

[329] UPDATE OF THE PIVOTAL, CLINICAL EFFICACY, PHASE 3 TRIAL OF BIONDVAX'S M-001 UNIVERSAL INFLUENZA VACCINE

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- **Investment Rational**

BiondVax's M-001 is the only Universal Flu Vaccine candidate in Phase 3 clinical trials. Current flu vaccines target 3-4 specific flu strains; With technology developed at the Weizmann, substantial government funding, NASDAQ investors, a European Investment Bank €20 million financing agreement, 6 successfully completed and 2 ongoing clinical trials, M-001 potentially offers vast improvement by offering multi-season, multi-strain flu protection.
- **Core Technology**

In contrast to currently available flu vaccines targeting only 3-4 flu strains, and achieving an average 40% vaccine effectiveness, M-001 is designed as a common denominator to all flu strains to provide multi-strain and multi-season protection against current and future, seasonal and pandemic influenza. M-001 can be manufactured and administered year-round and stockpiled for immediate response to any new pandemic.
- **Product Profile/Pipeline**

A pivotal, clinical efficacy, Phase 3 trial with ~10,000 participants is ongoing in Europe, as is an NIH-sponsored Phase 2 trial in the USA. Six clinical trials in 698 participants, including a Phase 2b conducted in collaboration with the EU-funded UNISEC consortium, indicate the Universal Flu Vaccine candidate is safe, well-tolerated, and immunogenic to a broad range of flu strains.
- **Business Strategy**

Following a successful Phase 3 trial, and after receiving regulatory and marketing approval, the NASDAQ-traded company anticipates entering the \$4.5 billion seasonal flu vaccine market. Approvals will be sought in additional age groups and geographies. As the only Universal Flu Vaccine candidate in Phase 3 trials, M-001's possible first-to-market advantage has global commercial and life-saving potential.
- **What's Next?**

Influenza kills up to 650,000 people annually. Following successful results in the ongoing pivotal, clinical efficacy, Phase 3 trial, BiondVax intends to bring M-001 universal flu vaccine to the market. The company's new Jerusalem-based mid-size commercial scale manufacturing facility will have capacity to annually produce ~20 million doses. Additional trials to expand M-001s indication and geographic approval will be planned.