



**FOR IMMEDIATE RELEASE:**

## **Akonni Biosystems Announces FDA 510(k) Submission for its TruDiagnosis® Multiplex Diagnostic System**

**FREDERICK, MD – January 4, 2019** – Akonni Biosystems, a molecular diagnostics (MDx) company that develops, manufactures, and intends to market [advanced MDx systems](#), today announced it has filed a 510(k) submission with the U.S. Food and Drug Administration (FDA) for approval of the TruDiagnosis® system, its proprietary, microarray-based technology. The TruDiagnosis system is an in vitro diagnostic device intended for genotyping multiple genes in a DNA sample utilizing on-slide polymerase chain reaction (PCR) gel-drop microarray technology. The system is comprised of the TruDx® 2000 Imager, TruSpot™ Software, and the TruArray® consumable test kit, all unique, patented technologies developed in-house at Akonni.

“Our submission of this 510(k) application to the FDA represents a significant milestone for our company, and is the result of a great deal of hard work, dedication, and determination by our passionate team members and strategic partners,” said Charles Daitch, CEO and Founder of Akonni Biosystems. “It represents a critical next step in realizing Akonni’s mission to develop, manufacture, and sell molecular diagnostic tools for rapid, affordable, and accurate diagnoses that have the potential to dramatically improve the health status and cost of healthcare for millions of people worldwide. We continue to make significant progress as we transition from a largely research and development-oriented company into a fully integrated commercial molecular diagnostics organization. We look forward to achieving our first FDA clearance and to launching commercially in 2019.”

### **About Akonni Biosystems**

Akonni Biosystems was founded in 2003 and has been issued 21 US and 37 International patents primarily covering sample preparation, microfluidic devices, bioinstrumentation, and integrated systems. Product development has been supported by a series of government grants and contracts from NIH, CDC, DOE, DOD, NIJ, and NSF. The company significantly advanced the original technology by improving the system’s capabilities from sample preparation to test result. Commercial products in Akonni’s near-term pipeline include rapid sample preparation technologies for nucleic acid extraction and multiplex panel assays for detecting clinically relevant genotypes for pharmacogenomics, human chronic diseases, and genotypes for infectious diseases such as multidrug-resistant tuberculosis (MDR-TB), extensively drug-resistant tuberculosis (XDR-TB), upper respiratory infections, viral encephalitis, and hospital-acquired infections (MRSA). Based on its recent analysis of microarray-based applications in the molecular diagnostics (MDx) market, Frost & Sullivan recognized Akonni Biosystems with the prestigious 2017 North American New Product Innovation Award. For more information visit: [www.akonni.com](http://www.akonni.com).

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