Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Taylor HS, Giudice LC, Lessey BA, et al. Treatment of endometriosis-associated pain with elagolix, an oral GnRH antagonist. N Engl J Med 2017;377:28-40. DOI: 10.1056/NEJMoa1700089

Appendix Table of Contents

Part 1: Elaris EM-I Study Sites and Principal Investigators

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UCSD, Suite 0633, 9500 Gilman Drive, La Jolla, CA 92093-0633, United States	Agarwal, Sanjay
CRC-CHUS, 3001, 12e Avenue Nord, Sherbrooke, QC J1H 5N4, Canada	Ainmelk, Youssef Bessette, Paul
Northeast Clinical Research of San Antonio, Suite 200, 5000 Schertz , Parkway, Schertz, TX 78154, United States	Akright, Bruce
University of Wisconsin LaCrosse, Suite 1030, 1300 Badger Street, LaCrosse, WI 54601, United States	Allen, Brian
Clinical Trials of Texas, Inc., Suite 700, 7940 Floyd Curl Drive, San Antonio, TX 78229, United States	Almendarez, Jr., Valentin
Visions Clinical Research, Suite 204, 8188 Jog Road, Boynton Beach, FL 33472, United States	Aqua, Keith
Thameside Ob/Gyn Centre, Suite 100, 491 Goldstar Highway, Groton, CT 06340, United States	Auerbach, Peter
Omega Research Consultants, LLC, Suite 100, 70 Spring Vista Drive Debary, FL 32713, United States	Ayesu, Kwabena
Ponce School of Medicine, CAIMED Center, 280 Monterrey Street Ponce, 00716, Puerto Rico	Barranco-Santana, Elizabeth
Institute of Michigan, Female Pelvic Medicine & Urogynecology Suite 450, 555 Mid Towne Street, NE, Grand Rapids, MI 49503, United States	Bennett, Michael
Clinical Trials Research Services, LLC, Suite 102, 201 South Highland Avenue Pittsburgh, PA 15206, United States	Berg, Saul Rosenberg, George L.
Dr. Richard A. Beyerlein, Suite 100, 10 Coburg Road, Eugene, OR 97401, United States	Beyerlein, Richard
Wake Research Associates, LLC, Suite 304, 3100 Duraleigh Road, Raleigh, NC 27612, United States	Bhiwandi, Pouru
Trinity Health Medical Arts Clinic, 831 South Broadway, Minot, ND 58701, United States	Billings, David
Mount Vernon Clinical Research, LLC, Suite 200, 755 Mount Vernon Highway, NE, Sandy Springs, GA 30328, United States	Blank, Stephen
Charleston Area Medical Ctr, Health Education and Research, Suite 806, 3100 MacCorkle Avenue, SE, Charleston, WV 25304, United States	Bracero, Luis Dietz, Paul
Desert Sun Clinical Research, LLC, Suite C, 7140 East Rosewood Street, Tucson, AZ 85710, United States	Brainard, C. Paige
Albuquerque Clinical Trials, Suite A16, 801 Encino Place NE, Albuquerque, NM 87102	Bretton, Elizabeth
Women's Clinical Research, Suite 300, 320 Santa Fe Drive, Encinitas, CA 92024, United States	Brody, Christine
Chattanooga Medical Research, LLC, Suite 300, 2341 McCallie Avenue Chattanooga, TN 37404, United States	Brody, Kirk
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Chattanooga GYN Oncology LLC, Suite 201, 1000 East Third Street, Chattanooga, TN 37403, United States	Chamberlain, Donald
Healthcare Clinical Data, Inc., Suite 417, 1065 NE 125 Street, North Miami, FL 33161, United States	Chavoustie, Steven
Montefiore Medical Center, Suite C, 3332 Rochambeau Avenue, Bronx, NY 10467, United States	Chudnoff, Scott
GTC Research, 21624 Midland Drive, Shawnee, KS 66218, United States	Clark, Gordon
All Womens Healthcare of West Broward, Suite D, 140 SW 84th Avenue, Plantation, FL 33324, United States	Cohen, Jay Steven
Ridgeview Research, Suite 200, 111 Hundertmark Road, Chaska, MN 55318, United States	Colley, Nancy Hansen, Cheryl Ann
The Woman's Clinic, P.A., Suite 414, 500 S. University Avenue, Little Rock, AR 72205, United States	Cope, Michael

CHI Health, Suite 200, 8141 West Center Road, Omaha, NE 68124, United States	Cote, John
Gynecology Reproductive Endocrinology and Fertility Inst, Suite 705, 1519 Ponce De Leon Avenue, Santurce, 00909, Puerto Rico	Cruz-Burgos, Rosa
Research Integrity, LLC, 1200 Breckenridge Street, Owensboro, KY 42303, United States	Dawson, Angela
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Danbury Clinical Research, LLC, DBA Clinical Research Center of CT, Suite 206, 27 Hospital Avenue, Danbury, CT 06810, United States	DiGrazia, Paul
Advanced RX Clinical Research, Suite 301, 18300 Gridley Road, Artesia, CA 90701, United States	Dinh, Dinh
Reliance Institute of Clinical Research, Suite 109, 13768 Roswell Avenue Chino, CA 91710, United States	Dinsay, Roselyn
Institute for the Study and Treatment of Endometriosis, Suite 200, 2425 West 22nd Street, Oak Brook, IL 60523, United States	Dmowski, W. Paul
The Women's Centre, Suite 121, 3321 Unicorn Lake Boulevard, Denton, TX 76210, United States	Dulemba, John
The South Bend Clinic Granger, 14950 State Road 23, Granger, IN 46530, United States	Durbin, Edward
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Southwest Clinical Research, Suite 203, 4901 Lang Avenue Northeast, Albuquerque, NM 87109, United States	Fisk, Frances
Clinical Physiology Associates, Suite 219, 4110 Center Pointe Drive, Fort Myers, FL 33916, United States	Fleishman, Kevin
Comprehensive Womens Care of Colorado Springs, LLC, Suite 110, 265 South Parkside Drive, Colorado Springs, CO 80910, United States	Foley, Steven
University Hospitals Landerbrook Health Center, Suite 300, 5850 Landerbrook Drive, Mayfield Heights, OH 44124, United States	Gangestad, Angelina
Willowbend Health and Wellness Associates, Suite 205, 4401 Coit Road, Frisco, TX 75035, United States	Gee, Phyllis
Radiant Research, Inc, Suite 202, 1275 Olentangy River Road, Columbus, OH 43212, United States	Green, Harold
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Clinical Trials of Texas, Inc., Suite 700, 7940 Floyd Curl Drive, San Antonio, TX 78229, United States	Hedges, Parke
Hawthorne Medical Research, Inc, 3000 Lyndhurst Avenue, Winston-Salem, NC 27103, United States	Hedrick, Jr., Richard
Great Lakes Research Group, Inc., Suite 170, 200 South Wenona Street, Bay City, MI 48706, United States	Heilbronn, Jr., Duane
Day Star Clinical Research, Inc, 880 Mull Avenue, Akron, OH 44313, United States	Hershberger, Vernon
ClinSite, LLC, 24 Frank Lloyd Wright Drive, Ann Arbor, MI 48106, United States	Hrozencik, Donna
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Granger Medical Clinic-Riverton, 12391 S. 4000W, Riverton, UT 84065, United States	Hutchison, Christopher
TMC Life Research, Inc, Suite 220, 7580 Fannin, Houston, TX 77054, United States	Jacobs, Mark
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Red Rocks OB/GYN, Suite 200, 255 Union Boulevard, Lakewood, CO 80228, United States	Johnson, Michael
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PMG Research of Charlotte, LLC, Suite 201, 1700 Abbey Place, Charlotte, NC 28209	Martimbeau, Pierre Raad, George
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Advanced Women's Health, Suite 907, 425 South Cherry Street, Denver, CO 80246, United States	Moore, Michael
Tidewater Physicians for Women, Suite 208, 844 Kempsville Road, Norfolk, VA 23502, United States	Morgan, Jr., Franklin
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KO Clinical Research, LLC, Suite 400, 1625 SE 3rd Avenue, Fort Lauderdale, FL 33316, United States	Osman, Khadra
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Sunstone Medical Research, 1700 East Barnett Road, Medford, OR 97504, United States	Palamara, Alan Schroeder, Paul
Central Utah Clinic, Womens Center, 1886 West 800 North, Pleasant Grove, UT 84062, United States	Parker, Jr., E. William Young, David
Women Under Study, 2627 General Pershing Street, New Orleans, LA 70115, United States	Perez, Brandon
University of South Florida, Department of Obstetrics & Gynecology, STC 6th floor, 2 Tampa General Circle, Tampa, FL 33606, United States	Plosker, Shayne
Advances in Health, Inc., Suite 360, 7515 South Main, Houston, TX 77030, United States	Poindexter, Alfred Poindexter, Yvette
Carolina Medical Trials, 114 Charlois Boulevard, Winston-Salem, NC 27103, United States	Ponder, Philip
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Clinical Trials of Virginia, Inc., Suite 305, 6767 Forest Hill Avenue, Richmond, VA 23225, United States	Prillaman, Prescott
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University of Puerto Rico, School of MedicineUniv District Hospital, Medical Sciences Campus, 1st floor, Rio Piedras, 00935, Puerto Rico	Romaguera-Agrait, Josefina
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Holston Medical Group (Seasons of Bristol), Suite 2C, 320 Bristol West Blvd. Bristol, TN 37620, United States	Samuel, Jr., Dennis
Complete Healthcare for Women, 5888 Cleveland Avenue, Columbus, OH 43231, United States	Samuel, Milroy
Florida Clinical Research Group, LLC, Suite 610, 2454 Mcmullen Booth Road Clearwater, FL 33759, United States	Sanchez, Mark
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Suncoast Clinical Research, Inc., 5604 Gulf Drive, New Port Richey, FL 34652, United States	Smith, Jr., Robert
Center for Womens Research, Suite 739, 1725 W. Harrison, Chicago, IL 60612 United States	Soltes, Barbara
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University of Cincinnati, ML 0457, Holmes Hospital Building, Room 4028, 200 Albert Sabin Way, Cincinnati, OH 45267-0457, United States	Sroga, Julie
Manitoba Clinic, 790 Sherbrook Street, Winnipeg, MB R3A 1M3, Canada	Stearns, Eric
American Health Network of IN LLC, Suite 645, 5250 E. US 36, Avon, IN 46123, United States	Stegemoller, Ronald
Alabama Clinical Therapeutics, LLC, Suite 203, 52 Medical Park East Drive Birmingham, AL 35235, United States	Summers, William
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Physician Care Clinical Research, LLC, Suite 2B, 1617 South Tuttle Avenue, Sarasota, FL 34239, United States	Swor, Gregory
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Arizona Research Center, Inc., Suite 114, 2525 W. Greenway Road, Phoenix, AZ 85023, United States	Taber, Louise
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Fellows Research Alliance, Suite 202, 11 Arley Way, Bluffton, SC 29910, United States	Thompson, Patricia
Hawthorne Medical Research, Inc, Physicians for Women of Greensboro, PA Suite 300, 802 Green Valley Road , Greensboro, NC 27408, United States	Tomblin, James
VERITAS Research Corp., 5779 NW 151 Street, Miami Lakes, FL 33014, United States	Tudela, Francisco
Corner Canyon Obstetrics and Gynecology, Suite 200, 11724 South State Street Draper, UT 84020, United States	Twede, Michael
New Horizon's Women's Care, 1950 West Frye Road, Chandler, AZ 85224 United States	Villa, Jr., Andrew
Saginaw Valley Medical Research Group, LLC, Suite 6100, 5400 Mackinaw Rd., Saginaw, MI 48604, United States	Wagner, Andrew
Downtown Womens Health Care, Denver, Suite 685, 3773 Cherry Creek Drive North, Denver, CO 80209, United States	Waldbaum, Arthur
Fellows Research Alliance, Suite 204, 1 Oglethorpe Professional Boulevard Savannah, GA 31406, United States	Walland, Debra
Clinical Research of West Florida, Inc., 2147 Northeast Coachman Road Clearwater, FL 33765, United States	Walter, Thomas
Cullman Clinical Research, Suite 302, 1800 Alabama Highway 157, Cullman, AL 35058, United States	Wideman, John
Noel R. Williams, MD, Suite 120, 1705 S Renaissance Blvd, Edmond, OK 73013, United States	Williams, Noel
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*All listed sites had patients randomized in Elaris EM-I.

