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Applied DNA reaches new milestones

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Singapore – Applied DNA Sciences, among the world's largest producers of linear DNA, has reached new technical milestones in the growth of its Contract Research (CRO) and Contract Manufacturing (CMO) businesses. In the past 12 months, Applied DNA has shipped over 8,000 milligrams of PCR-produced linear DNA for use in Diagnostic and Therapeutic applications. The Company has completed, or is progressing through, key milestones of a growing number of therapeutics research contracts for companies producing DNA and RNA vaccines and adoptive cell therapies. Key milestones of success for these gene therapies are delivery of DNA effectively into a cell, expressing the gene product from that DNA and eventually demonstrating the desired clinical outcome.

These projects are following the typical preclinical biotherapeutic path of proving efficacy at small scale prior to securing larger production appropriate for clinical trials and deployment.

Most DNA-based therapeutic products, both approved and in development, rely on legacy science of plasmid and viral vector production methods that are time-consuming, carry the risks of bacterial toxins and triggering complications or unintended consequences. Several recent clinical trials have been halted by FDA due to unintended consequences of plasmid-derived DNA. As an alternative, Polymerase Chain Reaction (PCR), is a well-proven technique of DNA amplification first introduced in the 1980's as an investigative tool in research and diagnostic laboratories. Applied DNA's patented large-scale PCR production capability is a breakthrough for therapeutic applications as it has already demonstrated that PCR product can be made available very cleanly and at the scale required for population-scale diagnostics.

"The milestones achieved to-date are a result of a multi-year business plan beginning with the acquisition of Vandalia Research assets three years ago. Now attracting new business at an accelerating rate and showing results that go toe-to-toe with legacy plasmid production is a major milestone for the viability of PCR-produced DNA for use in therapeutics," said Dr. James Hayward, president and CEO of Applied DNA. "We will continue to work with companies developing therapeutics to expand the processes necessary to grow this business alongside our mainstay tagging business."