John S Mahoney MD 13 Feb 2019

CURRICULUM VITAE

NAME: Mahoney M.D., John S. **DATE:** 13/Feb/2019

POSITION TITLE: Investigator

OFFICE ADDRESS:
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PROFESSIONAL LICENSURE: Commonwealth of Virginia Board of Medicine 0101042392 USA

EDUCATION/TRAINING:
(Include baccalaureate or other initial professional education such as nursing, postdoctoral training, GCP training.)

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Columbia Presbyterian Medical College, New York, NY, USA	Residency	1985-1988	Orthopedic Surgery
Baylor University Medical College, Dallas, TX USA	Internship	1983-1985	General Surgery
University of Texas at Houston, USA	Doctor of Medicine	1983	MD
University of Colorado, USA	B.A.	1975	B.A.- Biology

Specialization: Orthopedic Surgery

POSITIONS AND EMPLOYMENT:

2011-present Orthopedic Surgeon, Spectrum Medical, Inc. (formerly Danville Orthopedic Clinic, Inc.), Danville, Virginia, USA
2008-2011 Orthopedic Surgeon, LifePoint, Inc. Martinsville, Virginia, USA
1988-2008 Orthopedic Surgeon/Private Practice, Bone and Joint Center, Martinsville Virginia, USA

BOARD CERTIFICATIONS, OTHER EXPERIENCE, AND PROFESSIONAL MEMBERSHIPS:

1990-present American Board of Orthopaedic Surgery, Certification
present American College of Orthopaedic Surgeons
present Medical Society of Virginia

HOSPITAL AFFLIATION(S):

1988-present Memorial Hospital of Martinsville and Henry County, Martinsville, VA USA
2011-present Danville Regional Medical Center, Danville, VA USA

BRIEF RESEARCH EXPERIENCE:

A Randomized, Double-Blind, Placebo Controlled, Parallel group study to evaluate the efficacy and safety of XXX in patients with Hip Osteoarthritis. (2019-Present). Role: Principal Investigator

A Randomized, Double-Blind, Placebo controlled, 2-injection, 52 week study to evaluate the efficacy and safety of Intra-articular injections of XXX in subjects with chronic, Moderate-to Severe osteoarthritis knee pain. (Jan 2019-Present). Role: Sub Investigator

A Randomized, Multicenter, Open-label, Parallel Group Study in Postmenopausal Women with Osteoporosis to Evaluate the Non-inferiority of subjects administered XXX via auto injector/pen vs. Healthcare provider administered XXX via prefilled syringe. (Jan 2018-2019). Role: Sub-Investigator.

A Phase 4, Randomized, Double-Blind, Multicenter, Placebo Controlled Study to Evaluate the Safety and Efficacy of XXX in combination with XOI compared with XOI alone, in subjects with Gout and Estimated Creatinine Clearance 30 to <60 mL/min who have not achieved target serum uric acid levels on an XOI Alone. (Aug 2017-Feb 2019). Role: Sub-Investigator.

A **Phase 3**, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of the analgesic efficacy and safety of a dose titration regiment for the subcutaneous administration of XXX in subjects with osteoarthritis of the hip of knee. (2016-2018). Role: Sub-Investigator.

A **Phase 2A**, Randomized, Double-Blind, Placebo Controlled crossover study of the Safety and Efficacy of XXX in subjects with Osteoarthritis of the knee. (2016-2016). Role: Sub-Investigator.

A Double-Blind, Randomized, Study of the Effectiveness and Safety of XXX (Injectable) for the Treatment of Osteoarthritis of the Knee. **Device Study**. Role: Principal Investigator. (July 2015-2016).

A **Phase 3**, Randomized Withdrawal Double Blind Study of XXXX Monotherapy Compared to XXXX Monotherapy for Maintenance of Remission in Subjects With Rheumatoid Arthritis. (2015-2018). Role: Sub-Investigator

A **Phase 3**, Multi-Center Double-Blind, Randomized Controlled Study of XXXX and XXXX in Combination or as Monotherapy in Subjects with Psoriatic Arthritis. (2015-2017). Role: Sub-Investigator

A **Phase 3B**, Randomized, Double-Blind Clinical Trial to Evaluate the Efficacy and Safety of XXXX SC in Combination with XXXX Compared to XXX Monotherapy in Achieving Clinical Remission in Adults with Early Rheumatoid Arthritis who are XXXX Naïve. (2015-2018). Role: Sub-Investigator

Efficacy ,Safety, and Immunogenicity of XXXX versus XXXX in patients with Active Rheumatoid Arthritis: A Randomized , Double-blind , Parallel-arm, Multiple Dose, Active Comparator. **Phase 3. (2015-2018).** Role: Sub-Investigator.