Part 2: Elaris EM-II Study Sites and Principal Investigators

Study Sites*	Principal Investigators
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Northeast Clinical Research of San Antonio, Suites 100 & 200, 5000 Schertz Parkway, Schertz, TX 78154, United States	Akright, Bruce
Leicester Royal Infirmary, Univ Hosp of Leicester NHS, Rheumatology Research, Balmoral Building, Infirmary Square, Leicester, LE1 5WW, United Kingdom	Al-Azzawi, Farook
Southern Clinical Research Associates, LLC, Suite 209, 4720 South 1-10, Service Road, Metairie, LA 70001, United States	Alexander, Samuel
Clinical Trials of Texas, Inc., Suite 700, 7940 Floyd Curl Drive, San Antonio, TX 78229, United States	Almendarez Jr., Valentin
Instituto Medico de la Fundacion Estudios Clinicos, Italia 428, Rosario, Sante Fe CP, 2000, Argentina	Alonso, Eduardo
Visions Clinical Research, Suite 400, 1395 State Road 7, Wellington, FL 33414 United States	Aqua, Keith
Hospital Universitario Reina Sofia, Servicio de Aparato Digestivo/Hepatologia Edificio de Consultas Externas, planta 1, Avda. Menendez Pidal s/n, Cordoba-(Espana), 14004, Spain	Arjona Berral, Jose Eduardo
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Wojskowy Instytut Medyczny Centralny Szpital Kliniczny MON, Klinika Ginekologii i Ginekologii Onkologicznej, Szaserów 128, Warsaw 44, 04-141, Poland	Baranowski, Wlodzimierz
CM Zdrowie Kobiety, ul. Kosciuszki 44, Krakow, 30-114, Poland	Basta, Antoni
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Grand Rapids Women's Health, d/b/a Female Pelvic Medicine & Urogynecology Institute of MI, Suite 450, 555 Mid Towne Street NE, Grand Rapids, MI 49503, United States	Bennett, Michael
Karen L. Benz OB/GYN, Suite 270, 1250 8th Avenue, Fort Worth, TX 76104, United States	Benz, Karen
Prywatna Poliklinika "Na Grobli" SP Z.o.o, pl Hirszfelda 1, Wroclaw, 53 413, Poland	Bielanow, Tomasz
Chattanooga Medical Research, LLC, Suite 300, 2341 McCallie Avenue, Chattanooga, TN 37404, United States	Brody, Kirk
Southern Pines Womens Health Center P.C., 145 Applecross Road, Southern Pines, NC 28388, United States	Byron, John
Hospital Universitario Virgen de Valme, Autovia Seville-Cadiz S/N, Seville, 41014, Spain	Caballero, Virginia
Ospedale San Raffaele, UOC Clinica Ostetrico, Ginecologica, Via Olgettina 60 Milan, 20132, Italy	Candiani, Massimo
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Southern Clinical Trials Ltd., 3 Strickland Street, Beckenham, Christchurch, 8024, New Zealand	Carson, Simon
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NEA Baptist Womens Clinic, 4802 East Johnson Avenue, Jonesboro, AR 72401, United States	Cesare, Charles
University of Florida, 1600 S.W. Archer Rd., Gainesville, FL 32609, United States	Christman, Gregory
Oblastni Nemocnice Pribrram, a.s., Gynekologicko Porodnicke Oddeleni, Hradebni 84, Pribram, 261 26, Czech Republic	Chudacek, Petr

GTC Research, 21624 Midland Drive, Shawnee, KS 66218, United States	Clark, Gordon
Azienda Ospedaliera Universitaria Careggi, Dipartimento Materno Infantile, Largo Brambilla 3, Florence, 50134, Italy	Coccia, Maria
School of Clinical Research, LLC, 7309 West Flagler Street, Miami, FL 33144, United States	Columbie, Arsenio Ares-Romero, Patricia Nualart, Maria
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Bayshore Women's Healthcare, 3785 NW 82 Ave #307, Doral, FL 33166, United States	Cruz-Pachano, Francisco
NY Clinical Trials, 10th floor, 229 West 36th Street, New York, NY 10018, United States	Cuevas, Juana Simons, Monica
Universidade Federal do Rio Grande do Sul School of Medicine, Faculdade de Medicina, Hosp de Clinicas De Porto Alegre, Centro de Pesquisa Clinica Rue Ramiro Barcellos, 2350, Porto Alegre, RS 90035-903, Brazil	Cunha-Filho, Joao
Mayo Clinic, 200 First Street SW, Rochester, MN 55905, United States	Daftary, Guarang
A.O. Universitaria Policlinico Agostino Gemelli, Univ Cattolica del Sacro Cuore, Istituto di Clinica Osterica e Ginecologica, Largo Agostino Gemelli, 8 Rome, 00168, Italy	De Cicco Nardone, Fiorenzo
University of Sassari Gynecologic and Obstetric Clinic, Viale San Pietro n. 12 Sassari, 07100, Italy	Dessole, Salvatore
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Reliance Institute of Clinical Research, Suite 109, 13768 Roswell Avenue Chino, CA 91710, United States	Dinsay, Roselyn
Access Clinical Trials, Inc., Suite 212, 2201 Murphy Avenue, Nashville, TN 37203, United States	Dittus, Janet
Institute for the Study and Treatment of Endometriosis, Suite 200, 2425 West 22nd Street, Oak Brook, IL 60523, United States	Dmowski, W. Paul
The South Bend Clinic Granger, 14950 State Road 23, Granger, IN 46530, United States	Durbin, Edward
Barbara Gross Research Unit, Level 1, Royal Hospital for Women, Randwick, NSW 2031, Australia	Eden, John
Penn State Univ and Milton S. Hershey Medical Center, PSU College of Medicine, C3608, MC H103, 500 University Drive, Hershey, PA 17033, United States	Estes, Stephanie
Siófok Város Kórház-Rendelőintézete, Szülészeti és Nőgyógyászati Osztály 8600 Siófok, Semmelweis u.1., Hungary	Fenyohazi, Jeno
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Precision Trials, Suite 4200B, 3815 East Bell Road, Phoenix, AZ 85032, United States	Foltz, James
OB-GYN Clinic, Suite 440, 4429 ClaraStreet, New Orleans, LA 70115, United States	Gala, Rajiv
Columbus Urology Research LLC, Suite 315, 941 Chatham Lane, Columbus, OH 43221, United States	Gambla, Michael Somasundaram, Shivkamini
Universal Clinical Research Associates, Inc., Suite 503, 3650 NW 82nd Avenue Miami, FL 33166, United States	Garcia, Victoria
Willowbend Health and Wellness Associates, Suite 205, 4401 Coit Road, Frisco, TX 75035, United States	Gee, Phyllis
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Liverpool Womens Hospital NHS Foundation Trust, Crown Street, Liverpool, L8 7SS, United Kingdom	Hapangama, Dharani
Clinical Trials of Texas, Inc., Suite 700, 7940 Floyd Curl Drive, San Antonio, TX 78229, United States	Hedges, Parke
Great Lakes Research Group, Inc., 200 S. Wenona Street #170, Bay City, MI 48706, United States	Heilbronn, Duane
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*All listed sites had patients randomized in Elaris EM-II.

