

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 website.

Biomedicines

BACE Inhibitor (AZD3293/LY3314814) – Alzheimer’s Disease

- Eketjäll S, Janson J, Kaspersson K, Bogstedt A, Jeppsson F, Fälting J, Haerberlein SB, Kugler AR, Alexander RC, Cebers G. AZD3293: A novel, orally active BACE1 inhibitor with high potency and permeability and markedly slow off-rate kinetics. *Journal of Alzheimer's Disease.* 2016;50(4):1109-1123.

Baricitinib (LY3009104) – Rheumatoid Arthritis

- Genovese M, Kremer J, Zamani O, Ludivico C, Krogulec M, Xie L, Beattie S, Koch A, Cardillo T, de Bono S, Rooney T, Macias W, Schlichting D, Smolen J. Baricitinib in Patients with Refractory Rheumatoid Arthritis. *New England Journal of Medicine.* 2016;374(13):1243-1252.
- Taylor PC, Keystone EC, van der Heijde D, Weinblatt ME, Del Carmen Morales L, Reyes Gonzaga J, Yakushin S, Ishii T, Emoto K, Beattie S, Arora V, Gaich C, Rooney T, Schlichting D, Macias WL, de Bono S, Tanaka Y. Baricitinib versus Placebo or Adalimumab in Rheumatoid Arthritis. *New England Journal of Medicine.* 2017;376(7):652-662.
- Fleischmann R, Schiff M, van der Heijde D, Ramos-Remus C, Spindler A, Stanislav M, Zerbini CA, Gurbuz S, Dickson C, de Bono S, Schlichting D, Beattie S, Kuo WL, Rooney T, Macias W, Takeuchi T. Baricitinib, Methotrexate, or Combination in Patients with Rheumatoid Arthritis and No or Limited Prior Disease-Modifying Antirheumatic Drug Treatment. *Arthritis Rheumatology.* 2016;69(3):506-517.
- Dougados M, van der Heijde D, Chen YC, Greenwald M, Drescher E, Liu J, Beattie S, Witt S, de la Torre I, Gaich C, Rooney T, Schlichting D, de Bono S, Emery P. Baricitinib in patients with inadequate response or intolerance to conventional synthetic DMARDs: results from the RA-BUILD study. *Annals of the Rheumatic Diseases.* 2017;76(1):88-95.
- Genovese MC, Smolen JS, Takeuchi T, Hyslop D, Macias WL, Rooney TP, Chen L, Dickson CL, Riddle Camp J, Cardillo T, Ishii T, Winthrop K. Safety Profile of Baricitinib for the Treatment of Rheumatoid Arthritis up to 5.5 Years: An Updated Integrated Safety Analysis. *Arthritis Rheumatol.* 2017;69(suppl 10)

Baricitinib (LY3009104) – Atopic Dermatitis

- Guttman-Yassky E, Silverberg J, Nunes F, Janes J, Brown E, Donley D, Paik J, deLozier A, Nickoloff BJ, Simpson E. Baricitinib in patients with moderate-to-severe atopic dermatitis: a phase 2 parallel, double-blinded, randomized placebo-controlled multiple dose study. Presented at European Academy of Dermatology and Venereology - 26th Congress. 2017.

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.
- Detke HC, Wang S, Skljarevski V, Ahl J, Millen BA, Aurora SK, Yang J, Sexson M. A Phase 3 Placebo-Controlled Study of Galcanezumab in Patients with Chronic Migraine: Results from the 3-month Double-Blind Treatment Phase of the REGAIN study. *PAINWeek Abstract Book 2017*, *Postgrad Med*. 2017;129(suppl 1):47. Abstract 65.
- 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.

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.
- Ferrari MD, Färkkilä M, Reuter U, Pilgrim A, Davis C, Krauss M, Diener HC; European COL-144 Investigators. Acute treatment of migraine with the selective 5-HT_{1F} receptor agonist lasmiditan - a randomised proof-of-concept trial. *Cephalalgia*. 2010;30(10):1170-8.
- Nelson DL, Phebus LA, Johnson KW, Waincott DB, Cohen ML, Calligaro DO, Xu YC. Preclinical pharmacological profile of the selective 5-HT_{1F} receptor agonist lasmiditan. *Cephalalgia*. 2010;30(10):1159-69.
- 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.

