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PRESS RELEASE

Finox Biotech's Bemfola® Receives Marketing Authorisation in Australia for Treatment of Infertility

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Finox Biotech (Finox AG) announced today the Therapeutic Goods Administration (TGA), has granted a Marketing Authorisation (MA) for Bemfola® (follitropin alfa solution for injection in pre-filled pens), the first follicle stimulating hormone biosimilar therapy used for the treatment of infertility . The TGA decision allows Finox Biotech to market Bemfola® in Australia.

Bemfola® is registered in Australia for the treatment of infertility in adult women and adult men. In adult women Bemfola® is indicated for the treatment of anovulatory infertility in women who have been unresponsive to clomiphene citrate or where clomiphene citrate is contraindicated;- Controlled ovarian hyper stimulation in women undergoing assisted reproductive technologies;- Bemfola® in association with luteinising hormone (LH) preparation is recommended for the stimulation of follicular development in women with serve LH and FSH deficiency. In clinical trials these patients were defined by endogenous serum LH level < 1.2 IU/l;- In adult Men Bemfola® is indicated with the concomitant human chorionic gonadotropin (hCG) therapy for the stimulation of spermatogenesis in gonadotrophin-deficient men in whom hCG alone is ineffective.[1]

Gavin Jelic-Masterton, Chief Executive of Finox Biotech commented, "We are thrilled that the development of Bemfola® has resulted in the Marketing Authorisation for Australia. We are confident that IVF Patients and Doctors across Australia will benefit from our commitment to quality, cost effectiveness and easy to use fertility medicines and that Bemfola® will be a great success for our company''.

Warren J. Jenkins, VP and General Manager of Finox Biotech Pty Australia added, "This is the culmination of many years commitment to bringing a Swiss manufactured r-FSH to the market in Australia and I believe that with the cost effectiveness of the product and a pen designed to assist with patient compliance and ease of administration of Bemfola® will be very popular with physicians and patients".

About Bemfola®

Bemfola® was produced using recombinant DNA technology. Both Bemfola® and the reference product GONAL-f® are formulations of the naturally occurring hormone FSH, which plays a key role in human reproduction. Bemfola® is the result of a targeted drug development process aimed to replicate as closely as possible the reference product. The brief to the development engineers when designing the Bemfola® injector device was to produce a Pen that minimised the number of steps a patient needs to take when preparing the injection and to ensure that the patient and physician had maximum control and the least chance of a patient error. The result, the Bemfola® Pen, is therefore a simple, single-use, once-a-day disposable device, which allows the patient to self-inject.

About Bemfola® in other clinical development programs

Finox Biotech has agreed with the US-FDA to conduct a pivotal phase III study (FIN3002) for registration of Bemfola® (Afolia) in the USA. A US-IND has been opened and the FIN3002 study is now in progress[2].

About Finox Biotech

Finox Biotech (Finox AG) is a biopharmaceutical company with its corporate headquarters in Burgdorf, Switzerland. Finox' first product will be Bemfola®, a biosimilar r-FSH of Gonal-f®. Finox Biotech was founded in 2007 with a vision to become a leading company in the field of fertility therapies, by combining high quality Swiss medicines with innovative, award-winning delivery devices.

For further information please visit **www.finoxbiotech.com** or
contact us at: info@finoxbiotech.com / +41 (0)34 426 11 11

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References

1 Bemfola Australian Product Information 2015

2 Searchable database which provides patients, family members and the public with information about current ongoing clinical research studies. A service of the US National Institutes of Health. Available at https://clinicaltrials.gov/

Bemfola (follitropin alfa [rch]) **MINIMUM PRODUCT INFORMATION**

Please review Full Product Information before prescribing:

