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Nucleonics Challenges Validity of Benitec's U.S. Patent

HORSHAM, PA (October 4, 2004): Nucleonics, Inc., a biotechnology company focused on the development of novel expressed RNA interference-based (eiRNA) therapeutics, announced that today it has filed with the United States Patent and Trademark Office (U.S. PTO) a Request for Re-examination of Benitec and the Australian Commonwealth Scientific and Industrial Research Organisation's (CSIRO) U.S. Patent Number 6,573,099, entitled "Genetic Constructs For Delaying Or Repressing The Expression Of A Target Gene." The Request submits highly relevant prior art documents not previously considered by the U.S. PTO showing that the patent claims are invalid because they lack novelty and/or were obvious at the time the priority patent application was filed. Nucleonics also believes that the claims are ambiguous and that the application fails to provide adequate description or sufficient working examples to support the scope of the claimed subject matter.

This challenge follows Nucleonics' previously announced September 7 filing with The Commissioner of Patents in Australia of a Request for Re-Examination of Benitec and CSIRO's Australian Patent Number 743316, entitled "Control of Gene Expression."

"The filing of this Request for Re-examination in the U.S. PTO is yet another step in our on-going effort to use all available legal avenues to expose the inherent weaknesses in Benitec's patent portfolio," said Robert Towarnicki, Nucleonics' chief executive officer. "We will not allow Benitec to use its invalid patent claims to prevent those working to advance eiRNA technology from developing needed therapeutics for chronic viral diseases such as Hepatitis B, Hepatitis C and others, to help people around the world."

About Expressed Interfering RNA (eiRNA)
Post-transcriptional gene silencing, also known as RNA interference or RNAi, is a phenomenon in which genes are silenced in a sequence-specific manner through targeted mRNA (messenger RNA) degradation. Researchers believe RNAi may offer potential as a novel way to silence genes involved in disease, including genes encoded by viruses such as Hepatitis B, Hepatitis C and HIV, as well as genes involved in the establishment of inflammatory diseases and cancer.

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Nucleonics is licensed under the RNAi technology of Andrew Fire, Craig Mello and their colleagues, widely recognized as the seminal work in this area. Nucleonics employs an expressed interfering RNA (eiRNA) approach whereby scientists insert plasmid DNA coding for relevant double-stranded RNA (dsRNA) into targeted cells, letting the cells produce and deliver specific dsRNA sequences. Cellular mechanisms then cleave the dsRNA into specifically encoded siRNAs (short interfering RNA), which silence the targeted genes. Nucleonics' researchers have shown the ability of long or short dsRNA strands produced in this way to stably silence genes, including Hepatitis B, Hepatitis C, and HIV, in relevant cell lines. Moreover, they have silenced multiple genes, as well as HBV replication, in adult mice without triggering an interferon response. Plasmid DNA approaches similar to those used by Nucleonics for expression of dsRNA have demonstrated human safety in over 500 patients to date, as part of research in the field of DNA-based vaccines. Nucleonics is initially directing its technology to the development of eiRNA therapeutics for Hepatitis B virus and Hepatitis C virus infections.

About Nucleonics, Inc.
Nucleonics, founded in January 2001, is an emerging biotechnology company focused on the development of novel RNA interference-based therapeutics for viral and other diseases. Privately owned Nucleonics is headquartered in Horsham, Pennsylvania.

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