Part 3: Supplemental Methods

Inclusion Criteria

1. Participant provided written, informed consent.
2. Participant was a premenopausal woman between 18 and 49 years of age at the time of consent.
3. Women were surgically (laparoscopy or laparotomy) diagnosed with endometriosis within 10 years of study entry.
4. Women agreed to the washout interval of hormonal therapies if applicable.
5. Women agreed to switch from their usual analgesic rescue medication to only those permitted in the study.
6. Women agreed to use two forms of non-hormonal contraception throughout the study.
7. Women had a menstrual cycle with an interval of 24-38 days prior to entering the screening period.
8. Women had a Composite Pelvic Signs and Symptoms Score total score of ≥ 6 at screening with a score of at least moderate (2) for dysmenorrhea and at least moderate for nonmenstrual pelvic pain.
9. Women had at least two menstrual cycles with an interval of 24 to 38 days within the screening period.
10. Women had at least 45 days of e-Diary entries during the screening period.
11. Women had at least 2 days of moderate or severe dysmenorrhea and nonmenstrual pelvic pain during the last 35 days in the screening period.
12. Women had an average daily diary score of at least 0.5 for nonmenstrual pelvic pain during the last 35 days in the screening period.
13. Women had at least one of the following criteria using the e-Diary entries:
    a. Average nonmenstrual pelvic pain during screening of at least 1.0 (mild) the last 35 days of the screening period

b. At least 4 days of moderate or severe nonmenstrual pelvic pain during the last 35 days of the screening period.

14. Women had moderate or severe pain for dysmenorrhea and nonmenstrual pelvic pain using the Monthly Assessment of Endometriosis Pain on Day 1.
15. Women had no evidence of malignancy or pre-malignant changes in a pap test during screening.
16. Women 40 years or older in age had a normal mammogram within 1 year of randomization.

Exclusion Criteria

1. Women had a history of severe, life-threatening sensitivity to any drug.
2. Women were pregnant, breast feeding, planning a pregnancy within the next 24 months, or less than 6 months post partum, post-abortion, or post-pregnancy.
3. Women had an IUD, unless removed during washout period.
4. Women had a history of drug or alcohol abuse within 1 year of washout or screening.
5. Women tested positive for Hepatits A, B, or C, or HIV.
6. Women had taken known inducers of cytochrome P450 3A within 1 month prior to Day 1.
7. Women had clinically significant abnormalities in clinical chemistry, hematology or urinalysis.
8. Women had clinically significant abnormal ECG.
9. Women had a newly diagnosed or clinically significant medical condition requiring intervention or an unstable medical condition that makes the woman an unsuitable candidate for the study in the opinion of the investigator (e.g. uncontrolled diabetes mellitus, uncontrolled seizures, unstable angina, confirmed inflammatory bowel disease, hyperprolactinemia, active malignancy, or significant infection
10. Women had a history of major depression or post-traumatic stress disorder within 2 years of screening or a history of other major psychiatric disorder.
11. Women had a surgical history of hysterectomy, bilateral oophorectomy, procedure that interferes with gastrointestinal motility, any recent major or minor surgery.

12. Women had a history of previous non-response to gonadotropin-releasing hormone agonists, antagonists, DMPA, aromatase inhibitors.
13. Women had required more than 2 weeks of continuous use of prohibited long-acting narcotic or immediate release narcotic for treatment of endometriosis-associated pain within 6 months of study entry.
14. Women had chronic pelvic pain not caused by endometriosis that required chronic analgesic or other chronic therapy (e.g. interstitial cystitis, presumptive adenomyosis, fibroids, etc.).
15. Women had any other chronic pain syndrome that required chronic analgesic or other chronic therapy (e.g. fibromyalgia, chronic back pain, chronic headaches, etc.).
16. Women using any systemic steroids for over 14 days within 3 months prior to screening or likely to require such treatment during the course of the study.
17. Women participating in another investigational study or within 2 months prior to start of the screening period.
18. Women previously participated in an elagolix study.
19. Women had clinically significant gynecologic condition identified on the transvaginal ultrasound or endometrial biopsy during screening such as clinically significant endometrial pathology, persistent complex ovarian cyst larger than 3 cm or simple ovarian cyst larger than 5 cm, or single fibroid 4 cm or larger or more than 4 fibroids measuring at least 2 cm or symptomatic submucosal fibroid of any size.
20. Women had a current history of undiagnosed abnormal genital bleeding.
21. As judged by the investigator, women were unable or unwilling to comply with study-related assessments and procedures, including completion of the e-Diary and consistent use of non-hormonal dual contraception.
22. Women had a history of osteoporosis or other metabolic bone disease, including one or more of the following:

a. Screening dual-energy x-ray absorptiometry scan results of the lumbar spine, femoral neck, or total hip bone mineral density corresponding to 1.5 or more standard deviations below normal (Z-score at or below -1.5)
b. Any condition that would interfere with dual-energy x-ray absorptiometry measurements
c. History of a condition associated with a decrease in bone mineral density
d. Intercurrent bone disease
e. History of low trauma hip or vertebral fracture
f. History of pathologic or compression fractures
g. History of bilateral hip replacement
h. Clinically significant hypocalcemia, hypo- or hyperphosphatemia
i. Treatment with medication for osteoporosis, osteopenia or other bone disease associated with a decrease in bone mineral density

Efficacy Assessments

Women used an electronic diary to report daily pain assessments, protocol-specified rescue analgesic use, and uterine bleeding. The portion of the electronic diary assessing dysmenorrhea, nonmenstrual pelvic pain, and dyspareunia make up the Endometriosis Daily Pain Impact Diary;[1,2] the 4-point pain impact scales which include a functional component regarding the impact on activities of daily living were developed based on the Biberoglu and Behrman Severity Profile for Symptoms and Findings scoring system.[3]

To assess dysmenorrhea and nonmenstrual pelvic pain, women were first asked in the daily electronic diary whether or not they had their period. If yes, women rated their dysmenorrhea in the last 24 hours as none, mild (mild pain; almost no impact on daily life), moderate (moderate pain; some impact on daily life), or severe (severe pain; great impact on daily life). If no, women rated their nonmenstrual pelvic pain in the last 24 hours as none, mild, moderate, or severe (same definitions as dysmenorrhea severity categories). To assess dyspareunia, women were asked to rate their pain during sexual intercourse

during the last 24 hours as not applicable, none, mild, moderate, or severe (avoided sexual intercourse because of pain).

To assess endometriosis-associated pain with the Numeric Rating Scale, women were asked in the daily electronic diary to rate their endometriosis pain over the last 24 hours at its worst, on a scale of 0 to 10, no pain to worst pain ever.

To assess rescue analgesic use, women were asked in the daily electronic diary whether rescue analgesic medications were used in the last 24 hours. Options were Naproxen, 500 mg, or Hydrocodone 5mg/Acetaminophen, 300 or 325 mg (the opioid varied by country in Elaris EM-II; **Table S1**). Then women chose the number of tablets for each type of medication.

The Patient Global Impression of Change was assessed monthly at study visits (not in electronic diary). Women were asked how their endometriosis-associated pain has changed since beginning treatment and response options were very much improved, much improved, minimally improved, no change, minimally worse, much worse, very much worse.

Quality of life was assessed with the 30-item Endometriosis Health Profile, a self-administered questionnaire.[4] The Endometriosis Health Profile was conducted at month 1, 3, and 6 study visits. The 5 core dimensions of the Endometriosis Health Profile includes 11 questions assessing pain, 6 questions assessing control and powerlessness, 6 questions assessing emotional well-being, 4 questions assessing social support, and 3 questions assessing self-image. A modular questionnaire composed of 5 questions about sexual intercourse was also included. Response options for each question was never, rarely, sometimes, often, and always.

Safety Assessments

Clinical/laboratory tests, including serum lipids and fasting blood glucose, were measured at baseline, each month of treatment, and final visit. Adverse events, including hot flushes, were spontaneously reported and rated by severity (mild, moderate, severe) by the investigator. Adverse events starting between the first dose date and no later than 30 days after the last dose date are considered treatment-emergent.

To assess uterine bleeding, women were asked in the daily electronic diary whether they had any uterine bleeding in the last 24 hours. If yes, then response options were spotting (a light amount of bleeding noted, no protection or panty shield only), light (1 to 2 regular tampons or pads required in 24 hours), medium (3 to 4 regular tampons or pads required in 24 hours), heavy (more than 4 tampons or pads required in 24 hours). If no, then it was recorded as none for that day.

Endometrial thickness was measured by transvaginal ultrasound during screening (menstrual cycle day 4-8) and at month 6. Endometrial biopsies were performed in Elaris EM-I only, during screening and at month 6. Bone mineral density of the lumbar spine, femoral neck and total hip were measured by dual-energy x-ray absorptiometry scans (Hologic or GE Lunar) during screening and at month 6. Central laboratories were used for evaluation and reporting of dual-energy x-ray absorptiometry scans, biopsied endometrial tissue and transvaginal ultrasound images, and were blinded to the treatment group. Pregnancy outcomes were collected during follow-up.

