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## iBio Selects Lead Candidate for its Fibrosis Therapeutics Program

NEW YORK, March 14, 2018 (GLOBE NEWSWIRE) -- iBio, Inc. (NYSE AMERICAN:IBIO) ("iBio") announced today that it had selected an E4-Fc fusion protein as its lead candidate for further development of a drug against fibrotic diseases, including systemic sclerosis and idiopathic pulmonary fibrosis.

After Dr. Carol Feghali-Bostwick and her collaborators discovered and patented certain peptides and proteins based on sequences from the C-terminus of endostatin, iBio acquired an exclusive license to the patents, developed a series of proprietary peptides and proteins based on sequences from the C-terminus of endostatin, and extended the patent portfolio to cover these additional inventions.

Dr. Feghali-Bostwick had demonstrated that a 48-amino acid peptide derived from endostatin named E4 can inhibit and reverse dermal fibrosis in an *ex vivo* human skin model as well as in both dermal and lung fibrosis mouse models *in vivo*. However, the E4 peptide had physical properties that made it undesirable for use as a drug without further modification. Therefore, iBio developed a portfolio (designated IBIO-CFB03) of distinct but related drug candidates that share a common mechanism of action with the E4 peptide, from which the E4 fusion protein has now been selected as the lead candidate for further development. The Fc fusion candidate, now being scaled up at iBio's CDMO facility in Bryan, Texas, has improved pharmaceutical and pharmacologic properties when compared with other variants.

iBio is now conducting extensive evaluation of its Fc fusion lead candidate in animals and *ex vivo* human tissue to confirm and extend the earlier findings from multiple prior experiments. An unusual finding is that the E4-Fc fusion protein is efficacious in relieving (the standard bleomycin-induced) pulmonary fibrosis in rodent models when administered via either intravenous or oral routes.

Current tests are designed to determine minimal effective dosing by both oral and injection routes based upon prior data and to compare efficacy with FDA-approved fibrosis drugs. Data including body weight, lung weight, quantitative lung histopathology, and broncho – alveolar lavage collection and typing of inflammatory cells from lungs, will be used to support an application for human safety testing. Exploratory biomarker studies are also being conducted on harvested biofluids.

Upon completion of these studies, iBio will schedule manufacturing of cGMP compliant material at its Texas CDMO facility to support an IND filing and a human Phase 1 clinical trial. iBio plans to focus clinical research first on systemic sclerosis, for which iBio has U.S. Orphan Drug Designation, followed later by additional fibrotic disease indications as data

indicate. These may include pulmonary fibrosis, liver fibrosis, corneal fibrosis, and Chagas disease-induced cardiac fibrosis.

### **About Fibrotic Diseases**

Fibrotic diseases are characterized by the pathological accumulation of extracellular matrix proteins resulting in scarring or thickening of the affected tissue or organ(s). Fibrotic disease can occur in many organs including the lungs, kidneys, liver, skin, gastrointestinal tract, eyes, and heart, causing significant morbidity including organ failure, and death.

The underlying mechanisms of fibrosis appear to be similar in unrelated tissues and organs. Thus, some drug development programs may rationally be focused on a mechanism of action common to multiple types of fibrosis, or more narrowly on formulations and doses intended for organ-specific use.

Worldwide incidence and prevalence of most fibrotic diseases are difficult to estimate because there are few reliable registries of these diseases. Epidemiologists estimate the number of patients having systemic sclerosis (a form of fibrotic disease that affects multiple organs) to be approximately 250,000, and the prevalence of idiopathic pulmonary fibrosis in the U.S. and Europe to be approximately 200,000 patients. However, the number of persons affected by all forms of pulmonary fibrosis alone may be in the millions, and between two and three percent of the general population over the age of 40 worldwide are believed to suffer from fibrosis of the liver. Fibrotic diseases collectively are a major cause of death (40% of deaths world-wide are attributed at least in part to fibrotic complications), and treatment options are severely limited.

### **About iBio, Inc.**

iBio, a leader in developing plant-manufactured biopharmaceuticals, provides a range of product and process development, analytical, and manufacturing services at the large-scale development and manufacturing facility of its subsidiary iBio CDMO, LLC in Bryan, Texas. The facility houses laboratory and pilot-scale operations, as well as large-scale automated hydroponic systems capable of growing over four million plants as "in process inventory" and delivering over 300 kilograms of therapeutic protein pharmaceutical active ingredient per year.

iBio applies its technology for the benefit of its clients and the advancement of its own product interests. The Company's pipeline is comprised of proprietary candidates for the treatment of a range of fibrotic diseases including idiopathic pulmonary fibrosis, systemic sclerosis, and scleroderma. IBIO-CFB03, based on the Company's proprietary gene expression technology, is the Company's lead therapeutic candidate being advanced for IND development.

Further information is available at: [www.ibioinc.com](http://www.ibioinc.com)

### **Cautionary Statement Regarding Forward Looking Statements**

This release may contain "forward-looking statements" that are within the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by certain words or phrases such as "may", "will", "aim", "will likely

result", "believe", "expect", "will continue", "anticipate", "estimate", "intend", "plan", "contemplate", "seek to", "future", "objective", "goal", "project", "should", "will pursue" and similar expressions or variations of such expressions. These forward-looking statements reflect the Company's current expectations about its future plans and performance. These forward-looking statements rely on a number of assumptions and estimates which could be inaccurate and which are subject to risks and uncertainties. Actual results could vary materially from those anticipated or expressed in any forward-looking statement made by the Company. Please refer to the preliminary prospectus supplement, the accompanying prospectus, and the Company's most recent Forms 10-Q and 10-K and subsequent filings with the SEC for a further discussion of these risks and uncertainties. The Company disclaims any obligation or intent to update the forward-looking statements in order to reflect events or circumstances after the date of this release.

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