Prospective, Multi-Center, Randomized, Three–Arm, Parallel group, clinical study to evaluate the superiority of 3 weekly intra-articular doses of 2ml of Investigational Product as compared to Placebo and XXXX injected into the target knee for the treatment of pain in subjects with Osteoarthritis.
(2015) Role: Principal-Investigator. **Device Study.**

Double Blind, Placebo-controlled, Randomized, Parallel–group Study to Determine the Safety and Efficacy of a Topical Patch (XXXX) Following Daily Administration for 2 Weeks in Patients with Chronic Low Back Pain. **Phase 2.** (2015-2015) Role: Sub Investigator

A Randomized, Sham-Controlled Pilot Study of XXXX Therapy in the Treatment of Persistent Post-Operative Pain following a Total Knee Arthroplasty (**Device Study**). (2015-2016). Role: Principal Investigator

A **Phase 3**, Randomized, Double-Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of XXX (multiple doses/IR XR) in Subjects with Gout. Role: Sub-Investigator. (August 2014-2016).

A Randomized, Double-Blind, Multiple Center, Placebo Controlled Study Comparing the Safety and Efficacy of a Multiple Dose of Generic XXX to YYY in the Treatment of Acute Pain Due to Minor Ankle Sprain. (May 2014-October 2014). **Phase: 3**. Role: Principal Investigator.

A Double-Blind, Randomized, Parallel Group, Dose Ranging Study to Assess the Efficacy and Safety of XXX for the Treatment if pain in Patients with Osteoarthritis of the knee. (March 2014-2015). **Phase: 2**.Role: Principal Investigator

A Randomized, Double-Blind, Placebo Controlled **Phase 3** Study to Evaluate the Efficacy, Safety and Effect on Radiographic Progression of XXX in Subjects with Psoriatic Arthritis. (Feb 2014-2015). Role: Sub Investigator.

A Randomized, Placebo-controlled, Double-Blind Study to Evaluate the Efficacy and Safety of a single intra-articular injection of XXX in adults with pain due to osteoarthritis of the knee. (Jan. 2014- October 2014). **Phase 3**. 2 Week Enrollment Period. Role- Sub-Investigator.

A Randomized, Double-Blind, Placebo Controlled Study of the Safety and Efficacy of XXX for the Treatment of Adhesive Capsulitis of the Shoulder. **Phase 2b**. (Dec. 2013- Nov. 2014) Role: Sub-Investigator/Injector

A Phase IIb, Multi-center, Randomized, Double-Blind, Placebo Controlled, Multidose, 24 Week Study to Evaluate the Efficacy and Safety of XXX in Subjects with Systemic Lupus Erythematosus (SLE). **Phase 2b**. Role: Sub-Investigator (Dec 2013-2015).

Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter, Worldwide, Proof of Concept Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of XXX in Subjects with Active Rheumatoid Arthritis and Inadequate Response or Intolerance to Anti-TNF Therapy. (May 2013-October 2013). Role: Sub-Investigator

Placebo Controlled, Double Blind Evaluation of the Efficacy and Safety of XXX for the treatment of Ankle Sprain. (Nov. 2013-2015).**Phase 3**. Role: Sub Investigator.

A Randomized, Placebo-controlled, Double-Blind Study to Evaluate the Efficacy and Safety of Two Doses of intra-articular injection of XXX in adults with pain due to osteoarthritis of the knee. (April 2013-August 2013). Role- Sub-Investigator.

A Randomized, Double-Blind, Multicenter, Placebo Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY Alone in Lowering Serum Uric Acid and Resolving Tophi in Subjects with Tophaceous Gout.(March 2012- 2015). **Phase 3**. Role- Sub-Investigator

A Randomized, Double-Blind, Multicenter, Placebo Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY Alone in Subjects with Gout who had an inadequate hypouricemic response to Standard of Care YYY.(March 2012- September 2014). **Phase 3.** Role- Sub-Investigator

A Double-Blind, Randomized, Parallel Group, Dose-Ranging Study Comparing XXX vs. YYY in Patients with Osteoarthritis of the knee. **Phase 2**. (2011) Role: Sub-Investigator

A Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety in Osteoarthritis or Rheumatoid Arthritis Patients with or at High Risk for Cardiovascular Disease Comparing XXX with YYY and ZZZ.(2012-2016). **Phase 4.** Role: Sub-Investigator.

A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Active-Controlled, Parallel-group, Multicenter Trial of XXX to assess the analgesic efficacy and the management of opioid induced constipation in opioid experienced subjects with moderate to severe chronic low back pain and a history of opioid induced constipation who require around the clock opioid therapy. **Phase: 3** Role: Sub-Investigator. (2013-2014)

A 36 week open label extension study of XXX in treating acute gouty arthritis. **Phase 3.** Role: Sub-Investigator. (2012-2013)

An Open-Label extension study of XXX on the treatment and prevention of gout flares in patients with frequent Flares whom NSAIDS and/or colchicine are contraindicated, not tolerated or ineffective. **Phase 3.** (2012-2013). Role: Sub-Investigator.

A Multicenter, Randomized, Active Control, Phase 3B Study to Evaluate the Cardiovascular Safety of XXX and YYY in Subjects with Gout and cardiovascular Co-morbidities. **Phase 3B.** (2012-2017). Role: Sub-Investigator

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Written Notification of Change of Address Required Within 30 Days of Change

*Name Change Request Must be Accompanied by a Photocopy of Marriage License or Court Order

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DEPARTMENT OF HEALTH PROFESSIONS

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John Stephen Mahoney, MD

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