Secondary Efficacy Endpoints

Key and secondary efficacy endpoints are outlined in **Table S3**. Additional secondary efficacy endpoints compared each elagolix dose to placebo and included the proportion of dysmenorrhea and nonmenstrual pelvic pain responders at month 6, mean percentage change from baseline to months 1 through 6 in dysmenorrhea and nonmenstrual pelvic pain scores, the number and percentage of women who responded 'much' or 'very much improved' on the Patient Global Impression of Change at month 6, and the mean change from baseline to months 1, 3, and 6 on each Endometriosis Health Profile dimension.

Continued Statistical Methods of Efficacy Endpoints

For the co-primary efficacy analysis, women were considered responders/non-responders based on a reduction in pain scores greater than or equal to the threshold determined by a receiver operating characteristics analysis and stable analgesic use specified in **Table S2**. The receiver operating characteristics analysis used to determine the clinically meaningful reduction in pain scores (dysmenorrhea and separately, nonmenstrual pelvic pain) included all randomized and treated women and

was conducted prior to unblinding, using 'much improved' and 'very much improved' responses on the Patient Global Impression of Change at month 3. Last observation carried forward was used in the co-primary analysis for women who prematurely discontinued at or prior to the analysis month. The co-primary analysis was based on a logistic regression model with baseline as a covariate and treatment as a main effect. Calculation of odds ratios based on the model was pre-specified in the statistical analysis plan; risk ratios were calculated post-hoc based on the same logistic regression model. A sensitivity analysis was conducted using a non-responder imputation for subjects who prematurely discontinued at or prior to month 3 and analyzed using the same logistic regression model specified for the co-primary analysis.

To control for Type I error, a Bonferroni adjustment was made to correct for multiple dose groups. Within each dose group, the co-primary and key secondary endpoints were tested hierarchically at a level of α=0.025. All p-values were two-sided.

Dysmenorrhea, nonmenstrual pelvic pain, and dyspareunia responses were coded to scores of 0 (none), 1 (mild), 2 (moderate), or 3 (severe), and daily scores were averaged over a 35 day window at baseline and each month separately. Women who only recorded dyspareunia as 'not applicable' during the baseline window or post-baseline window were excluded from the dyspareunia analysis of the change from baseline for the given month. Daily Numeric Rating Scale scores assessing endometriosis-associated pain and rescue analgesic pill counts were separately averaged for the 35 day window at baseline and each month. The statistical significance between each elagolix dose and placebo on each hierarchically tested key secondary endpoints were tested using a separate mixed effects model with repeated measures using observed data with treatment as the main effect, visit number as the repeated measure, baseline value as a covariate and an interaction between treatment and visit. Additionally, the same model was used for the statistical comparisons between treatment groups for the mean percentage change from baseline to each month dysmenorrhea and nonmenstrual pelvic pain scores. Heterogeneity among treatment groups for baseline age and BMI were tested using a one-way analysis of variance (ANOVA);

for race was tested using a Chi-square test; for baseline mean pain scores were tested using a contrast within a one-way ANOVA.

The number and percentage of women were summarized for each response on the Patient Global Impression of Change at month 6. A chi-square test was used to test the statistical significance between each elagolix group and placebo for the number of women responding 'much' or 'very much' improved vs. the combined number of women with 'minimally improved,' 'no change,' 'minimally worse,' 'much worse,' and 'very much worse' responses.

The 30-item Endometriosis Health Profile responses were coded to 0 (never), 1 (rarely), 2 (sometimes), 3 (often), and 4 (always) and were normalized to a scale of 0 to 100 for each dimension such that lower scores indicate better quality of life. Statistical significance for each elagolix compared with placebo for the mean change from baseline to months 1, 3, and 6 was based on contrasts within an one-way analysis of covariance (ANCOVA) model with treatment as the main effect and baseline value as a covariate.

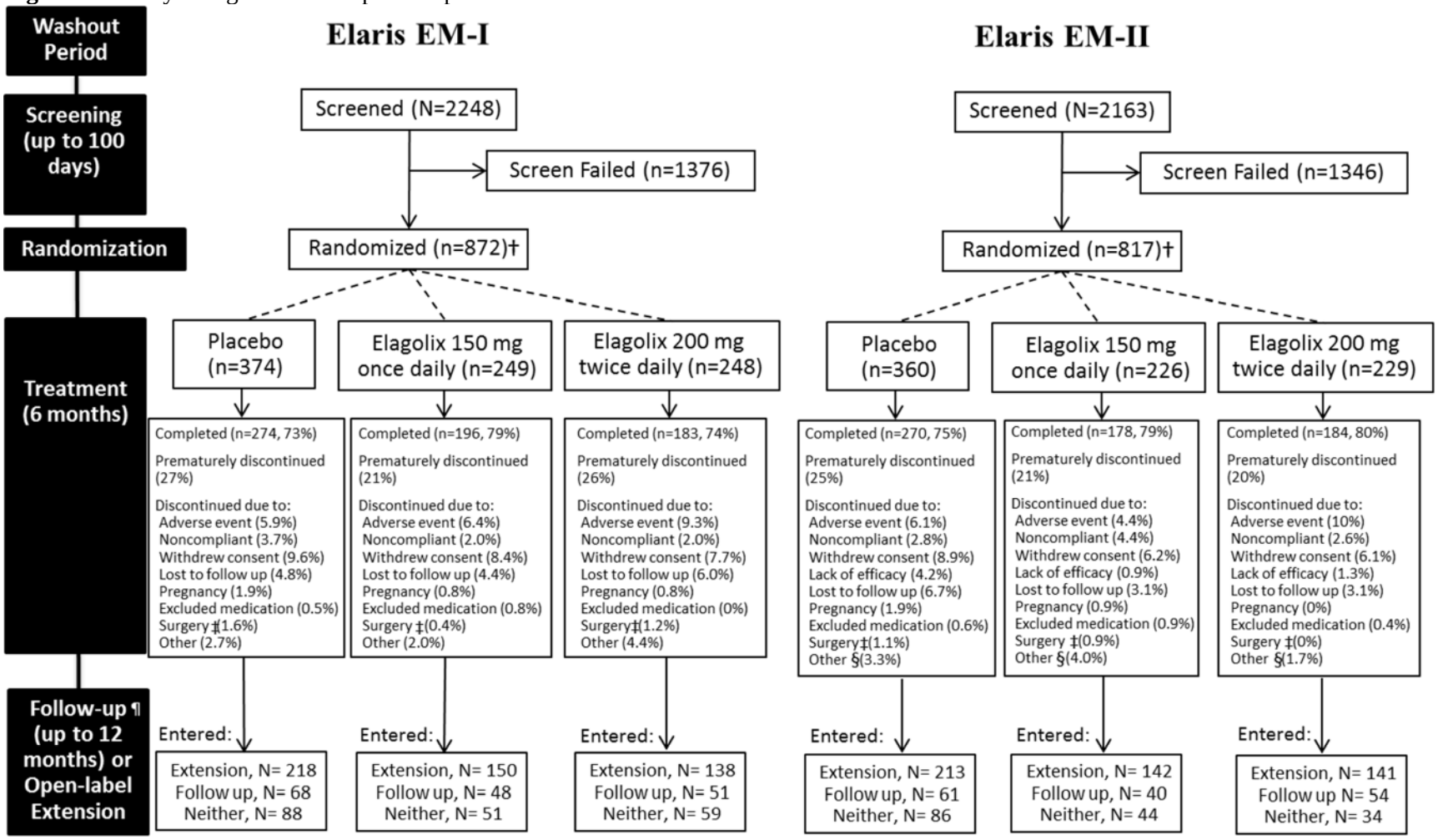
Continued Statistical Methods of Safety Assessments

The differences between each treatment group compared to placebo for the incidence of any adverse event and each preferred term was based on a Fisher's exact test using observed data. Mean percentage change from baseline to month 6 bone mineral density was analyzed for each elagolix group compared with placebo using contrasts within a one-way ANOVA and observed data. Categorical analysis of the mean percentage change from baseline to month 6 bone mineral density for individual women was compared between elagolix and placebo groups using a Fisher's exact test. Bone mineral density Z-scores at baseline and month 6 were also summarized. Heterogeneity among treatment groups for lipid measures at baseline were tested using a contrast within a one-way ANOVA. The mean change from baseline to month 6 in serum lipids were analyzed with an ANCOVA model with treatment as the main effect and baseline value as the covariate. The mean change from baseline to month 6 in fasting blood glucose was analyzed using contrasts within a one-way ANOVA model. The mean change from baseline to month 6 was summarized for each treatment group. Categorical biopsy results were

summarized with descriptive statistics. For both studies, data as of May 5, 2017 were included in this manuscript. SAS software (SAS Institute, Inc.) for the UNIX operating system was used for all analyses.

