



## FOR IMMEDIATE RELEASE

# AMAG AND ENDOCEUTICS ENTER INTO AN EXCLUSIVE U.S. LICENSE AGREEMENT FOR INTRAROSA™ (PRASTERONE)

Recently approved first-of-its-kind, non-estrogen prescription therapy for a common symptom of menopause

Conference call scheduled for 8 a.m. ET today

WALTHAM, Mass. and Quebec, Canada (February 14, 2017) - AMAG Pharmaceuticals, Inc. (Nasdaq: AMAG) and Endoceutics, Inc. today announced that they have entered into an exclusive license agreement that provides AMAG with U.S. commercial rights to Intrarosa<sup>TM</sup> (prasterone). Intrarosa is the only FDA-approved, locally administered, daily, non-estrogen product for the treatment of moderate-to-severe dyspareunia (pain during intercourse), a common symptom of vulvar and vaginal atrophy (VVA), due to menopause. Unlike conventional pharmacological estrogen-containing medications, Intrarosa does not carry a boxed safety warning in its label.

"AMAG is pleased to add another product to its expanding women's health portfolio and to work with Endoceutics founder Dr. Fernand Labrie, a world-renowned endocrinologist who led the development of this innovative treatment approach," said William Heiden, chief executive officer of AMAG. "Intrarosa will address a compelling unmet medical need for post-menopausal women suffering today from moderate-to-severe dyspareunia who are interested in alternatives to their current treatment or most of whom choose to go untreated due to safety concerns about conventional synthetic estrogen-containing therapies. We look forward to introducing this new, differentiated therapy to women and their healthcare providers."

The transaction represents a further expansion into women's health and is an important step in continuing to execute AMAG's growth strategy. Earlier this month, AMAG announced the closing of a license agreement with Palatin Technologies, Inc., for the exclusive North American rights to develop and commercialize Rekynda<sup>TM</sup> (bremelanotide), a potential novel treatment for hypoactive sexual desire disorder, the most common form of female sexual dysfunction (FSD). The addition of these two products will allow AMAG to address key needs across the continuum of women's healthcare, with three potential new product launches over the next

two years, starting with Intrarosa in 2017, followed by the Makena subcutaneous auto-injector and Rekynda, if approved.

Intrarosa enters an existing billion dollar-plus market for intravaginal prescription therapies that treat VVA symptoms. There are an estimated 64 million post-menopausal women in the U.S., and as many as 32 million women suffer from VVA symptoms. Studies suggest that between 44 percent and 78 percent of women with VVA suffer from dyspareunia. According to patient survey data, more than half of women who report symptoms of dyspareunia are not currently being treated with a prescription therapy or seeking treatment.

Intrarosa contains prasterone, a precursor of hormones that is converted locally inside the vaginal cells into androgens and estrogens with no meaningful increases detected in the blood. Intrarosa does not carry the boxed warnings currently included in the labels of conventional estrogen-containing medications which highlight the increased risk of certain types of cancers, such as endometrial cancer, as well as cardiovascular disorders and probable dementia. While Intrarosa is currently approved for the treatment of moderate-to-severe dyspareunia, Endoceutics and AMAG have agreed to co-develop the product as a potential treatment for FSD in post-menopausal women.

"As a non-estrogen containing treatment, Intrarosa is a novel vaginal prescription therapy that provides an important alternative for patients with moderate-to-severe dyspareunia, a common symptom of post-menopausal VVA," said Dr. Fernand Labrie, founder and chief executive officer of Endoceutics. "Intrarosa stimulates the body's natural ability to produce hormones locally and thus significantly reduces pain during intercourse. Because Intrarosa does not contain estrogen, patients may feel more comfortable seeking treatment than with synthetic traditional estrogen-containing hormone therapies."

"Endoceutics is committed to ensuring that Intrarosa becomes the standard of care for the treatment of VVA. In addition to AMAG's investments in the success of Intrarosa, Endoceutics plans to put an additional \$20 million toward supporting educational programs in 2017," Dr. Labrie continued.

AMAG will be expanding its women's health sales force beyond the current 100-person Makena- and CBR-focused team with approximately 150 additional sales representatives dedicated to the commercialization of Intrarosa. This expanded sales force will allow AMAG to call on a larger number of OB/GYNs, as well as provide AMAG with future sales force deployment flexibility in women's health, such as the potential launch of Rekynda in early 2019. AMAG expects to launch Intrarosa in the U.S. in mid-2017.

