Is Well Tolerated, and Results in Faster Absorption of Insulin Lispro. Poster presented at American Diabetes Association; June 9, 2017; San Diego, CA.
- Leohr J, Pratt EJ, Heilmann C, Johnson J, Kelly RP, Landschulz W. A Novel Insulin Lispro Formulation Containing Citrate and Treprostinil Demonstrates Faster Absorption and Onset of Insulin Action in Healthy Subjects. Poster presented at American Diabetes Association; June 9, 2017; San Diego, CA.
- Kazda C, Leohr J, Liu R, Reddy S, Dellva MA, Lim ST, Loh MT, Knadler MP, Hardy T, Plum-Moerschel L. A Novel Formulation of Insulin Lispro Containing Citrate and Treprostinil Shows Faster Absorption and Improved Postprandial Glucose Excursions vs. Humalog in Patients with T1DM. Poster presented at American Diabetes Association; June 9, 2017; San Diego, CA.
- Kapitzka C, Leohr J, Liu R, Reddy S, Dellva MA, Matzopoulos M, Knadler MP, Loh MT, Hardy T, Kazda C. A Novel Formulation of Insulin Lispro Containing Citrate and Treprostinil Shows Significantly Faster Absorption and an Improvement in Postprandial Glucose Excursions vs. Humalog in Patients with T2DM. Poster presented at American Diabetes Association; June 9, 2017; San Diego, CA.

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Oncology

Abemaciclib – Lung Cancer

- Patnaik A, Rosen LS, Tolaney SM, Tolcher AW, Goldman JW, Gandhi L, Papadopoulos KP, Beerman M, Rasco DW, Hilton JF, Nasir A, Beckmann RP, Schade AE, Fulford AD, Nguyen TS, Martinez R, Kulanthaivel P, Li LQ, Frenzel M, Cronier DM, Chan EM, Flaherty KT, Wen PY, Shapiro GI. Efficacy and safety of abemaciclib, an inhibitor of CDK4 and CDK6, for patients with breast cancer, non-small cell lung cancer, and other solid tumors. *Cancer Discovery.* 2016;6(7):740-53.
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- Karen Kelly, Jonathan W. Goldman, Pilar Garrido, Shadia Jalal, Daruka Mahadevan, Martin Gutierrez, Luis G. Paz-Ares, Mariano Provencio, Eric Schaefer, Monte Shaheen, Erica L. Johnston, Na Cai, William J. John, Edward S. Kim. LY2835219: Abemaciclib in combination with single agent options in stage IV NSCLC, a phase 1b study. *World Conference on Lung Cancer;* 2015; Denver, CO.

Abemaciclib – Mechanistic Data

- Torres-Guzmán R, Calsina B, Hermoso A, Baquero C, Alvarez B, Amat J, McNulty AM, Gong X, Boehnke K, Du J, de Dios A, Beckmann R, Buchanan S, Lallena MJ. Preclinical Characterization

of Abemaciclib in Hormone Receptor Positive Breast Cancer. *OncoTarget*. 2017.

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- LM Gelbert, S Cai, X Lin, C Sanchez-Martinez, M del Prado, MJ Lallena, R Torres, RT Ajamie, GN Wishart, RS Flack, B Neubauer, J Young, EM Chan, P Iversen, D Cronier, E Kreklau, A De Dios. Preclinical characterization of the CDK4/6 inhibitor LY2835219: in-vivo cell cycle dependent/independent anti-tumor activities alone/in combination with gemcitabine. *Invest New Drugs*. (2014); 32:825-837.

Cyramza – 1st and later line gastric (with pembrolizumab)