Part 4: Supplemental Figures

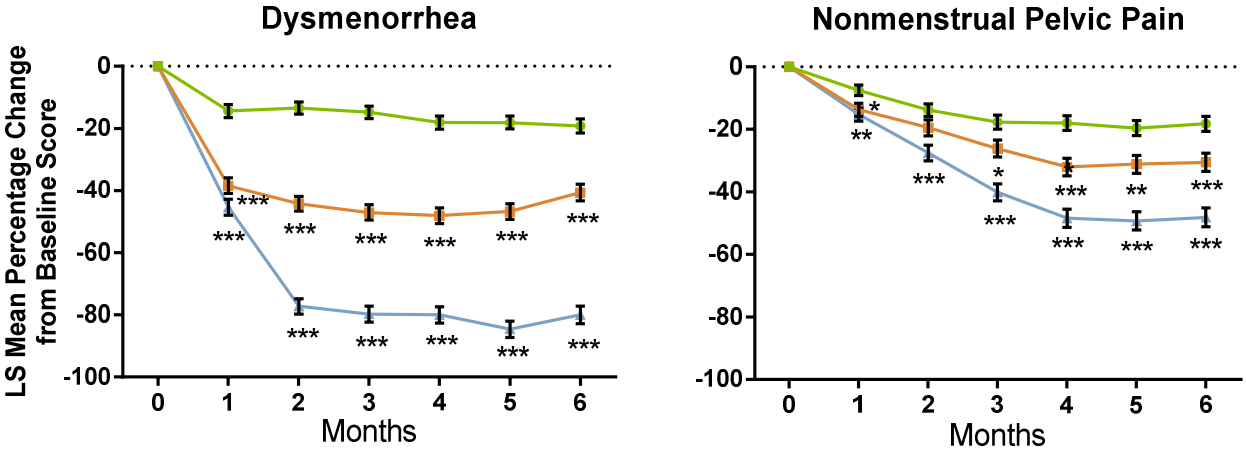
Figure S1. Study Design and Participant Disposition



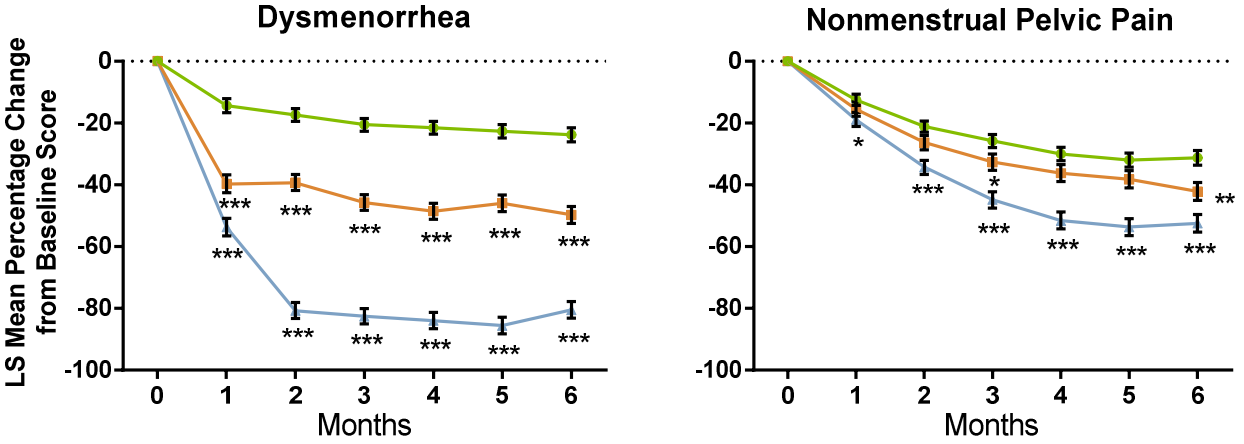
† 1 woman in Elaris EM-I and 2 women in Elaris EM-II were randomized but not treated
‡ Women required surgery or invasive intervention for endometriosis
§ Other category includes transvaginal ultrasound finding
¶ Women were to enter the follow-up period if they prematurely discontinued treatment, declined to participate in the extension study, or did not qualify for enrollment in the extension.

Figure S2. Mean Percentage Change from Baseline in Dysmenorrhea and Nonmenstrual Pelvic Pain Scores

A. Elaris EM-I

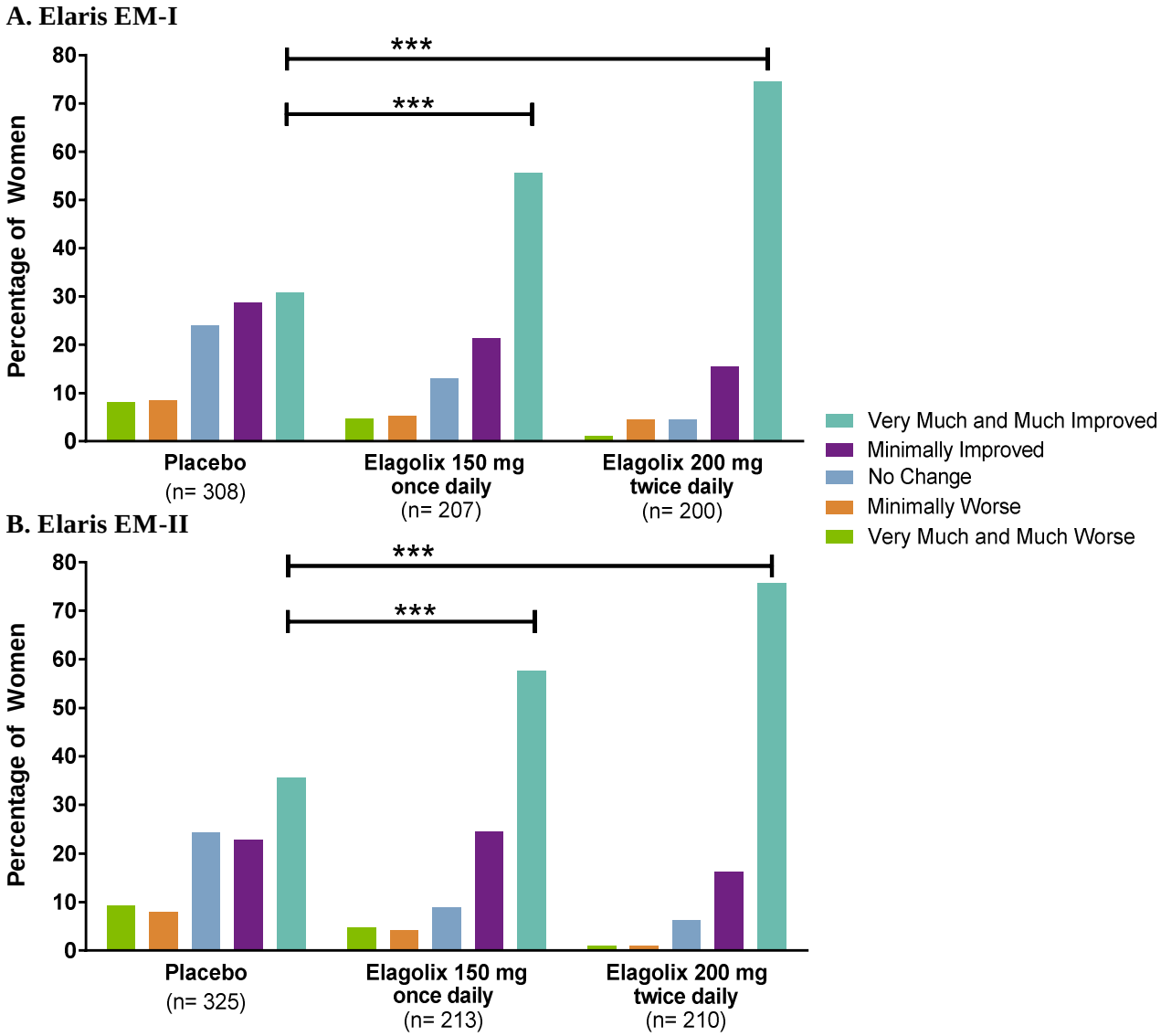


B. Elaris EM-II



Statistical significance compared with placebo for the mean percentage change from baseline score in Elaris EM-I (A) and Elaris EM-II (B) was based on a mixed-effects model with repeated measures with treatment as the main effect, visit as the repeated measure, baseline value as a covariate and an interaction between treatment and visit, using observed data, indicated by $P<0.05$ (*), $P<0.01$ (**), and $P\leq0.001$ (***). Error bars represent standard error.

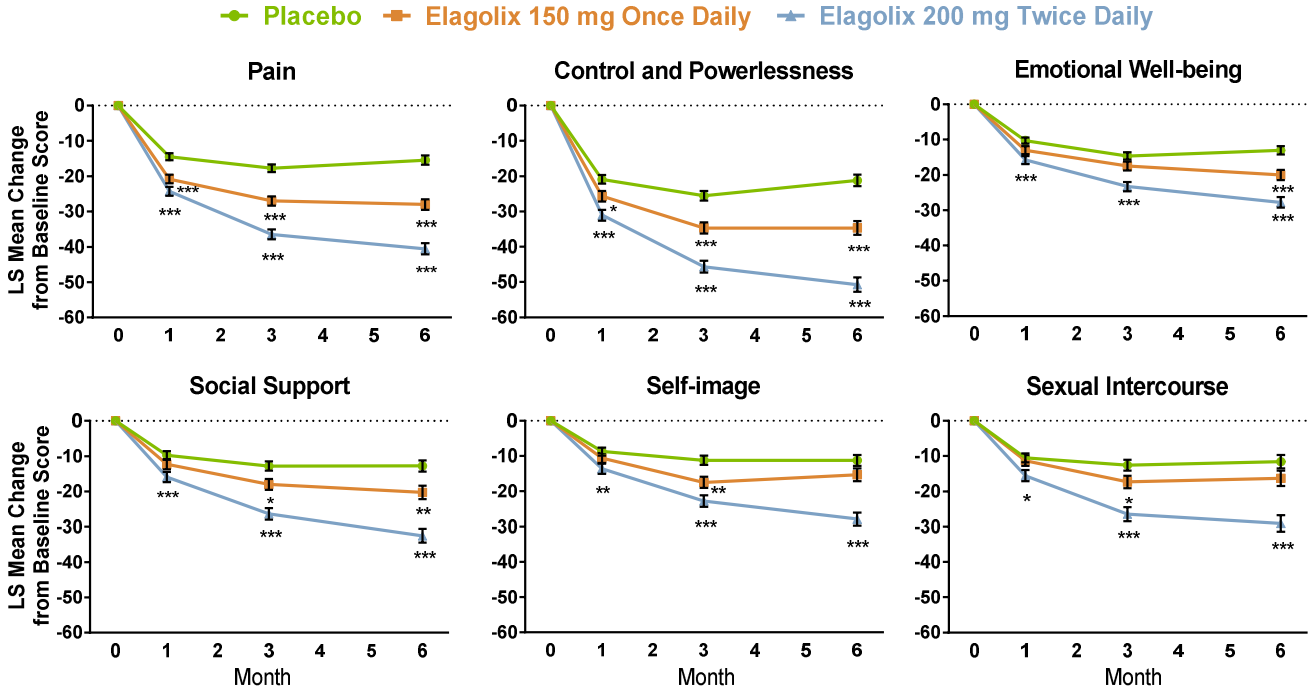
Figure S3. Patient Global Impression of Change Responses at Month 6



