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# **Fortress Biotech Subsidiary, Altamira Bio, Acquires NIH License and CRADAs Relating to the Development of N-acetyl-D-mannosamine (ManNAc) for Rare Genetic Disorders**

## **ManNAc to be Studied as Potential Treatment of Hereditary Inclusion Body Myopathy (HIBM) and Various Nephropathies Associated With Hyposialylation**

NEW YORK, July 17, 2015 (GLOBE NEWSWIRE) -- Fortress Biotech, Inc. (NASDAQ:FBIO) announced that its subsidiary, Altamira Bio, acquired from New Zealand Pharmaceuticals Ltd (NZP), a license from the National Institutes of Health (NIH) and Cooperative Research and Development Agreements (CRADAs) for the development of oral N-acetyl-D-mannosamine (ManNAc), a key compound in the sialic biosynthetic pathway, for the treatment of hyposialylation disorders. Hyposialylation disorders are a group of pathologies associated with abnormal sialylation of tissues, characteristic of Hereditary Inclusion Body Myopathy (HIBM), also known as GNE myopathy – a rare genetic disorder which causes progressive muscle-wasting and weakness.

New Zealand Pharmaceuticals Ltd (NZP) manufactures ManNAc (DEX-M74) and will remain the exclusive global supplier of ManNAc to Altamira Bio.

"HIBM, a severe debilitating muscle-wasting disease with unmet medical need, has a clearly established genetic link," said Dr. Lindsay A. Rosenwald, Chairman, President and CEO of Fortress Biotech. "Thanks to the work conducted by NIH scientists to date, we have very compelling data on how ManNAc administration could supplement the genetic insufficiency to help these patients to normalize protein sialylation and retain their muscle strength. We are pleased to be working with NIH scientists in the NHGRI division who are leaders in this field in bringing this potential therapy to patients. We are also encouraged by recent discoveries on the possible involvement of hyposialylation in kidney diseases and testing ManNAc in patients with nephropathies for improving their kidney function."

### **About GNE Myopathy**

HIBM (GNE Myopathy) is a rare genetic disease inflicting approximately 2000 people

worldwide. Disease symptoms emerge in adulthood and slowly lead to progressive muscle weakness. Most patients develop symptoms in their early 20s and eventually require a wheelchair as their arm, hand and leg muscles weaken. The disease is caused by mutations in GNE gene, which codes for a rate-limiting enzyme in the sialic acid synthesis pathway. Dysfunction in GNE in HIBM leads to impaired sialylation of certain glycoproteins and glycolipids believed to be responsible for the gradual muscle deterioration.

### **About ManNAc**

N-acetyl-D-mannosamine (ManNAc) is an intermediate in sialic acid biosynthesis generated by functional GNE protein. Supplementation of ManNAc to the cells with dysfunctional GNE protein bypasses the need for GNE function and enables protein sialylation. ManNAc has been demonstrated in human studies to significantly increase circulating levels of sialic acid and is shown to treat disease in mouse models of both HIBM and kidney diseases. The FDA has provided orphan designation for ManNAc in HIBM. ManNAc is currently under investigation in an open label Phase I/II study for the treatment of the rare muscle-wasting disease Hereditary Inclusion Body Myopathy (HIBM), also known as GNE Myopathy. A protocol for a Phase I study to further investigate ManNAc safety and tolerability in various kidney diseases (nephropathies) associated with hyposialylation is under IRB review.

### **About Altamira Bio**

Altamira Bio is a development stage company focused on the clinical development and commercialization of N-acetyl-D-mannosamine (ManNAc) and other therapies for orphan/rare disorders.

### **About Fortress Biotech**

Fortress Biotech, Inc. ("Fortress" or "the Company") is a biopharmaceutical company dedicated to acquiring, developing and commercializing novel pharmaceutical and biotechnology products. Fortress plans to develop and commercialize products that it acquires both directly as well as indirectly by establishing subsidiary companies, also known as Fortress Companies. The Company intends to leverage its biopharmaceutical business expertise and drug development capabilities to help the Fortress Companies achieve their goals. Additionally, the Company intends to provide funding and management services to each of the Fortress Companies and from time to time the Company and the Fortress Companies will seek licensing, partnerships, joint ventures, and/or public and private financings to accelerate and provide additional funding to support their research and development programs. For more information, visit [www.fortressbiotech.com](http://www.fortressbiotech.com).

### **Forward-Looking Statements**

This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated are: risks related to our growth strategy; risks relating to the

results of research and development activities; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; uncertainties relating to preclinical and clinical testing; our dependence on third-party suppliers; our ability to attract, integrate, and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

CONTACT: Lucy Lu, MD, Executive Vice President &  
Chief Financial Officer  
Fortress Biotech, Inc.  
781-652-4525; [ir@fortressbiotech.com](mailto:ir@fortressbiotech.com)

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