



Iron Horse Diagnostics

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Iron Horse Diagnostics, Inc. Announces License Agreement with Global IVD Powerhouse EUROIMMUN AG for First to Market ALS Diagnostic Test

Euroimmun granted license to launch first ALS Biologic Diagnostic Test in Europe

Scottsdale, AZ – Iron Horse Dx announced today that they have signed a non-exclusive license agreement with Euroimmun Medizinische Labordiagnostika AG (Lübeck, Germany) to launch the first biological diagnostic test for Amyotrophic Lateral Sclerosis (“ALS”), more commonly known as Lou Gehrig’s Disease.

ALS is a progressive neurological disease with an average life span of 3-5 years from diagnosis. Current clinical methods to diagnose ALS can take over 1 year leaving patients helpless to act during the early stages of the disease and limiting their ability to join clinical trials of newer disease modifying therapeutics in drug development.

The ALS Test is based on over 20 years of research by Dr. Robert Bowser, President of Iron Horse DX, and is shown to be 93% accurate (Positive Predictive Value = 0.939 and Negative Predictive Value = 0.917), providing a first biological based diagnostic test for ALS. According to Dr. Bowser, *“We have come a long way in researching and understanding the complexities of ALS over the past few years. The ALS Test will benefit patients by aiding physicians to make a more rapid and definitive diagnosis, allowing more efficient clinical trials in particular in early phases of ALS, thereby shorting the time to finding a cure.”*

Under the terms of the license agreement, Euroimmun AG, with over 2,100 employees worldwide and distribution into over 130 countries, will have the non-exclusive rights to launch the ALS diagnostic assays as a CE marked product, while Iron Horse is launching the assay in the U.S. as a laboratory-developed test in CLIA-certified laboratories. Iron Horse is working in close collaboration with the ALS Association (ALSA) and has received funding from the National Institutes of Health, Biogen and the State of Arizona.

According to Dr. Winfried Stöcker - President and Managing Director of Euroimmun, *“Euroimmun has extensive expertise in the fields of neuroimmunology. Together with Iron Horse Dx, we were able to develop this novel CE-marked assay for neurofilament heavy chain,*

complementing our portfolio of neurological diagnostics. With the launch next month, the test will be distributed worldwide to reach as many people as possible with this devastating disease.”

Iron Horse Dx was formed to create breakthrough diagnostic tests in neurologic disorders with high-unmet medical need. The company was founded in 2012 and has received funding from The National Institutes of Health, The ALS Association, The Arizona Commerce Authority and Biogen to finalize development and commercialize the ALS Test. The novel ALS assay has been validated in 2 CLIA labs and results published in numerous prestigious scientific publications. Iron Horse will release the ALS Test in the U.S. in 2016. Iron Horse’s neurologic diagnostic innovations also include a simple blood based TBI/concussion diagnostic test set for release in 2018 as well as biomarker assay services for some of the most innovative companies in the U.S.

EUROIMMUN AG produces test systems and automation solutions for medical laboratory diagnostics. The company was founded in September 1987, with its headquarters in Lübeck, Germany. The enterprise has 12 international subsidiaries, covering around 35 countries, and cooperates with more than 60 distributors. Overall, EUROIMMUN distributes its products in about 130 countries in Europe, America, Asia, Australia and Africa. The company’s development is shaped by continuous growth. The company offers jobs in more than 60 professions and vocational training in 11 different specific areas. EUROIMMUN has more than 2100 employees worldwide. The annual turnover of the group in 2015 amounted to over 205 million Euros. The company is ISO-certified (EN ISO 9001, EN ISO 13485/CMDCAS).

For further information concerning Iron Horse Dx and the novel products in its pipeline, please contact Dr. Robert Bowser, PhD at 602-810-0812, rbowser@ironhorsesdx.com or Michael Hull at (602) 617-7609, mhull@ironhorsesdx.com

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