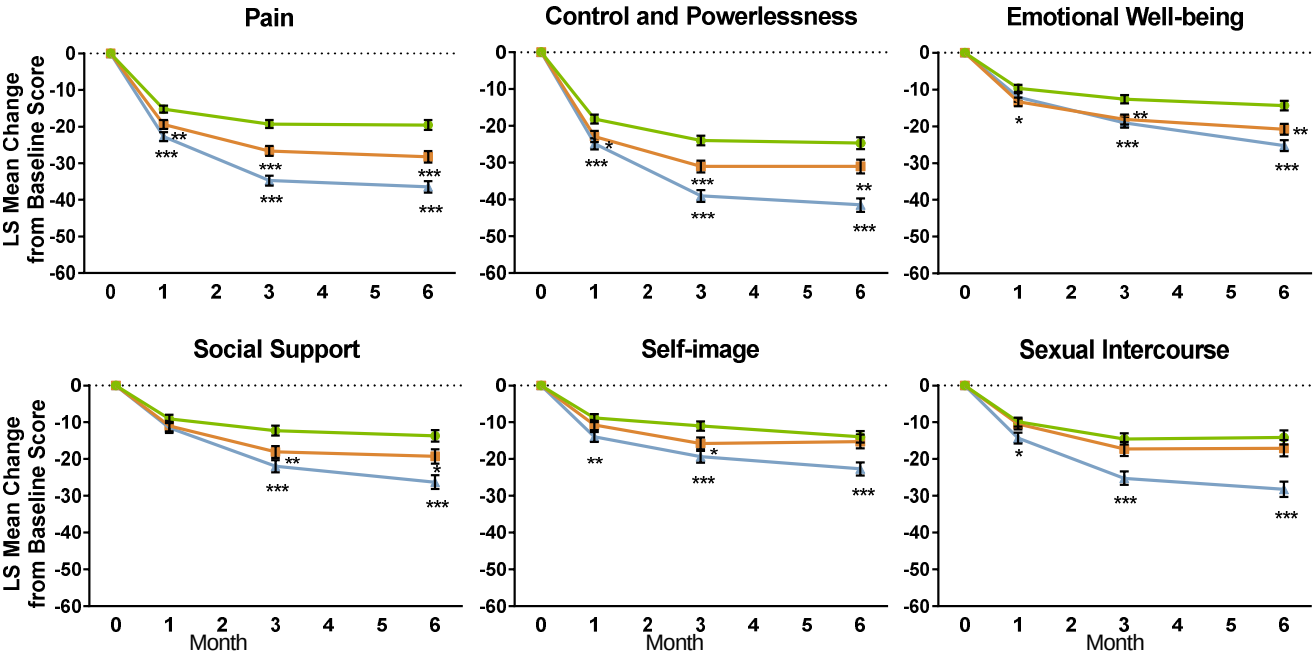
The Patient Global Impression of Change is a scale of change (very much worse to very much improved). Statistical significance versus placebo for the 'very much' or 'much improved' responses compared with other categories combined was based on a chi-square test using last observation carried forward for women who prematurely discontinued prior to the analysis time point, indicated by two-sided P<0.001 (***).

Figure S4. Mean Change from Baseline to Month 6 in 30-item Endometriosis Health Profile Scores, By Dimension

A. Elaris EM-I



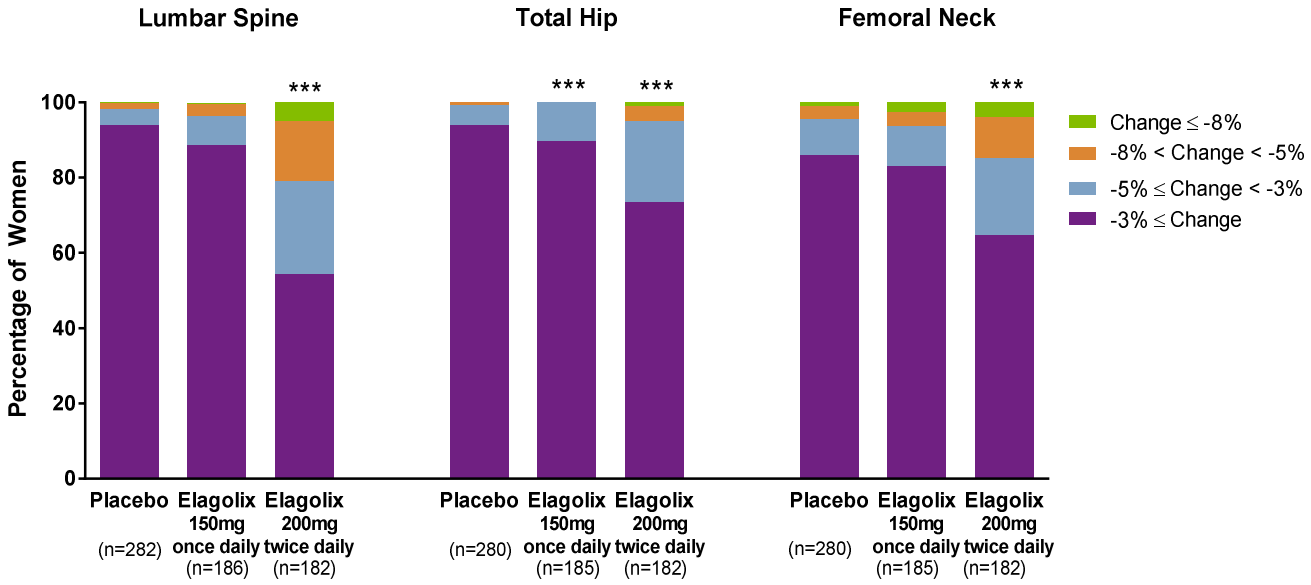
B. Elaris EM-II



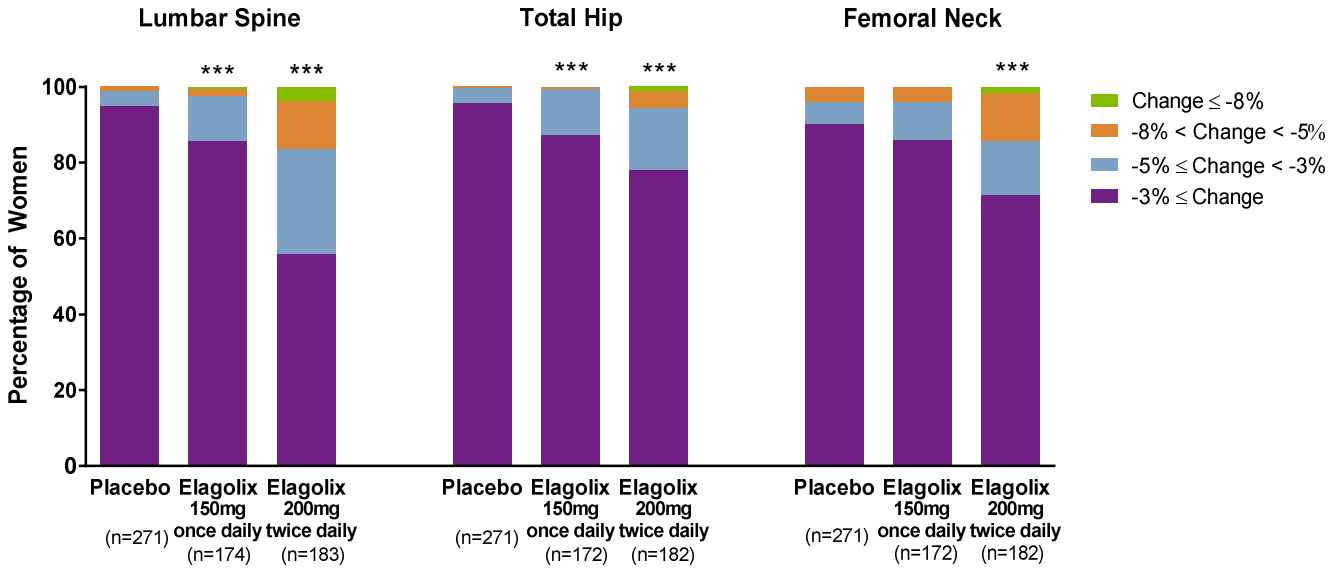
A. Elaris EM-I. B. Elaris EM-II. Each dimension had multiple questions. Each EHP-30 question was scored from 0 [never] to 4 [always]), and normalized to a scale of 0-100 for each dimension. Lower scores indicate better quality of life.
Statistical significance based on contrasts within a one-way ANCOVA with treatment as the main effect and baseline value as a covariate for the mean difference from placebo is indicated for two-sided P<0.05 (*), P<0.01 (**), P<0.001 (***). Error bars represent standard error. Month 0 refers to baseline.

