

Forendo Pharma announces the US licensing of fispemifene to Apricus Biosciences targeting urological conditions in men

STOCKHOLM, October 20, 2014. Forendo Pharma Oy, a Karolinska Development AB portfolio company, announced today that it has entered into a definitive agreement to out-license the US development and commercialization rights for fispemifene to Apricus Biosciences Inc. Forendo is entitled to success driven milestone payments totaling up to of \$305 million plus sales royalties. Karolinska Development has an ownership of 21 percent in Forendo Pharma.

Under the terms of the agreement, Apricus will make a \$5 million upfront cash payment to Forendo, and will transfer approximately 3.6 million Apricus common shares, representing \$7.5 million in value based on the 360-day average market price of the Apricus stock. The agreement includes additional potential clinical and regulatory milestones payments to Forendo for up to \$45 million, including FDA approval, as well as commercial milestone payments totaling up to \$260 million based on achieving specified annual net sales of fispemifene levels up to \$1 billion in the US. Apricus will also pay tiered double-digit royalties based on net sales once the product is commercialized. Apricus will be responsible for the clinical development and costs of the program, as well as all future commercialization in the US. Apricus anticipates to commence a Phase IIb clinical trial during the first half of 2015 to confirm the optimal fispemifene doses to treat men with secondary hypogonadism, and provide proof-of-concept data to evaluate the anti-estrogenic and anti-inflammatory effects on the lower urinary tract and prostate in aging men.

Fispemifene is an oral once-daily, novel tissue-specific selective estrogen receptor modulator (“SERM”) with a unique profile to treat both secondary hypogonadism, chronic prostatitis and lower urinary tract symptoms affecting in men. Fispemifene acts as an antiestrogen at the level of the hypothalamic pituitary axis, inhibiting the negative feedback of estrogen. Two successful US-based Phase II trials have demonstrated clinical proof-of-concept for the treatment of male secondary hypogonadism, without exhibiting the negative effects on prostate health associated with testosterone replacement therapies.

“Having previously developed and partnered two SERMS that are approved and marketed in the US, we are excited to work with the Apricus team, which has a demonstrated track record of innovation within men’s health and a strategy committed to addressing the unmet needs of these patients. Fispemifene, a unique SERM targeted for use in men, will offer both patients and physicians a differentiated alternative for treating urological conditions in ageing men”, said Risto Lammintausta, CEO, Forendo Pharma.

“The in-licensing of fispemifene in the United States is a transformative event for Apricus, signifying the achievement of a key corporate objective to build upon our current development pipeline with a complementary, mid-staged clinical program”, stated Richard Pascoe, CEO, Apricus Biosciences.

“The agreement combines Forendo’s established leadership in SERM drug discovery with Apricus’ expertise in men’s health, and further underpins the potential for fispemifene to improve quality-of-life for the millions of men affected with hypogonadism and other male urological conditions” said Bruno Lucidi, CEO, Karolinska Development.

Conference Call Details

Apricus will host a live conference call and webcast today at 8 a.m. Eastern Time to discuss the in-license agreement and related matters. The live audio webcast and associated slide presentation can be accessed via the Investor section of the Company's website at www.apricusbio.com and a replay will also be available in the website.

Note: Karolinska Development's ownership of 21% includes indirect ownership through KCIF Co-Investment Fund KB.

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TO THE EDITORS

About Forendo Pharma Oy

Forendo Pharma is a drug development company based in Turku, Finland. Its core competence resides in organ specific hormone mechanisms, giving new opportunities to unmet needs in women's and men's health. The company's key assets are fispemifene, a program with positive Phase II data aimed at treatment of low testosterone levels, and 17 β -HSD1 enzyme inhibitors, aimed at treatment of endometriosis and based on research at the University of Turku. The founding team includes leading academic professionals in endocrinology and pioneers within Finnish drug development. For more information, please visit www.forendo.com

About Fispemifene

Fispemifene is a once daily orally administered selective estrogen receptor modulator (SERM). A Phase 2b clinical trial is expected to commence during the first half of 2015 to confirm the optimal fispemifene doses to treat men with secondary hypogonadism, and provide proof-of-concept data to evaluate the anti-estrogenic and anti-inflammatory effects of reducing prostate volume and improving urodynamics. Fispemifene acts in secondary hypogonadism by inhibiting the negative feedback of testosterone production via an estrogen-blocking effect at the level of the pituitary, resulting in increased testosterone production in the testes, which in turn restores circulating testosterone levels to within, but not beyond, the normal range. In line with fispemifene's mechanism of action, the treatment has been shown in Phase 2a studies involving a total of 149 hypogonadal men to normalize testosterone levels while retaining and, in some men, restoring testicular function, a feature of importance for infertile younger men with hypogonadal symptoms. Additionally, in line with fispemifene's anti-estrogenic action on the lower urinary tract (LUT), no negative effects on prostate volume, prostate specific antigen (PSA), or urodynamic obstructive symptoms were observed. Expanding on these observations seen in three-month clinical studies in hypogonadal men, preclinical studies involving fispemifene have shown the potential beneficial anti-estrogenic effects of fispemifene of reducing prostate volume and inflammation and improving urodynamics, opening up additional potential indications for this SERM in men with obstructive LUT conditions and chronic prostatitis.

About Apricus Biosciences, Inc.

Apricus Biosciences, Inc. (APRI) is a biopharmaceutical company advancing innovative medicines to meet the needs of patients. The Company's lead product, Vitaros[®], for the treatment of erectile dysfunction, is approved in Europe and Canada and commercialized in several countries in Europe. Apricus' marketing partners for Vitaros[®] include Abbott Laboratories Limited, Takeda Pharmaceuticals International GmbH, Hexal AG (Sandoz), Recordati Ireland Ltd. (Recordati S.p.A.), Bracco S.p.A. and Laboratoires Majorelle. The Company's second-generation Vitaros room temperature device is under development and is expected to enhance the product's commercial value. The Company recently initiated a Phase 2a trial for RayVa[™], the Company's product candidate for the treatment of Raynaud's phenomenon. Femprox[®], the Company's product candidate for the treatment of female sexual interest/arousal disorder, has successfully completed an approximately 400-subject proof-of-concept study. The Company is currently seeking a strategic partner for Femprox. In October 2014, Apricus gained U.S. development and commercialization rights for fispemifene, a selective estrogen receptor modulator, in Phase 2 development.

For further information on Apricus, visit <http://www.apricusbio.com>.

About Karolinska Development AB

Karolinska Development aims to create value for patients, researchers, investors and society by developing innovations from world class science into differentiated products that can be partnered. The business model is to: SELECT the most commercially attractive medical innovations that can potentially satisfy unmet medical needs; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading universities, delivers a continuous flow of innovations. Today, the portfolio consists of 33 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

Karolinska Development is listed on NASDAQ OMX (KDEV). Karolinska Development may be required to disclose the information provided herein pursuant to the Securities Markets Act.