"Three Orange Book-listed patents with terms out to 2031, a sizeable untapped market and overlap with our current physician call points make Intrarosa an excellent strategic opportunity for AMAG that will help drive growth and sustained shareholder value," said Frank Thomas, president and chief operating officer of AMAG. "The additions of FDA-approved Intrarosa and recently licensed Rekynda will meaningfully add to our expanding women's health portfolio.

AMAG's strong cash position, combined with the cash-generating potential of our current businesses, puts us in an excellent position to continue to pursue additional acquisition and licensing opportunities."

## **Transaction Details**

Under the terms of the license agreement, AMAG will receive the right to commercialize and develop Intrarosa in the U.S. for the treatment of VVA and FSD. At closing, AMAG will pay Endoceutics \$50 million of total upfront consideration and issue Endoceutics 600,000 unregistered shares of AMAG common stock. In addition, AMAG will pay Endoceutics up to \$10 million upon delivery of adequate launch quantities of Intrarosa and \$10 million upon the first anniversary of the effective date of the agreement. Endoceutics will be entitled to certain sales milestone payments, including a first sales milestone payment of \$15 million, which would be triggered when Intrarosa annual net U.S. sales exceed \$150 million, and a second milestone payment of \$30 million, which would be triggered when annual net U.S. sales exceed \$300 million. Should annual net U.S. sales exceed \$500 million, there are additional sales milestone payments of up to \$850 million, which would be triggered at various sales thresholds. AMAG will also pay Endoceutics tiered royalties as a percent of Intrarosa net sales ranging from the mid-teens (for calendar year net sales up to \$150 million) to the mid-twenties (for any calendar year net sales that exceed \$1 billion). At closing, AMAG and Endoceutics will also enter into a supply agreement, under which Endoceutics will supply Intrarosa to AMAG.

AMAG has also committed to co-fund a Phase 3 clinical program, which would be conducted by Endoceutics to support regulatory approval of Intrarosa for the treatment of certain types of FSD in post-menopausal women. The direct costs of the potential FSD label expansion study will be shared equally by the parties and capped at up to \$20 million for AMAG. The transaction does not include the transfer of any Endoceutics employees or facilities.

The license transaction is expected to close in the first half of 2017 and is subject to customary closing conditions, including U.S. antitrust approval.

# **Advisors**

EVOLUTION Life Science Partners LLC, a division of Gordian Investments, LLC acted as advisor to Endoceutics. Goodwin Procter LLP served as AMAG's legal advisor on the transaction and Cooley LLP served as legal advisor to Endoceutics.

## **Conference Call and Webcast Access**

AMAG Pharmaceuticals, Inc. will host a conference call and webcast today at 8:00 a.m. ET to discuss the Intrarosa license agreement, as well as the company's 2016 financial results announced today in a separate news release.

## **Dial-in Number**

U.S./Canada Dial-in Number: (877) 412-6083 International Dial-in Number: (702) 495-1202

Conference ID: 65936323

Replay Dial-in Number: (855) 859-2056

Replay International Dial-in Number: (404) 537-3406

Conference ID: 65936323

A telephone replay will be available from approximately 11:00 a.m. ET on February 14, 2017 through midnight on February 21, 2017.

The webcast with slides will be accessible through the Investors section of AMAG's website at www.amagpharma.com. A replay of the webcast will be archived on the website for 30 days.

# About Intrarosa<sup>™</sup> (Prasterone)

Intrarosa is the only FDA-approved, locally administered, daily non-estrogen steroid for the treatment of moderate-to-severe dyspareunia (pain during intercourse), a symptom of vulvar and vaginal atrophy (VVA), due to menopause. Intrarosa contains prasterone, also known as dehydroepiandrosterone (DHEA). Prasterone is an inactive endogenous steroid, which is converted locally into androgens and estrogens to help restore the vaginal tissue as indicated by improvements in the percentage of superficial cells, parabasal cells, and pH. The mechanism of action is not fully established.

In two primary 12-week placebo-controlled efficacy trials, women taking Intrarosa experienced a significant reduction in dyspareunia, as well as significant improvements in the percentage of vaginal superficial cells and parabasal cells, as well as vaginal pH. In clinical trials, the most common adverse reactions were vaginal discharge and abnormal pap smear. Intrarosa has not been studied in women with a history of breast cancer.

