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FOR IMMEDIATE RELEASE

ExsoMed Corporation Announces FDA 510(k) Clearance of
InFrame™ Intramedullary Micro Nail for Proximal Phalanx Fractures

Aliso Viejo, CA - September 1, 2020 - ExsoMed Corporation, a privately held U.S.-based medical device company providing orthopaedic surgeons with innovative solutions in hand surgery, received 510(k) clearance from the United States Food and Drug Administration to commercialize its *InFrame Intramedullary Micro Nail*. The threaded micro nail provides surgeons with a simple, minimally invasive solution to optimize outcomes of proximal phalanx fracture surgeries.

"The proximal phalanx fracture is one of the biggest problems in hand surgery," said Lloyd Champagne, MD of Arizona Center for Hand to Shoulder Surgery and one of *InFrame's* lead design surgeons. "Despite modern fixation advancements, outcomes are still frequently poor, resulting in digits with severe permanent range of motion deficits. *InFrame* offers the first permanent stable intramedullary fixation that controls rotation, allowing phalanges to resume immediate motion and tendon gliding. This new product is going to change the way that hand surgeons treat proximal phalanx fractures."

A 2017 proximal phalanx fracture study by Lögters et al., shows that "clinical success is achieved when acceptable fracture alignment and stability occur in the setting of unobstructed tendon gliding and early active range of motion." *InFrame* is designed and sized specifically for the proximal phalanx intramedullary canal to facilitate early, active mobilization for accelerated healing and faster return to daily activities. The 2.0mm diameter design provides surgeons with the ability to easily achieve cross implantation constructs, enhancing rotational control and stability, cortical bone purchase, and intramedullary fit. This is made possible by a unique, patent-pending delivery mechanism of the device via the dual diameter guidewire, providing precise placement while eliminating the need for a dedicated reamer and reaming step.

Statistically significant internal bench test data has shown that *InFrame* has superior construct stability compared to traditional approaches for proximal phalanx fractures. Comparatively, *InFrame* provided 97% more bending stability and 341% more rotational stability than 2 crossed 0.045" K-wires; 473% more bending stability and 166% more rotational stability than dorsal plates and screws; and 48% more bending stability and 1,533% more rotational stability than headless compression screws.

“Surgeons have shared with us on numerous occasions that an effective solution for P1 fractures is desperately needed in the hand surgery space,” shared James Young Kim, ExsoMed’s Managing Director of Global Sales and Marketing. “We have answered their calls and are proud to introduce *InFrame*. We are eager to get our latest innovation in the hands of these surgeons, so that they can enhance outcomes for proximal phalanx fractures, ultimately raising the standard of care for patients.”

The *InFrame Intramedullary Micro Nail* will be available in the fourth quarter of 2020. Surgeon education and training opportunities will begin rolling out in the Fall. Consistent with the other products in ExsoMed’s portfolio, all instrumentation for *InFrame* will be sterile-packed and single-use, for stream-lined use in the operating room.

About ExsoMed

ExsoMed is a privately held medical device company providing orthopaedic surgeons with innovative solutions in hand surgery. We believe that our solutions raise the standard of care in hand surgery by providing state of the art surgical tools that streamline use in the operating room, reduce the global cost of care, and enhance outcomes so that patients can get back to life faster. For more information regarding ExsoMed, please visit www.exsomed.com.

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