- I Chau, J Bendell, E Calvo, R Santana-Davila, HT Arkenau, G Mi, J Jin, J Rege, D Ferry, R Herbst, C Fuchs. Ramucirumab (R) plus pembrolizumab (P) in treatment naive and previously treated advanced gastric or gastroesophageal junction (G/GEJ) adenocarcinoma: A multi-disease phase I study. Presented at American Society of Clinical Oncology Annual Meeting (2017); Chicago, IL.
- C Fuchs, J Taberero, S Al-Batran, I Chau, D Ilson, E Van Cutsem, K Shitara, D Ferry, M Emig, V Vanvoorden, Y Hsu, Y Xu, A Sashegyi, M Das, M Shah. RAINFALL: A randomized, double-blind, placebo-controlled phase III study of cisplatin (Cis) plus capecitabine (Cape) or 5FU with or without ramucirumab (RAM) as first-line therapy in patients with metastatic gastric or gastroesophageal junction (G-GEJ) adenocarcinoma. Presented at American Society of Clinical Oncology - Gastrointestinal Cancers Symposium 2018; Abstract 5.
- Roy S. Herbst, Ian Chau, Daniel P. Petrylak, Hendrik-Tobias Arkenau, Johanna Bendell, Rafael Santana-Davila, Emiliano Calvo, Nicolas Penel, Juan Martin-Liberal, Andres Soriano, Philippe Cassier, Matthew G. Krebs, Nicolas Isambert, Ryan C Widau, Gu Mi, Jin Jin, David Ferry, Charles Fuchs, Luis Paz-Ares. Activity of ramucirumab (R) with pembrolizumab (P) by PD-L1 expression in advanced solid tumors: Phase 1a/b study in later lines of therapy. Presented at American Society of Clinical Oncology. *J Clin Oncol* 36, 2018 (suppl; abstr 3059)
- Kohei Shitara, Manish A. Shah, Maria Di Bartolomeo, Sara Lonardi, Salah-Eddin Al-Batran, Eric Van Cutsem, David H. Ilson, Ian Chau, Maria Alsina, Jill Lacy, Daisuke Takahari, Naotoshi Sugimoto, Johanna C. Bendell, Zev A. Wainberg, Mustapha Tehfe, David Raymond Ferry, Ran Wei, Richard A. Walgren, Mayukh Das, Charles S. Fuchs. Effect of post-discontinuation therapy (PDT) on survival in metastatic gastric-gastroesophageal junction (G-GEJ) adenocarcinoma patients from the RAINFALL trial: An exploratory analysis *J Clin Oncol* 36, 2018 (suppl; abstr 4044)

Cyramza – 2nd line lung (with osimertinib)

- H Yu, D Planchard, J C-H Yang, K H Lee, P Garrido, K Park, J-H Kim, D H Lee, S He, K Wolff, B H Chao, L Paz-Ares. Osimertinib with Ramucirumab or Necitumumab in Advanced T790M-positive EGFR-Mutant NSCLC: Preliminary Ph1 Study Results. Presented at 18th World Congress on Lung Cancer (2017); Yokohama, Japan.

- David Planchard, Helena Yu, James Chih-Hsin Yang, Ki Hyeong Lee, Pilar Garrido, Keunchil Park, Joo-Hang Kim, Dae Ho Lee, Huzhang Mao, Bo H. Chao, Luis G. Paz-Ares. Efficacy and safety results of ramucirumab in combination with osimertinib in advanced T790M-positive EGFR-mutant NSCLC. *J Clin Oncol* 36, 2018 (suppl; abstr 9053)

Cyramza – 1st line lung

- K Nakagawa, E Garon, L Paz-Ares, S Ponce, J Corral, O Vidal, E Nadal, K Kiura, K Park, R Widau, E Alexandris, S He, P Lee, M Reck. Randomized phase 1b/3 study of erlotinib + ramucirumab in untreated EGFR mutation-positive stage IV NSCLC: phase 1b outcomes. Presented at 18th World Congress on Lung Cancer (2017); Yokohama, Japan.
- Martin Reck, Edward B. Garon, Luis Paz-Ares, Santiago Ponce, Jesus Corral Jaime, Oscar Juan Vidal, Ernest Nadal, Katsuyuki Kiura, Ryan Widau, Shuang He, Rita Dalal, Pablo Lee, and Kazuhiko Nakagawa. Randomized, double-blind phase Ib/III study of erlotinib plus ramucirumab or placebo in previously untreated EGFR-mutant metastatic non-small-cell lung cancer (RELAY): phase Ib results. *Clin Lung Cancer*. 2017; Epub ahead of print. <http://dx.doi.org/10.1016/j.clcc.2017.11.003>

Cyramza – 2nd line liver

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