

## **Aurora Spine Corporation Announces Newly Published Paper on First 6-month Clinical Evaluation of its ZIP™ Fusion Implant**

CARLSBAD, Calif., Dec. 04, 2023 — Aurora Spine Corporation (“Aurora Spine” or the “Company”) (TSXV: ASG) (OTCQB: ASAPF), a designer and manufacturer of innovative medical devices that improve spinal surgery outcomes, today announced the publication of the first 6-month clinical evaluation of its ZIP™ fusion implant in the Journal of Pain Research.

Lumbar interlaminar decompression with interspinous fixation is an established safe and effective treatment for spinal stenosis. Early maintenance of improvements in pain intensity and function are critical for durability of symptom relief. The purpose of this study is to investigate the efficacy of minimally invasive treatments for low back pain during the early period after treatment and their utility in setting the course for longer term success.

The scientific paper titled “[Early Functional Outcomes in Low Back Pain Subjects with a Novel Interspinous Fusion Device: REFINE Study 6-Month Results](#)”, is a pivotal multi-center study of its ZIP™ Interspinous Fixation device for patients suffering from back pain due to symptomatic degenerative disc disease and spinal stenosis.

The REFINE Screwless™ ZIP Study utilized patient evaluations at 3- and 6-months following treatment and is part of an actively enrolling, institutional review board (IRB) approved, single-arm, multicenter, prospective, open-label 12-month study. Clinical efficacy was assessed primarily using the change from baseline in Oswestry Disability Index (ODI), Visual Analog Scale (VAS) of the back and leg pain during walking and standing, and Zurich Claudication Questionnaire (ZCQ), and secondarily using the Patient Global Impression of Change (PGIC) and Patient-Reported Outcomes Measurement Information System (PROMIS).

This 6-month interim analysis at 42% enrollment of patients was conducted to determine prolonged safety and efficacy of the ZIP interspinous fusion device. Our analysis showed a sustained improvement in clinical efficacy, and safety endpoints, when compared to the 3-months evaluations, across both interventional pain and neurosurgery specialties.

The ZIP™ device is an alternative to more invasive traditional spinal surgery. The ZIP device’s minimally invasive surgical technique works through a single, small surgical cut. Once in place, the device acts as a fusion support column to open the passageways that contain the spinal cord and nerve roots. This procedure may reduce the compression on the nerves, resulting in potential pain relief in the leg, groin, and buttocks, and then return to a more active lifestyle.

“We appreciate all the support from the remarkable group of physicians from the neurosurgery and interventional pain management specialties across the country to bring the REFINE ZIP multicenter study to success,” said Trent J. Northcutt, President and Chief

Executive Officer of Aurora Spine.

Dr. Sebastian Koga, a neurosurgeon from Covington, LA emphasized, “Our study demonstrates that the ZIP device provides a stable platform for posterior fusion. The patients go home the same day as the surgery and use less medications for chronic pain. I am happy to contribute objective clinical evidence to this area of spine surgery. In my practice I use the device as an adjuvant to most single-level decompressions.”

According to a functional neurosurgeon Dr. Steven Falowski, who enrolled the first patient for the REFINE study, “Many of my patients suffering from lower back or leg pain could benefit from the ZIP minimally invasive outpatient treatment option that replaces traditional more invasive spinal decompression surgery commonly done with pedicle screws. I am very excited with these interim prospective 6 months results showing extremely positive outcomes demonstrating the strong future of the ZIP Screwless procedure. I am proud to participate as one of the Principal Investigators in this groundbreaking multicenter study. The purpose of this study is to develop the highest level of scientific evidence and bring this landmark therapy to the forefront.”

Dr. Jason E. Pope, one of the Principal Investigators in the study, a pain physician and anesthesiologist, highlighted that “the ZIP device procedure operationalizes the ability to perform a posterior interspinous fusion for those specially trained pain physicians, offering an additional minimally invasive option to remove pain and improve function in select patients suffering from degenerative disc disease accompanied by neurogenic claudication.”

The ZIP System was 510(k) cleared by the FDA in 2013 and has been commercially available in multiple sizes in the US since 2014. With thousands of procedures already completed worldwide, the ZIP device is safe and effective in an outpatient setting. The ZIP device provides physicians the ability to remove targeted ligament, bone, and facet capsule material. This quick decompression involves minimal collateral tissue disruption and can also work under local anesthesia. A previously published retrospective study has also demonstrated the ZIP device’s safety and effectiveness in the hands of interventional pain physicians.

### **About Aurora Spine**

Aurora Spine is focused on bringing new solutions to the spinal implant market through a series of innovative, minimally invasive, regenerative spinal implant technologies. Additional information can be accessed at [www.aurora-spine.com](http://www.aurora-spine.com) or [www.aurorapaincare.com](http://www.aurorapaincare.com).

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### **Forward-Looking Statements**

*This news release contains forward-looking information that involves substantial known and unknown risks and uncertainties, most of which are beyond the control of Aurora Spine, including, without limitation, those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Information” in Aurora Spine’s final prospectus (collectively, “forward-looking information”). Forward-looking information in this news release includes information concerning the proposed use and success of the Company’s products in surgical procedures. Aurora Spine cautions investors of Aurora Spine’s securities about important factors that could cause Aurora Spine’s actual results to differ materially from those projected in any forward-looking statements included in this news release. Any statements that express, or involve discussions as to, expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking and may involve estimates, assumptions and uncertainties which could cause actual results or outcomes to differ unilaterally from those expressed in such forward-looking statements. No assurance can be given that the expectations set out herein will prove to be correct and, accordingly, prospective investors should not place undue reliance on these forward-looking statements. These statements speak only as of the date of this press release, and Aurora Spine does not assume any obligation to update or revise them to reflect new events or circumstances.*

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