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Apricus Biosciences and Elis Pharma Sign License Agreement for Vitaros(R) in the Gulf and Part of the Middle East

[Press Release](#)

SAN DIEGO and DUBAI, United Arab Emirates, Jan. 4, 2011 (GLOBE NEWSWIRE) -- Apricus Biosciences, Inc. ("Apricus Bio") (Nasdaq:APRI - News) and Elis Pharmaceuticals ("Elis"), announced today that the two companies have entered into a licensing agreement granting Elis the exclusive rights to market Apricus Bio's new drug for erectile dysfunction, Vitaros(R), in the Gulf and part of the Middle East. "This new agreement is the next step in our strategy of seeking to partner Vitaros in more than 100 countries around the world," said Dr. Bassam Damaj, President and Chief Executive Officer of Apricus Bio.

The agreement with Elis follows the December 22 announcement of a similar agreement granting Bracco SpA ("Bracco") the exclusive rights to market Vitaros in Italy.(http://www.apricusbio.com/press_12222010.html)

The drug was approved by Health Canada in November as the first topical treatment for erectile dysfunction ("ED") for marketing in Canada. This validation will also make it possible to register the drug in other countries that recognize Canadian approval. The application for approval to market Vitaros in the territory licensed to Elis is scheduled to be filed in the first half of 2011.

Under the terms of the agreement, Elis has exclusive rights in The Gulf Countries and part of the Middle East (including, Lebanon, Syria, Jordan, Iraq and Yemen) to commercialize and market Vitaros. Apricus Bio is entitled to receive up to \$2.1 million in payments for signing, regulatory and sales milestones. Further, Apricus Bio will receive tiered double digit royalties based on Elis's sales of the product. "We are delighted to reach another major milestone in the history of this product," said Dr. Damaj. "This is another partnership in a series of commercialization agreements which we plan to execute for Vitaros. With their proven success in building new markets, Elis is a great partner for launching this product in The Gulf Countries and part of the Middle East."

"This exciting collaboration allows Elis to expand into a complementary therapeutic area utilizing its proven sales and marketing expertise," said Rashed Assouma, Chief Executive Officer of Elis. "We believe that Vitaros has the potential to be an important new therapy for ED in our region."

-Ends-

About the ED Market

According to IMS data, the ED market in The Gulf Countries and part of the Middle East in 2010 (MAT Q3) was estimated to be \$103 million (data include Jordan, Kuwait, Lebanon, Saudi Arabia, UAE only, since data are not available for some markets). Despite the availability of today's oral and other therapies, there is still a need for new, safe and effective treatments, especially for those patients who cannot or do not respond well to oral medication.

Vitaros offers potential advantages compared to oral PDE5 drugs like Viagra(R), Cialis(R) and Levitra(R). It is applied directly to the penis as a cream, instead of as a pill that is absorbed systemically. The topical application helps to minimize side effects and enables men who cannot take, or do not do well with the existing drugs, to have a patient-friendly alternative.

In addition, Vitaros causes erections to occur in a more localized fashion and more quickly when compared to oral treatments. Vitaros contains a previously marketed ED drug, known by the chemical name of alprostadil, which directly boosts blood flow, thereby causing an erection.

Alprostadil is currently marketed as an injectable drug or as a pellet inserted into the urethra. Apricus Bio incorporated alprostadil with its NexACT(R) delivery technology, resulting in a rapid and efficient topical delivery of the drug into the penis

and providing a more patient-friendly alternative. In clinical studies, Vitaros worked in patients suffering from mild to severe ED, including men who did not respond to Viagra.

Viagra is a registered trademark of Pfizer, Inc.; Cialis is a registered trademark of Lilly, USA; Levitra, is a registered trademark of Bayer A.G.; Vitaros is a registered trademark of Apricus Bio.

About Apricus Biosciences

Backed by NexMed, USA and Bio-Quant, Inc., its revenue generating CRO business, Apricus Bio has leveraged the flexibility of its proven NexACT drug delivery technology to enable multi-route administration of new and improved compounds across numerous therapeutic classes. Future growth is expected to be driven primarily through out-licensing of this technology for the development and commercialization of such compounds to pharmaceutical and biotechnology companies, worldwide. Concurrently, the Company is seeking to monetize its existing product pipeline, including its approved drug erectile dysfunction treatment, Vitaros, as well as compounds in development from pre-clinical through Phase 3, currently focused on dermatology, sexual dysfunction and cancer. For further information on Apricus Bio and its subsidiaries, visit <http://www.apricusbio.com>.

About Elis Pharmaceuticals Limited

Established in the UAE, Elis Pharmaceuticals is one of the region's leading companies dedicated to developing, manufacturing and marketing prescription and generic, pharmaceuticals. The Company markets and distributes products in three main categories: prescription medications, OTC and generics. With over 1000 pharmaceutical products in its portfolio, Elis Pharma is uniquely poised to maximize the market potential of emerging products and is the likely choice for commercializing and marketing any new pharmaceutical products in its territory. The company serves drug wholesalers, distributors of pharmaceuticals, ministries and departments of health; public, private, industry and military hospitals, clinics and healthcare systems and affiliated organizations worldwide. For further information on Elis Pharma and its subsidiaries, visit <http://www.elispharmaceuticals.com>.

Apricus Bio's Forward-Looking Statement Safe Harbor

Statements under the Private Securities Litigation Reform Act: with the exception of the historical information contained in this release, the matters described herein contain forward-looking statements that involve risks and uncertainties that may individually or mutually impact the matters herein described for a variety of reasons that are outside the control of the Company, including, but not limited to, timing for seeking foreign approvals for Vitaros, timing and success of the commercial launch of Vitaros in The Gulf Countries and part of the Middle East, the ability to receive the potential milestone payments under the license agreement and the ability to execute additional commercialization agreements for other territories. Readers are cautioned not to place undue reliance on these forward-looking statements as actual results could differ materially from the forward-looking statements contained herein. Readers are urged to read the risk factors set forth in the Company's most recent annual report on Form 10-K and subsequent quarterly reports filed on Form 10-Q. Copies of these reports are available from the SEC's website or without charge from the Company.

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