TNI BioTech, Inc. through its wholly owned subsidiary TNI BioTech International Ltd., provides progress report on bridging trial for HIV/AIDS in Nigeria

ORLANDO, Fla. and DUBLIN, Dec. 4, 2014 /PRNewswire/

TNI BioTech, Inc., (OTC-TNIB) (the "Company"), a specialty pharmaceutical company involved in the manufacture, distribution and marketing of novel, immunotherapies to combat chronic, life-threatening diseases through the activation and modulation of the body's immune system, announced the finalization of logistics and patient recruitment for the initiation of the Company's 90-day bridging trial in Nigeria of Lodonal™ in patients with HIV/AIDS.

Noreen Griffin, the Company's CEO, said, "This approval is the most important step we have accomplished this year as it launches the last clinical bridging trial before potential market authorization in Nigeria. We believe Lodonal™ will offer meaningful clinical benefit for patients with HIV/AIDS where there continues to be serious unmet medical needs. We believe this is the first step in providing an affordable, easy to administer, immune therapy into emerging nations."

The Commissioner of Health and Permanent Secretary gave final patient approval from the Ministry of Health from Osun State Government for the 90-day trial. In coordination with the Nigerian National Agency for Food and Drug Administration and Control ("NAFDAC"), the Osun State Research and Ethics Committee ("OSHREC") will oversee all aspects of the 90-day trial. It is expected that quantitative data that includes CBC with differentials, CMP, CD4 and alpha-interferon and qualitative data that is based on the Company's developed questionnaire, will be collected on Day 1, Day 45 and Day 90 of the trial.

Dr. Gloria B. Herndon, a consultant for the Company and former director said, "Nigeria, as the leader in Africa, made this monumental step toward enhancing a health advantage for its country and the continent of Africa. Just as Nigeria took the leadership in Africa against Ebola, it is once again taking up the charge of supporting innovative immune therapy. At the brink of this 90-day trial, it is with great anticipation that some of our supporters such as US Doctors for Africa ('USDFA') and founder Ted M. Alemayhu, look forward to the results of this NAFDAC approval process so that more people affected by AIDS/HIV can be given another chance for higher quality life. Results of this 90-day trial will further support the resolution on Lodonal™ during the first ever Pan-African Health Summit, led by USDFA, in May 2014."

Dr. Richards Afonja, President & CEO of AHAR Pharma, who serves as Principal Investigator for the 90-day trial, has secured all funding and resources for the duration of the study. Chief Consultant on this trial, Dr. Abayomi Oni, will oversee all quantitative and qualitative data collection. Dr. Oni reports to the Directors of the OSHREC and subsequently NAFDAC.

Dr. Afonja said, "With the AIDS epidemic in Africa and other types of immune compromised states, affordable, available and effective treatment with Lodonal™ resulting in increased CD4 count, reducing opportunistic infections and the high mortality rate associated with these infections, the continent of Africa stands to gain tremendously as the population decimation by these infections is dangerous to Africa's health, economic and political development compared to other continents in the world."

On December 8-11, 2014, Dr. Afonja, will be speaking at the National Association of Resident Doctors meeting, where approximately 3,000 doctors, will hear about post training options, medical technologies and innovative treatments such as Lodonal™. The Company believes that this group hearing about the 90-day trial and the effectiveness of Lodonal™ will enable the wide-spread use of Lodonal™ in Nigeria.

In honor of her husband's memory Ms. Jackie Bihari stated earlier this week, "How appropriate that today, Monday, December 1st is World Aids Day and I cannot convey to all of you how thrilled and delighted I am that a clinical trial using Lodonal™ in combating the HIV virus will begin shortly in Nigeria. It was always Dr. Bihari's dream that one day these trials would begin and would lead to the logical conclusion that everyone would have access to this affordable drug. Thanks to all of your unending hard work and belief in Lodonal™, his wish has become a reality. Hopefully one day Lodonal™ will become available to everyone in developing countries; especially to the millions of people in Africa who have long been suffering with the HIV virus. I thank you from the bottom of my heart -- you are absolutely the best and I am honored to be part of your team. I am sending you my blessings and love and know that with all of your positive passion for Lodonal™, the trial will be a success. The saddest part of this day is that Dr. Bihari never had the privilege and honor to meet all of you ... you are all as the song title goes 'Simply the Best.'"

Dr. Bernard Bihari's research on 4.5mg Naltrexone, referred to as "Low Dose Naltrexone" and trademarked Lodonal™, began over 25 years ago on patients suffering from HIV/AIDS, various cancers, Multiple Sclerosis and numerous neurodegenerative diseases.

Cautionary Note Regarding Forward-Looking Statements

This document includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements about the plans, objectives, expectations and intentions of the Company and other statements that are not historical facts. These statements are based on the current expectations and beliefs of our management and are subject to uncertainty and changes in circumstances. We caution readers that any forward-looking information is not a guarantee of future performance and that actual results may vary materially from those expressed or implied by the statements herein due to changes in economic, business, competitive, technological, strategic and/or regulatory factors, as well as other factors affecting the operation of the businesses of the Company. More detailed information about these factors may be found in our filings with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K in the sections entitled "Cautionary Note Regarding Forward-Looking Statements" and "Risk Factors." Various other factors could cause actual results to differ from those set forth in the forward-looking statements. We are under no obligation to, and expressly disclaim any such obligation to, update or alter our forward-looking statements, whether as a result of new information, future events, or otherwise. The Company undertakes no obligation to publicly release any revisions to such forward-looking statements to reflect events or circumstances after the date hereof. For further information, please see http://www.tnibiotech.com.

Contact: Dennis S. Dobson, 203-258-0159

SOURCE TNI BioTech, Inc.