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.
- Siemers E, Sundell K, Carlson C, Case M, Sethuraman G, Liu-Seifert H, Dowsett SA, Pontecorvo M, Dean RA, DeMattos R. Phase 3 solanezumab trials: Secondary outcomes in mild Alzheimer’s disease patients. *Alzheimer’s & Dementia.* 2016;12(2):110-120.
- Liu-Seifert H, Siemers E, Holdridge K, Andersen S, Lipkovich I, Carlson C, Sethuraman G, Hoog S, Hayduk R, Doody R, Aisen P. Delayed-start analysis: mild Alzheimer patients in solanezumab trials, 3.5 years. *Alzheimer’s & Dementia.* 2015;1(2):111-21.
- Liu-Seifert H, Siemers E, Price K, Han B, Selzler K, Henley D, Sundell K, Aisen P, Cummings J, Raskin J, Mohs R. Cognitive Impairment Precedes and Predicts Functional Impairment in Mild Alzheimer’s Disease Dementia. *Journal of Alzheimer’s Disease.* 2015;47(1):205-14.
- Siemers E, Holdridge K, Sundell K, Liu-Seifert H. Function and clinical meaningfulness of treatments for mild Alzheimer’s disease. *Alzheimer’s & Dementia: Diagnosis, Assessment & Disease Monitoring.* *Alzheimer’s & Dementia.* 2016;2:105-112.

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].
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- 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

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
- Pieber TR, Famulla S, Eilbracht J, Cescutti J, Soleymanlou N, Johansen OE, Woerle HJ, Broedl UC, Kaspers S. Empagliflozin as adjunct to insulin in patients with type 1 diabetes: a 4-week, randomized, placebo-controlled trial (EASE-1). *Diabetes, Obesity and Metabolism*. 2015;17(10):928-35. doi: 10.1111/dom.12494
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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]
- Yale JF, Dulude H, Egeth M, Piché CA, Lafontaine M, Carballo D, Margolies R, Dissinger E, Shames AR, Kaplowitz N, Zhang MX, Zhang S, Guzman CB. Faster Use and Fewer Failures with Needle-Free Nasal Glucagon Versus Injectable Glucagon in Severe Hypoglycemia Rescue: A Simulation Study. *Diabetes, Technology & Therapeutics.* 2017; 19(7):423-32. doi: 10.1089/dia.2016.0460
- Seaquist ER, Dulude H, Zhang MX, Rampakakis E, Rabasa-Lhoret R, Tsoukas GM, Conway JR, Weisnagel SJ, Gerety G, Woo V, Zhang S, Carballo D, Triest M, Piché CA, Guzman CB. Nasal Glucagon for the Treatment of Moderate-to-Severe Hypoglycemic Episodes in Real-World Settings in Adults with Type 1 Diabetes. Oral presentation at: American Diabetes Association; June 9, 2017; San Diego, CA.
- Deeb LC, Dulude H, Zhang MX, Zhang S, Reiner BJ, Piché CA, Guzman CB. Nasal Glucagon for the Treatment of Moderate to Severe Hypoglycemic Episodes in Children and Adolescents with Type 1 Diabetes in Home or School Settings. Poster presented at: International Society of Pediatric and Adolescent Diabetes; October 27, 2016; Valencia, Spain.
- Dulude H, Sicard E, Rufiange M, Sadoune AA, Carballo D, Triest M, Tafreshi M, Rampakakis E, Piché CA. Effects of Nasal Congestion from Common Cold on the PK and PD of Nasal Glucagon. Poster presented at American Diabetes Association; June 10, 2016; New Orleans, LA.
- Rickels MR, Ruedy KJ, Foster NC, Piché CA, Dulude H, Sherr JL, Tamborlane WV, Bethin KE, DiMeglio LA, Wadwa RP, Ahmann AJ, Haller MJ, Nathan BM, Marcovina SM, Rampakakis E, Meng L, Beck RW. Intranasal glucagon for treatment of insulin-induced hypoglycemia in adults with type 1 diabetes: A randomized crossover non-inferiority study. *Diabetes Care.* 2016; 39(2):264-70. doi: 10.2337/dc15-1498
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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.
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PCSK9 – CV Disease