Indications: In adult women Bemfola is indicated for the treatment of anovulatory infertility in women who have been unresponsive to clomiphene citrate or where clomiphene citrate is contraindicated; - Controlled ovarian hyper stimulation in women undergoing assisted reproductive technologies; - Bemfola in association with luteinising hormone (LH) preparation is recommended for the stimulation of follicular development in women with serve LH and FSH deficiency. In clinical trials these patients were defined by endogenous serum LH level < 1.2 IU/l; - In adult Men Bemfola is indicated with the concomitant human chorionic gonadotropin (hCG) therapy for the stimulation of spermatogenesis in gonadotrophin-deficient men in whom hCG alone is ineffective. **Dosage**: Complex refer to full PI, Treatment with Bemfola should be initiated under the supervision of a physician experienced in the treatment of fertility disorders. For women with anovulatory infertility a commonly used regimen commences at 75 – 150 IU (5.5 to 11 microgram) FSH daily and is increased in increments of 37.5 IU (2.75 microgram) up to 75 IU (5.5 microgram) at 7 or 14 day intervals if necessary, to obtain an adequate, but not excessive response. For women undergoing assisted reproductive technologies a commonly used regimen for superovulation involves the administration of 150 IU (11 microgram) to 225 IU (16.5 microgram) of Bemfola daily, commencing on days 2 or 3 of the cycle. Treatment is continued until adequate follicular development has been achieved (as assessed by monitoring of serum oestrogen concentrations and/or ultrasound examination), with the dose adjusted according to the patient's response, to usually not higher than 450 IU (33 microgram) daily. For women with serve LH and FSH deficiency a recommended regimen commences at 75 IU of lutropin alfa daily with 75-150 IU FSH. For Men with Hypogonadotrophic Hypogonadism, Bemfola should be given concomitantly at the dosage of 150 IU (11 microgram) three times a week. **Contraindications:** Bemfola is contraindicated for safety reasons in: cases of prior hypersensitivity to follitropin alfa, or to any excipients of Bemfola tumours of the hypothalamus or pituitary gland; FSH therapy is contraindicated for safety reasons where the following exist: **In women:** pregnancy and lactation, ovarian enlargement or ovarian cyst of unknown aetiology, gynaecological haemorrhages of unknown aetiology, ovarian, uterine or breast carcinoma, FSH is contraindicated when an effective response cannot be obtained, such as**: In women,** primary ovarian failure as indicated by high levels of FSH (ovarian dysgenesis, premature menopause)' malformations of sexual organs incompatible with pregnancy fibroid tumours of the uterus incompatible with pregnancy. **In men:** Elevated gonadotrophin levels that indicate primary testicular failure, Infertility disorders other than hypogonadotrophic hypogonadism. **Precautions:** For patients with known hypersensitivity to gonadotrophin first injection of Bemfola must be performed under the medical supervision; **Treatment in Women**: Ovarian Hyperstimulation Syndrome (OHSS) can become a serious complication of human gonadotrophin therapy and sometimes leads to fatal complications if not adequately treated. Mild manifestations of OHSS include abdominal pain, abdominal discomfort and distension, and enlarged ovaries. Moderate OHSS may additionally present with nausea, vomiting, ultrasound evidence of ascites and marked ovarian enlargement. Severe OHSS further includes symptoms such as severe ovarian enlargement, weight gain, dyspnoea or oliguria. Clinical evaluation may reveal hypovolaemia, haemoconcentration, electrolyte imbalances, ascites, pleural effusions or acute pulmonary distress. Very rarely, severe OHSS may be complicated by ovarian torsion or thromboembolic events, such as pulmonary embolism, ischaemic stroke or myocardial infarction. Thromboembolic Events including thrombophlebitis, pulmonary embolism, stroke and arterial occlusion both in association with, and separate from OHSS, have been reported following gonadotrophin therapy. In rare cases, thromboembolic events have resulted in death. The patient should be advised of the potential risk of multiple births before starting treatment; **Use in Pregnancy**: Follitropin alfa is not intended for use during pregnancy (see CONTRAINDICATIONS); **Use in Lactation:** the treating physician will make the decision to continue or discontinue Bemfola; **Treatment in Men**: Elevated endogenous FSH levels are indicative of primary testicular failure. Such patients are unresponsive to Bemfola/hCG therapy. Semen analysis is recommended in assessing the response to treatment. **Interactions:** No clinically significant drug interactions have been reported during Bemfola therapy. **Adverse effects: General;-** Injection site reactions (e.g. pain, erythema, haematoma, swelling and/or irritation at the site of injection). **In women;-** Ovarian cyst, mild to moderate ovarian enlargement , mild or moderate OHSS (including symptomatology), intermenstrual bleeding, abdominal pain, abdominal distension, abdominal discomfort, diarrhoea, nausea, vomiting, headache, dizziness; **In men;-** Gynaecomastia, acne and weight gain.

Full Product Information is available on request from Finox Biotech Australia Pty Ltd. 1 Garigal Road, Belrose NSW 2086, Australia or call +61 2 8998 1854

PBS INFORMATION: Bemfola is not listed on the PBS