## **About AMAG**

AMAG is a biopharmaceutical company focused on developing and delivering important therapeutics, conducting clinical research in areas of unmet need and creating education and support programs for the patients and families we serve. Our currently marketed products support the health of patients in the areas of women's health, anemia management and cancer supportive care. Through CBR®, we also help families to preserve newborn stem cells, which are used today in transplant medicine for certain cancers and blood, immune and metabolic disorders, and have the potential to play a valuable role in the ongoing development of regenerative medicine. For additional company information, please visit <a href="https://www.amagpharma.com">www.amagpharma.com</a>.

# **About Endoceutics**

Endoceutics is a private pharmaceutical company operating in the field of women's health and hormone-sensitive cancer prevention and treatment. Endoceutics research focuses on developing non estrogen-based therapies for vulvar and vaginal atrophy, sexual dysfunction and the other symptoms of menopause, including hot flashes, osteoporosis, muscle loss and type 2 diabetes. Hormonal therapies for breast, uterine and prostate cancer, male hypogonadism as well as endometriosis are also under development.

Endoceutics has five Phase 3 product candidates addressing large market opportunities and two Phase 1/2 product candidates. Endoceutics has exclusive worldwide rights to patents, patent applications, technology and know-how related to all its products.

# **Forward-Looking Statements**

This press release contains forward-looking information about AMAG Pharmaceuticals, Inc. within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein which do not describe historical facts, including, among others, statements regarding AMAG's anticipated further expansion in and commitment to women's health through the licensing transaction with Endoceutics, Inc., including beliefs that AMAG will serve key needs across the continuum of women's healthcare; the ability of Intrarosa to treat moderate-to-severe dyspareunia; beliefs as to the timing of the commercial launch of Intrarosa, the Makena subcutaneous auto-injector and Rekynda; beliefs regarding Intrarosa's potential benefits and market opportunity; whether patients may feel more comfortable seeking treatment with Intrarosa than with traditional estrogen-containing hormone therapies; AMAG's commercialization launch strategy of Intrarosa, including its plans to invest significantly and expand its existing sales force; the ability of patents covering Intrarosa and AMAG's current physician call points to make Intrarosa a growth opportunity that drives shareholder value; expected investments by Endoceutics in education programs in 2017; the ability to execute future acquisition and licensing opportunities; anticipated clinical development plans and costs for Intrarosa to support regulatory approval of FSD; expected timing for the closing of the transaction; the timing and amounts of future milestone payments; expected investment amounts by AMAG in the potential FSD label expansion and beliefs that newborn stem cells have the potential to play a valuable role in the development of regenerative medicine are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, among others, (1) the possibility that the closing conditions set forth in the License Agreement, including, those related to antitrust clearance, will not be met and that the parties will be unable to consummate the proposed transactions; (2) the possibility that AMAG will not realize the expected benefits of the transaction, including the anticipated market opportunity and the ability of its current or expanded sales force to successfully commercialize Intrarosa; (3) the possibility that significant safety or drug interaction problems could arise with respect to Intrarosa; (4) the ability of AMAG to drive awareness of dyspareunia and the potential benefits of Intrarosa; (5) uncertainties regarding the manufacture of Intrarosa; (6) uncertainties relating to patents and proprietary rights associated with Intrarosa in the United States; (7) that the cost of the transaction to AMAG will be more than planned and/or will not provide the intended positive financial results; (8) that AMAG or Endoceutics will fail to fully perform their respective obligations under the License Agreement or the Supply Agreement; (9) uncertainty regarding AMAG's ability to compete in the dyspareunia market in the United States; and (10) other risks identified in AMAG's Securities and Exchange Commission ("SEC") filings, including its Annual Report on Form 10-K

for the year ended December 31, 2015, its Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016 and subsequent filings with the SEC, including its Current Reports on Form 8-K filed with the SEC on January 9, 2017 and February 3, 2017, as well as in its upcoming Annual Report on Form 10-K for the year ended December 31, 2016. AMAG cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made.

# **CONTACT:**

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<sup>1</sup> Wysocki et al. Management of Vaginal Atrophy: Implications from the REVIVE Survey. *Clinical Medicine Insights: Reproductive Health* 2014:8 23–30.

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> F. Palma et al: Vaginal atrophy of women in postmenopause. Results from a multicentric observational study: The AGATA study.

<sup>&</sup>lt;sup>4</sup> Multiple publications based on patient surveys.