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Sandoz builds oral contraceptive portfolio with the launch of Loryna®, a generic version of YAZ®

Princeton, New Jersey; May 4, 2011 – Sandoz today announced the US Food and Drug Administration (FDA) approval and US launch of its new oral contraceptive brand Loryna® (drospirenone 3 mg/ethinyl estradiol 0.02 mg tablets), a generic equivalent of YAZ®.

Sandoz is the second company to launch a generic version of YAZ®, which is indicated for the prevention of pregnancy as well as for the treatment of moderate acne in women at least 14 years of age only if the patient desires an oral contraceptive for birth control.

“Oral contraceptives are a natural extension of our comprehensive product line,” said Don DeGolyer, President of Sandoz Inc. “Sandoz is committed to serving the needs of women in the US, including through the launch of these products, which offer cost-saving options for fertility control.”

Among women in the US who practice contraception (approximately 62% of women aged 15 to 44), twenty eight percent choose oral contraceptives, which are the most commonly used form of contraception.¹

According to IMS Health, US sales for branded and generic versions of YAZ® were approximately USD 578 million for the 12 months ending in February 2011. Sandoz is marketing Loryna in a dosage regimen consisting of 24 active film-coated tablets, each containing 3 mg of drospirenone and 0.02 mg of ethinyl estradiol, and four inert (without hormones) film-coated tablets. This dosage regimen is identical to that of YAZ®.

In 2011, Sandoz added three generic oral contraceptives to its product portfolio. Sandoz established its oral contraceptive portfolio with the recent launches of Altavera and Introvale in the US, and expects to further expand this portfolio with the launch of additional key US products.

US Loryna Indications and Safety Information

Loryna (drospirenone and ethinyl estradiol tablets) is indicated for the prevention of pregnancy as well as for the treatment of moderate acne in women at least 14 years of age only if the patient desires an oral contraceptive for birth control.

¹ Mosher WD and Jones J, Use of contraception in the United States: 1982–2008, Vital and Health Statistics, 2010, Series 23, No. 29.

Cigarette smoking increases the risk of serious cardiovascular events from combination oral contraceptives (COC) use. This risk increases with age, particularly in women over 35 years of age, and with the number of cigarettes smoked. For this reason, COCs should not be used by women who are over 35 years of age and smoke.

Loryna is a birth control pill. It contains two female hormones, a synthetic estrogen called ethinyl estradiol and a progestin called drospirenone. Loryna tablets are contraindicated for women who are known to have renal impairment, adrenal insufficiency, a high risk of arterial or venous thrombotic diseases – the risk of blood clots is highest during the first year of use, undiagnosed abnormal uterine bleeding, breast cancer or other estrogen- or progestin-sensitive cancer, now or in the past, liver tumors, benign or malignant, or liver disease, and pregnancy, because there is no reason to use COCs during pregnancy.

Warnings and Precautions:

- Vascular risks: Stop drospirenone and ethinyl estradiol tablets if a thrombotic event occurs. Stop at least 4 weeks before and through 2 weeks after major surgery. Start no earlier than 4 weeks after delivery, in women who are not breastfeeding.
- Hyperkalemia: DRSP has antimineralocorticoid activity. Do not use in patients predisposed to hyperkalemia. Check serum potassium level during the first treatment cycle in women on long-term treatment with medications that may increase serum potassium.
- Liver disease: Discontinue drospirenone and ethinyl estradiol tablets if jaundice occurs.
- High blood pressure: Do not prescribe drospirenone and ethinyl estradiol tablets for women with uncontrolled hypertension or hypertension with vascular disease.
- Carbohydrate and lipid metabolic effects: Monitor prediabetic and diabetic women taking drospirenone and ethinyl estradiol tablets. Consider an alternate contraceptive method for women with uncontrolled dyslipidemia.
- Headache: Evaluate significant change in headaches and discontinue drospirenone and ethinyl estradiol tablets if indicated.
- Uterine bleeding: Evaluate irregular bleeding or amenorrhea.

The progestin drospirenone may increase potassium. Therefore, Loryna should not be prescribed to women with kidney, liver or adrenal disease because this could cause serious heart and health problems. Women receiving daily, long-term treatment for chronic conditions or diseases with medications that may increase serum potassium should have their serum potassium level checked during the first treatment cycle.

Other drugs that may also increase potassium include:

- NSAIDs (ibuprofen [Motrin, Advil], naproxen [Aleve and others] when taken long-term and daily for treatment of arthritis or other problems)
- Potassium-sparing diuretics (spironolactone and others)
- Potassium supplementation
- ACE inhibitors (Capoten, Vasotec, Zestril and others)
- Angiotensin-II receptor antagonists (Cozaar, Diovan, Avapro and others)
- Heparin

- Aldosterone antagonists

Common side effects include headache/migraines, menstrual irregularities, nausea/vomiting, breast pain/tenderness and mood changes.

Birth control pills help to lower the chances of becoming pregnant when taken as directed. They do not protect against HIV infection (AIDS) and other sexually transmitted diseases.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “launch,” “committed,” “expects,” or similar expressions, or by express or implied discussions regarding potential future approvals of additional oral contraceptive products, or regarding potential future revenues from Loryna or such other products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any additional oral contraceptive products will be submitted or approved by Sandoz for sale. Nor can there be any guarantee that Loryna or any such other products will achieve any particular levels of revenue in the future. In particular, management’s expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally, including potential FDA approval of additional versions of YAZ®; unexpected product development difficulties; competition in general; government, industry and general public pricing pressures; unexpected patent litigation outcomes; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Sandoz

Sandoz, a Division of the Novartis group, is a global leader in the field of generic pharmaceuticals, offering a wide array of high-quality, affordable products that are no longer protected by valid and enforceable third-party patents. Sandoz has a portfolio of approximately 1000 compounds and sells its products in about 130 countries. Key product groups include cardiovascular medicines, anti-infectives, treatments for central nervous system and alimentary tract disorders, oncology and respiratory therapies, as well as medications for blood and blood forming organ disorders. Sandoz develops, produces and markets these medicines along with pharmaceutical and biotechnological active substances. In addition to strong organic growth in recent years, Sandoz has made a series of acquisitions including Lek (Slovenia), Sabex (Canada), Hexal (Germany), Eon Labs (US), EBEWE Pharma (Austria), and Oriel Therapeutics (US). In 2010, Sandoz employed more than 23,000 people (full-time equivalents) worldwide and achieved net sales of USD 8.5 billion for the full year.

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For further information

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YAZ® is a registered trademark of Bayer HealthCare Pharmaceuticals Inc.