

## **PRESS RELEASE**

### **Inmedix Meets with FDA to Discuss the Development Plan Supporting Commercialization of its ANS Neuroscan™**

*Premarket development plan designed to provide data to support potential approval of ANS Neuroscan™ as a predictor of treatment outcomes for patients with Rheumatoid Arthritis (RA)*

Seattle, WA – March 28, 2016 – Inmedix, the leader in heart rate variability (HRV) application as an informative diagnostic tool in autoimmune disease, today announced that the FDA has provided guidance for the required development work that can lead to commercialization for the Inmedix ANS Neuroscan™ diagnostic. During a meeting in late 2015 with its Office of In Vitro Diagnostics and Radiological Health (OIR), the FDA and Inmedix identified a mutually agreed upon option which can result in marketing approval. As a result, Inmedix will focus first on completing the development work necessary to secure an FDA approval that will result in the incorporation of the ANS Neuroscan into the rheumatoid arthritis (RA) patient workup.

Last month, the company filed additional regulatory documents requesting a meeting with the Center for Drug Evaluation and Research (CDER), OIR and the Center for Diagnostics and Radiological Health (CDRH) to seek guidance for the necessary development work that would result in approval for using ANS Neuroscan as an actionable predictor of therapeutic outcome for the treatment of RA. Since this effort potentially impacts the biologic agent which Inmedix chooses to predict, the company learned in 2015 that the pathway to such an unprecedented claim may require a coordinated review among a variety of FDA agencies. Last week, this combined FDA meeting was scheduled for May 4, 2016.

Andrew J. Holman, MD, CEO & Co-founder of Inmedix said the he was appreciative of the advice received and that Inmedix is committed to working with the FDA to complete the necessary development work and then seek approval. “This is an exciting time for Inmedix, our Scientific Advisory Board and our potential investors as we press ahead to transform outcomes for patients with autoimmune diseases.”

The ANS Neuroscan measures autonomic nervous system (ANS) status which has been shown to influence many human immune functions at work in RA and in other autoimmune diseases. Through an electrocardiogram (ECG) tracing, the ANS Neuroscan uses proprietary heart rate variability (HRV) technology to assess the patient’s ANS profile. Inmedix shared with the FDA its published proof-of-concept study (n=33) of observed accuracy – with 90% sensitivity and 95.7% specificity – for the ANS Neuroscan to predict therapeutic biologic response for RA.<sup>1,2</sup> At one year, 0% of patients with a baseline poor ANS profile achieved disease control using either etanercept (Enbrel®, Amgen) or adalimumab (Humira®, AbbVie). For patients with a baseline

beneficial ANS profile, 65% achieved disease control as defined by an ACR70 response, a standard endpoint for measuring efficacy in RA.

Inmedix will follow FDA guidance to develop the ANS Neuroscan as a tool for rheumatologists to more effectively understand why three out of four patients with RA fail to attain disease control despite over a dozen currently available biologic and non-biologic therapies. According to the Center for Disease Control and Prevention (CDC), the lifetime risk for developing RA is 3-4%. The disease affects nearly two million Americans, including children, at a tangible societal cost of \$19.3 billion per year (2005 dollars).<sup>3</sup> In the US, specialty pharmaceutical costs exceeded \$87 billion in 2014, with rheumatologists responsible for 25%, mostly for biologic treatment of RA.

### **About Inmedix, LLC**

Seattle-based biotech Inmedix is committed to engaging in world class research to discover innovative solutions for pressing healthcare needs related to the autonomic nervous system (ANS). Inmedix's ANS Neuroscan is the leading heart rate variability (HRV) application as an informative diagnostic tool in autoimmune disease, beginning with U.S. patients with rheumatoid arthritis (RA). The company's science and technology raises therapeutic outcomes and retention so that patients no longer need to cycle through failure of one biologic after another. Visit [www.inmedix.com](http://www.inmedix.com)

### **References**

1. Holman AJ, Ng E. Heart rate variability predicts anti-tumor necrosis factor therapy response for inflammatory arthritis. *Autonomic Neurosci Basic Clinical* 2008 Dec 5;143(1-2):58-67.
2. Holman AJ, Ng E. How substantive is Heart Rate Variability as a Predictor of Anti-TNF Treatment Outcome for Inflammatory Arthritis? *Arthritis Rheumatol* 2015;67(suppl 10)
3. Birnbaum H, Pike C, Kaufman R et al. Societal cost of rheumatoid arthritis patients in the US. *Curr Med Res Opin* 2010 Jan;26(1):77-90.

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