Figure S5. Categorical Changes in Bone Mineral Density from Baseline to Month 6

A. Elaris EM-I



B. Elaris EM-II



A. Elaris EM-I. B. Elaris EM-II. The changes ≥ -3% category includes women with increases and no change in bone mineral density. Statistical significance compared to placebo based on a Fisher's exact test using observed data is indicated for two-sided P<0.001 (***).

Part 5: Supplemental Tables

Table S1. Permitted Rescue Analgesics for Endometriosis-associated Pain

Medication Class	Medication Name	Permitted Doses	Country
NSAID	Naproxen	500 mg*	All
Opioid	Hydrocodone + acetaminophen	5 mg hydrocodone + 300 mg or 325 mg acetaminophen	United States†‡ and Puerto Rico†
	Codeine phosphase + acetaminophen	30 mg codeine + 300 mg acetaminophen	Canada†
	Codeine phosphate + acetaminophen	30 mg codeine + 500 mg acetaminophen	Argentina‡, Australia‡, Brazil‡, Italy†‡, United Kingdom†‡
	Codeine	30 mg codeine	New Zealand‡
	tramadol + acetaminophen	37.5 mg tramadol + 325 mg acetaminophen	Austria‡, Czech Republic‡, Hungary‡, Poland‡, South Africa‡, Spain‡

All rescue analgesics were directed to be used according to the product prescribing information.
* 550 mg tablets were allowed if 500 mg tablets were not locally available.
† Elaris EM-I
‡ Elaris EM-II

Table S2. Rescue Analgesic Responder Definition

Analgesic Used at Baseline	Status of Analgesic Dose at Final Visit			Analgesic Responder Status
	Dosing change from baseline	**Added NSAID**	**Added opioid**	
None	None	not applicable	not applicable	Responder
	not applicable	Yes	No	Non-responder
	not applicable	No	Yes	Non-responder
	not applicable	Yes	Yes	Non-responder
NSAID	Stopped, decreased, or stable	not applicable	No	Responder
	≥15% increase	not applicable	No	Non-responder
	Any	not applicable	Yes	Non-responder
Opioid	Stopped, decreased, or stable	No	not applicable	Responder
	Stopped or decreased	Yes, any dose	not applicable	Responder
	Stable	Yes	not applicable	Non-responder
	≥15% increase	not applicable	not applicable	Non-responder
NSAID and Opioid	**NSAID Dose Change**	**Opioid Dose Change**		
	Stopped or decreased	Stopped, decreased, or stable		Responder
	Stopped or decreased	≥15% increase		Non-responder
	Stable	≥15% increase		Non-responder
	Stable	Stable		Responder
	≥15% increase	Stopped or decreased		Responder
	≥15% increase	Stable		Non-responder
	≥15% increase	≥15% increase		Non-responder

The non-steroidal anti-inflammatory drug (NSAID) allowed in these studies was naproxen, and the narcotic varied by country. Responder was defined in the co-primary analysis as a woman who meets the protocol-specified pain score criteria and no increase in analgesic use, i.e. a woman must be a pain responder and analgesic responder. Stable refers to the average analgesic use at the time point being an increase less than 15%. Dose changes were based on average pill counts.

Table S3. Key and Additional Secondary Endpoints

Key (hierarchically tested) Secondary Endpoints
1. Mean change from baseline to month 3 in Numeric Rating Scale Score
2. Mean change from baseline to month 6 in dysmenorrhea score
3. Mean change from baseline to month 6 in nonmenstrual pelvic pain score
4. Mean change from baseline to month 3 in pill count of any rescue analgesic used
5. Mean change from baseline to month 6 in pill count of any rescue analgesic used
6. Mean change from baseline to month 3 in dyspareunia
7. Mean change from baseline to month 3 in opioid pill count
Additional Secondary Endpoints
Percentage of dysmenorrhea responders at month 6
Percentage of nonmenstrual pelvic pain responders at month 6
Mean percentage change from baseline to each month in dysmenorrhea scores
Mean percentage change from baseline to each month in nonmenstrual pelvic pain scores
Number and percentage of women who responded 'much improved' or 'very much improved' on the Patient Global Impression of Change
Mean change from baseline to months 1, 3, and 6 on each dimension of the 30-item Endometriosis Health Profile Questionnaire

Scales and ranges are fully described in the supplemental methods on pages 20 and 21.

Table S4. Odds Ratios from the Logistic Regression Analysis of Dysmenorrhea and Nonmenstrual Pelvic Pain Responders

	Elaris EM-I, Elagolix		Elaris EM-II, Elagolix	
Odds ratio (97.5% CI)	150 mg QD	200 mg BID	150 mg QD	200 mg BID
Dysmenorrhea Responders, Month 3	3.6 (2.4, 5.4)	13 (8.3, 20)	2.6 (1.7, 4.0)	9.2 (5.9, 14)
Dysmenorrhea Responders, Month 6	2.4 (1.6, 3.6)	10 (6.6, 16)	2.5 (1.7, 3.8)	10 (6.4, 16)
Nonmenstrual pelvic pain Responders, Month 3	1.8 (1.2, 2.6)	2.2 (1.5, 3.1)	1.7 (1.1, 2.5)	2.4 (1.6, 3.6)
Nonmenstrual pelvic pain Responders, Month 6	1.6 (1.1, 2.3)	3.1 (2.1, 4.5)	1.6 (1.1, 2.3)	2.4 (1.6, 3.6)

The odds ratio significantly favor elagolix if the value and CI are greater than 1. The odds ratios for each elagolix group compared to placebo were based on a logistic regression model including treatment as the main effect and baseline value as a covariate using last observation carried forward for women who prematurely discontinued. Sample size for Elaris EM-I, month 3 (month 6): elagolix 150mg QD = 248 (247), elagolix 200 mg BID, 244 (243); Elaris EM-II, month 3 (month 6): elagolix 150mg QD = 221 (221), elagolix 200 mg BID, 225 (225).

Table S5. Sensitivity Analyses of the Co-primary Endpoints Based on a Non-responder Imputation for Women who Prematurely Discontinued

	Elaris EM-I			Elaris EM-II		
	Placebo	**Elagolix**		**Placebo**	**Elagolix**	
Percentage of Responders at Month 3	N=373	150 mg QD N=249	200 mg BID N=247	N=355	150 mg QD N=224	200 mg BID N=227
Dysmenorrhea	16%	40%	66%	19%	40%	64%
Difference from placbeo		24%	50%		21%	45%
Odds ratio [97.5% CI]		3.6 [2.3, 5.5]	10.1 [6.5, 15.7]		2.9 [1.9, 4.5]	7.8 [5.0, 12.0]
Two-sided P-value		P<0.001	P<0.001		P<0.001	P<0.001
Nonmenstrual pelvic pain	32%	46%	48%	34%	46%	54%
Difference from placebo		13%	16%		12%	21%
Odds ratio [97.5% CI]		1.7 [1.2, 2.5]	2.0 [1.3, 2.9]		1.7 [1.1, 2.5]	2.4 [1.6, 3.5]
Two-sided P-value		P=0.001	P<0.001		P=0.004	P<0.001

These analyses were the same as the co-primary endpoint, using the same logistic regression model, except that women who prematurely discontinued at or prior to month 3 were considered non-responders.

Table S6. Adverse Events Occuring in at least 5% of any Elagolix Group and Not Significantly Different between Elagolix and Placebo Groups

	Elaris EM-I			**Elaris EM-II**		
	Placebo	**Elagolix**		**Placebo**	**Elagolix**	
Adverse events occurring in ≥ 5% of any elagolix group,† n (%)		150 mg once daily	200 mg twice daily		150 mg once daily	200 mg twice daily
	N=374	N=249	N=248	N=360	N=226	N=229
Nausea	51 (14)	25 (10)	40 (16)	41 (11)	26 (12)	36 (16)
Urinary Tract Infection	36 (9.6)	19 (7.6)	16 (6.5)	27 (7.5)	10 (4.4)	19 (8.3)
Fatigue	23 (6.1)	14 (5.6)	16 (6.5)	15 (4.2)	8 (3.5)	9 (3.9)
Upper Respiratory Tract Infection	24 (6.4)	19 (7.6)	8 (3.2)	16 (4.4)	11 (4.9)	12 (5.2)
Sinusitis	17 (4.5)	14 (5.6)	12 (4.8)	14 (3.9)	10 (4.4)	15(6.6)
Nasopharyngitis	7 (1.9)	13 (5.2)	11 (4.4)	21 (5.8)	15 (6.6)	16 (7.0)
Acne	16 (4.3)	13 (5.2)	10 (4.0)	17 (4.7)	8 (3.5)	9 (3.9)
Anxiety	15 (4.0)	6 (2.4)	16 (6.5)	10 (2.8)	9 (4.0)	8 (3.5)
Depression	10 (2.7)	9 (3.6)	13 (5.2)	6 (1.7)	4 (1.8)	5 (2.2)
Back pain	26 (7.0)	10 (4.0)	10 (4.0)	15 (4.2)	10 (4.4)	13 (5.7)

MedDRA version 18.0 for Elaris EM-I and version 19.0 for Elaris EM-II were used. The adverse event statistical comparison versus placebo was based on Fisher's exact test using observed data.