- Kastelein JJP, Nissen SE, Rader DJ, Hovingh GK, Wang MD, Shen T, Krueger KA. Safety and efficacy of LY3015014, a monoclonal antibody to proprotein convertase subtilisin/kexin type 9 (PCSK9): a randomized, placebo controlled phase 2 study. *European Heart Journal*. 2016;137(17):1360-9]. doi:10.1093/eurheartj/ehv707
- Schroeder KM, Beyer TP, Hansen RJ, Han B, Pickard RT, Wroblewski VJ, Kowala MC1, Eacho PI. Proteolytic cleavage of antigen extends the durability of an anti-PCSK9 monoclonal antibody. *Journal of Lipid Research*. 2015;56(11):2124-2132. doi: 10.1194/jlr.M061903
- Shen T, James DE, Krueger KA. Population pharmacokinetics (PK) and pharmacodynamics (PD) analysis of LY3015014, a monoclonal antibody to protein convertase subtilisin/kexin type 9 (PCSK9) in healthy subjects and hypercholesterolemia patients. *Pharmaceutical Research*. 2017;34(1):185-92. doi: 10.1007/s11095-016-2054-6.

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.

- Goldman JW, Shi P, Reck M, Paz-Ares L, Koustenis A, Hurt KC. Treatment rationale and study design for the JUNIPER study: A randomized phase 3 study of abemaciclib plus best supportive care versus erlotinib plus best supportive care in patients with stage IV non-small-cell lung cancer with a detectable KRAS mutation whose disease has progressed after platinum-based chemotherapy. *Clin Lung Cancer.* 2016;17(1):80-4.
- Goldman JW, Gandhi L, Patnaik A, Rosen LS, Hilton J, Papadopoulos KP, Tolaney SM, Beeram M, Raso DW, Beckmann RP, Kulanthaivel P, Frenzel M, Cronier D, Chan EM, Flaherty KT, Wen PY, Tolcher AW, Shapiro GI. Clinical activity of LY2835219, a novel cell cycle inhibitor selective for CDK4 and CDK6, in patients with non-small cell lung cancer. American Society of Clinical Oncology; 2014; Chicago, IL.
- 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. <http://dx.doi.org/10.18632/oncotarget.17778>
- 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 Tabernero, 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.

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.

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

- A Zhu, J Park, B-Y Ryoo, C-J Yen, R Poon, D Pastorelli, J-F Blanc, H Chung, A Baron, T E F Pfiffer, T Okusaka, K Kubackova, J Trojan, J Sastre, I Chau, S-C Chang, P Abada, L Yang, J D Schwartz, M Kudo. Ramucirumab as Second-Line Treatment in Patients with Advanced Hepatocellular Carcinoma Following First-Line Therapy with Sorafenib: Results from the Randomized Phase III REACH Study. *Lancet Oncology*. 2015 July; 16(7):859-870. doi: 10.1016/S1470-2045(15)00050-9.

Cyramza – Bladder

- Petrylak, De Wit, Chi, Drakaki, Sternberg, Nishiyama, Castellano, Hussain, Fléchon, Bamias, Yu, van der Heijden, Matsubara, Alekseev, Necchi, Géczi, Ou, Coskun, Su, Hegemann, Percent, Lee, Tucci, Semenov, Laestadius, Peer, Tortora, Safina, del Muro, Rodriguez-Vida, Cicin, Harputluoglu, Widau, Liepa, Walgren, Hamid, Zimmermann, Bell-McGuinn, Powles. Ramucirumab plus docetaxel versus placebo plus docetaxel in patients with locally advanced or metastatic urothelial carcinoma after platinum-based therapy (RANGE): a randomised, double-blind, phase 3 trial. *Lancet* 2017;390:2266–2277. DOI: [http://dx.doi.org/10.1016/S0140-6736\(17\)32365-6](http://dx.doi.org/10.1016/S0140-6736(17)32365-6)

Cyramza – Biomarkers

J Taberero, R. Hozak, T Yoshino, A Cohn, Radka Obermannova, Gyorgy Bodoky, Rocio Garcia-Carbonero, Tudor-Eliade Ciuleanu, D Portnoy, J Prausová, R Siegel, R Konrad, Haojun Ouyang, S Melemed, D Ferry, F Nasroulah, E Van Cutsem. Analysis of Angiogenesis Biomarkers for Ramucirumab Efficacy in Patients with Metastatic Colorectal Cancer from RAISE, a Global, Randomized, Double-Blind, Phase III Study. *Annals of Oncology*. Epub ahead of print. <https://doi.org/10.1093/annonc/mdx767>