Biomet Inc. (NASDAQ-BMET) announced today that the US Food & Drug Administration has granted marketing clearance for its patented ArComXL™ Highly Crosslinked Polyethylene, an engineered polymer that has demonstrated a 47-64% volumetric wear rate reduction over Biomet’s own ArCom® Polyethylene.

“ArComXL™ is a new bearing material based on the already proven ArCom® product that delivers superior wear characteristics without the adverse consequences of reduced mechanical integrity or potential for oxidation that defines the currently marketed generation of highly crosslinked polyethylenes,” stated Biomet’s President & Chief Executive Officer, Dane A. Miller, Ph.D. “ArComXL™ sets a new performance standard in terms of mechanical strength, oxidation resistance, and wear resistance in polyethylene, which is attributable to our patented processing technique.”

Biomet is the first and only orthopedic company to offer a second-generation highly crosslinked polyethylene material. Extensive in-vitro testing was conducted internally and in conjunction with independent laboratories to measure metrics such as resistance to abrasive wear, subluxation wear, oxidation, fatigue, and crack propagation. The results of comparison testing to ArCom® were universally positive and have validated the utility of Biomet’s patented process:

- 47-64% volumetric wear rate reduction
- 30% increase in ultimate tensile strength in longitudinal axis
- No measurable oxidation by Fourier Transform Infrared Spectroscopy after accelerated aging (OI<0.4)

ArComXL™ will not replace Biomet’s traditional ArCom® material, but will be another bearing option from which surgeons can choose. Dr. Miller continued, “ArComXL™ offers substantial advantages over the first generation highly crosslinked materials still promoted by our competitors, and as the first and only company to market directionally engineered polyethylene, we expect to enjoy a strong technological advantage in the highly crosslinked market for a significant period of time.”