† In descending order by elagolix overall for Elaris EM-I, then Elaris EM-II

Table S7. Hot Flush by Severity and Discontinuation Incidence

	Elaris EM-I			Elaris EM-II		
	Placebo	Elagolix		Placebo	Elagolix	
		150 mg once daily	200 mg twice daily		150 mg once daily	200 mg twice daily
n (%)	N=374	N=249	N=248	N=360	N=226	N=229
Hot flush	26 (7.0)	59 (24)***	105 (42)***	37 (10)	51 (23)***	109 (48)***
Hot flush severity Mild	19	42	56	20	32	55
Moderate	7	13	38	16	19	48
Severe	0	4	11	1	0	6
Discontinued due to hot flush	0	2 (0.8)	7 (2.8)	0	2 (0.9)	5 (2.2)

MedDRA version 18.0 for Elaris EM-I and version 19.0 for Elaris EM-II were used. The maximum severity is reported in this table for women who had multiple hot flush AEs of differing severity. Statistical significance vs. placebo based on a Fisher's Exact Test using observed data is indicated for two-sided $P<0.05$ (*), $P<0.01$ (**), and $P\leq0.001$ (***).

Table S8. Serious and Severe Adverse Events

Serious adverse events occurring in ≥ 2 women in any elagolix group, n (%)	Elaris EM-I			Elaris EM-II		
	Placebo	Elagolix		Placebo	Elagolix	
		150 mg once daily	200 mg twice daily		150 mg once daily	200 mg twice daily
	N=374	N=249	N=248	N=360	N=226	N=229
Endometriosis*	1 (0.3)	0	2 (0.8)	1 (0.3)	2 (0.9)	0
Appendicitis	1 (0.3)	0	1 (0.4)	0	0	2 (0.9)
Abdominal pain	0	0	0	3 (0.8)	2 (0.9)	0
Back pain	0	0	0	0	2 (0.9)	0
Uterine polyp	0	0	0	0	2 (0.9)	0
Severe adverse events occurring in ≥ 2 women in any elagolix group, n (%)						
Hot flush	0	4 (1.6)	11 (4.4)	1 (0.3)	0	6 (2.6)
Headache	3 (0.8)	4 (1.6)	4 (1.6)	4 (1.1)	3 (1.3)	2 (0.9)
Abdominal pain	5 (1.3)	3 (1.2)	2 (0.8)	4 (1.1)	2 (0.9)	1 (0.4)
Migraine	3 (0.8)	1 (0.4)	3 (1.2)	1 (0.3)	0	0
Insomnia	0	1 (0.4)	3 (1.2)	0	0	0
Endometriosis*	2 (0.5)	0	3 (1.2)	4 (1.1)	5 (2.2)	0
Nausea	5 (1.3)	2 (0.8)	1 (0.4)	3 (0.8)	1 (0.4)	2 (0.9)
Depression	0	1 (0.4)	2 (0.8)	0	0	0
Night sweats	0	2 (0.8)	1 (0.4)	0	0	0
Pelvic pain	4 (1.1)	1 (0.4)	1 (0.4)	1 (0.3)	2 (0.9)	1 (0.4)
Anxiety	0	0	2 (0.8)	1 (0.3)	0	0
Vomiting	1 (0.3)	1 (0.4)	0	0	0	3 (1.3)
Back pain	4 (1.1)	0	0	1 (0.3)	3 (1.3)	1 (0.4)

Serious adverse events are life-threatening, require hospitalization or medical/surgical intervention to prevent serious events, result in death, or result in persistent disability/incapacity. The severity of each adverse event was rated by the investigator as mild, moderate, or severe; severe adverse events are listed here. Preferred terms are listed in the order of highest incidence for elagolix groups overall for Elaris EM-I and then EM-II. MedDRA version 18.0 for Elaris EM-I and version 19.0 for Elaris EM-II were used.

*This preferred term is defined as the worsening of endometriosis.

Table S9. Mean Change from Baseline to Month 6 in Blood Glucose

	Elaris EM-I			Elaris EM-II		
	Placebo	Elagolix		Placebo	Elagolix	
Blood Glucose in milligrams per deciliter		150 mg once daily	200 mg twice daily		150 mg once daily	200 mg twice daily
	N=232	N=169	N=156	N=265	N=179	N=183
Mean at baseline	86.0	85.5	85.4	87.2	88.2	88.2
Mean (SD) change from baseline to month 6	0.34 (14.4)	1.03 (11.0)	0.43 (10.2)	2.0 (13.5)	-0.30 (12.7)	0.09 (12.9)
Difference from placebo		0.69	0.08		-2.3	-2.0

Statistical significance versus placebo was tested using a contrast within a one-way ANOVA using observed data; no significant differences were found.

Table S10. Endometrial Thickness, Uterine Bleeding Patterns, and Incidence of Amenorrhea by Month

	Elaris EM-I			Elaris EM-II		
	Placebo	Elagolix		Placebo	Elagolix	
		150 mg once daily	200 mg twice daily		150 mg once daily	200 mg twice daily
Endometrial Thickness in mm	N=272	N=190	N=176	N=261	N=172	N=182
Mean at baseline	6.8	6.5	6.5	6.3	6.4	6.4
Mean (SD) change from baseline to month 6	1.1 (3.3)	0.7 (3.6)	-1.4 (3.2)	1.0 (3.3)	0.4 (3.7)	-0.8 (3.6)
Mean number of days with bleeding/spotting, Days 141-168*	N=261	N=180	N=173	N=239	N=168	N=168
No bleeding	22.6	24.0	26.6	23.5	24.9	27.3
Spotting	1.9	1.5	0.8	1.5	1.2	0.2
Light	1.4	1.2	0.4	1.2	0.8	0.2
Medium	1.2	0.8	0.2	1.1	0.7	0.2
Heavy	1.0	0.5	0.1	0.7	0.4	0.1
Spotting to heavy	5.4	4.0	1.4	4.5	3.1	0.7
Light to heavy	3.6	2.5	0.6	3.0	1.9	0.5
Women with amenorrhea†, n/N (%)						
Month 1	22/358 (6.1)	41/242 (16.9)	43/234 (18.4)	18/344 (5.2)	39/218 (17.9)	42/221 (19.0)
Month 2	12/338 (3.6)	66/228 (28.9)	131/216 (60.6)	11/325 (3.4)	46/207 (22.2)	142/211 (67.3)
Month 3	5/323 (1.5)	61/221 (27.6)	131/209 (62.7)	13/310 (4.2)	64/202 (31.7)	138/205 (67.3)
Month 4	11/307 (3.6)	62/210 (29.5)	113/196 (57.7)	10/291 (3.4)	59/193 (30.6)	128/198 (64.6)
Month 5	14/299 (4.7)	60/200 (30.0)	118/188 (62.8)	11/281 (3.9)	53/187 (28.3)	126/190 (66.3)
Month 6	11/261 (4.2)	25/180 (13.9)	82/173 (47.4)	8/239 (3.3)	47/168 (28.0)	110/168 (65.5)

There were no prespecified statistical comparisons between treatment groups.

*Month 6

†In the electronic diary, women responded ‘no’ to whether or not she had her period in the past 24 hours and ‘no bleeding’ when quantifying uterine bleeding for all 28 days in that month. Days with missing electronic diary entries were considered ‘no bleeding’ days.

Table S11. Endometrial Diagnosis Based on Histological Interpretation of the Biopsied Tissue in Elaris EM-I

	Placebo		**Elagolix 150 mg once daily**		**Elagolix 200 mg twice daily**	
Category, N (%) **Subcategory, N (%)**	Baseline N=373	Month 6 N=282	Baseline N=246	Month 6 N=186	Baseline N=248	Month 6 N=176
Normal quiescent or minimally stimulated	10 (2.7)	6 (2.1)	8 (3.3)	26 (14)	4 (1.6)	107 (61)
Normal secretory/mixed/ breakdown/menstrual	156 (42)	141 (50)	98 (40)	51 (27)	93 (38)	12 (6.8)
Normal secretory	100 (27)	88 (31)	59 (24)	33 (18)	63 (25)	7 (4.0)
Mixed pattern (proliferative/secretory)	2 (0.5)	2 (0.7)	0	0	1 (0.4)	1 (0.6)
Menstrual/Breakdown	54 (14)	51 (18)	39 (16)	18 (9.7)	29 (12)	4 (2.3)
Proliferative	200 (54)	129 (46)	131 (53)	105 (56)	143 (58)	46 (26)
Hyperplasia	0	0	1 (0.4)	0	0	0
Reactive/inflammatory	0	0	0	1 (0.5)	0	0
Polyp	0	2 (0.7)	3 (1.2)	0	0	0
Insufficient tissue	3 (0.8)	5 (1.8)	1 (0.4)	4 (2.2)	5 (2.0)	15 (8.5)
Women without biopsy results	1	92	3	63	0	72

Percentages are based on number of women randomized, dosed, and had a biopsy, which are represented at the column header. Each category had subcategories to which biopsy data could be coded, and results from one biopsy could be coded to multiple categories. There were no prespecified statistical comparisons between treatment groups.

Table S12. Number of Pregnancies during Treatment Period, the Outcomes and Estimated Annualized Pregnancy Rate

	Elaris EM-I			**Elaris EM-II**		
	Placebo	**Elagolix**		**Placebo**	**Elagolix**	
		150 mg once daily	200 mg twice daily		150 mg once daily	200 mg twice daily
	N=374	N=249	N=248	N=360	N=226	N=229
Pregnancies	8 (2.1)	4 (1.6)	2 (0.8)	7 (1.9)	2 (0.9)	0
Live births	5	2	1	1	0	0
Spontaneous abortion	0	0	0	3	1	0
Termination of pregnancy	0	1	0	1	1	0
Ectopic pregnancy	1	0	0	0	0	0
Still birth	1	0	0	0	0	0
Lost to follow-up	1	1	1	2	0	0
Ongoing	0	0	0	0	0	0
Exposure (days)	57888	39251	37379	56303	36703	36867
Estimated Annualized Rate (%)	5.05	3.72	1.95	4.54	1.99	0

There were no prespecified statistical comparisons between treatment groups.

Part 6: Appendix References

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