



XBiotech Announces Successful Completion of GMP Audit

December 3, 2018

First Audit in Company's New Manufacturing Facility Shows Compliance with GMP Guidelines

AUSTIN, Texas, Dec. 03, 2018 (GLOBE NEWSWIRE) -- XBiotech Inc. (NASDAQ:XBIT) today announced a successful GMP (Good Manufacturing Practices) audit by Eurofins Amatsigroup. The audit was conducted in connection with XBiotech's distribution in Europe of its US-manufactured biological drug product. XBiotech manufactures bermekimab at its campus facility in Austin, Texas and regularly ships the drug to clinics in various countries in the European Union and the United Kingdom. Drugs manufactured outside of Europe may only be distributed in Europe through a qualified organization that can assure quality of drug product and manufacturing practices. The Company recently retired its old operations, which included a GMP manufacturing facility, consolidating its programs in a state-of-the-art manufacturing and R&D center on its campus in Austin. This is the first audit of the new facility.



Image of XBiotech headquarters which incorporates state-of-the-art manufacturing operations, R&D laboratories and administrative space.



XBiotech upstream manufacturing technology.



Disposable process reducing complexity.

Norma Gonzalez, XBiotech's Vice President of Quality, commented, "We are revolutionizing the manufacturing of biological drugs in many ways, including in terms of robustness and ease of GMP compliance. We were pleased to be able to once again demonstrate this in the audit process."

XBiotech recently consolidated operations at its new headquarter facility in Austin, Texas. Operations are now exclusively housed in one complex that includes a custom-built state-of-the-art manufacturing operation, R&D laboratories and administrative space. XBiotech's facilities are located on a 48 acre estate located only minutes from Austin's city center. XBiotech developed manufacturing technology using bioreactors designed and built by the Company, employing its technology to dramatically reduced capital costs, plant and equipment operating complexity, and improve production flexibility compared to existing manufacturing commonly used to produce marketed biologics. XBiotech currently produces all of its clinical drug material and plans to manufacture commercial drug product from its Austin headquarters.

About True Human™ Therapeutic Antibodies

XBiotech's True Human™ antibodies are derived without modification from individuals who possess natural immunity to certain diseases. With discovery and clinical programs across multiple disease areas, XBiotech's True Human antibodies have the potential to harness the body's natural immunity to fight disease with increased safety, efficacy and tolerability.

About XBiotech

XBiotech is a fully integrated global biosciences company dedicated to pioneering the discovery, development and commercialization of therapeutic antibodies based on its True Human™ proprietary technology. XBiotech currently is advancing a robust pipeline of antibody therapies to redefine the standards of care in oncology, inflammatory conditions and infectious diseases. Headquartered in Austin, Texas, XBiotech also is leading the development of innovative biotech manufacturing technologies designed to more rapidly, cost-effectively and flexibly produce new therapies urgently needed by patients worldwide. For more information, visit www.xbiotech.com.

Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements, including declarations regarding management's beliefs and expectations that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "would," "could," "expects," "plans," "contemplate," "anticipates," "believes," "estimates," "predicts," "projects," "intend" or "continue" or the negative of such terms or other comparable terminology, although not all forward-looking statements contain these identifying words. Forward-looking statements are subject to inherent risks and uncertainties in predicting future results and conditions that could cause the actual results to differ materially from those projected in these forward-looking statements. These risks and uncertainties are subject to the disclosures set forth in the "Risk Factors" section of certain of our SEC filings. Forward-looking statements are not guarantees of future performance, and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate, may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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Photos accompanying this announcement are available at

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