ThromboGenics’ JETREA®, the first and only medicine for treating vitreomacular traction, now launched in the UK

First EU JETREA® order triggers €45 million milestone payment from Alcon to ThromboGenics

Leuven, April 11, 2013 – ThromboGenics NV (Euronext Brussels: THR), an integrated biopharmaceutical company focused on developing and commercializing innovative ophthalmic and oncology medicines, today announces that its partner Alcon has launched JETREA® (ocriplasmin) in the UK, its first market in Europe. The first sale of JETREA® by Alcon triggers a €45 million milestone payment to ThromboGenics. ThromboGenics recently received €45 million from Alcon when JETREA® gained European approval for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns.

Alcon, a division of Novartis, acquired the rights to commercialize JETREA® outside the United States in March 2012. ThromboGenics retains the right to commercialize the drug in the US. ThromboGenics launched JETREA® in the US in mid-January 2013 where it is approved for the treatment of patients with symptomatic vitreomacular adhesion (VMA).

JETREA® is currently undergoing a single technology appraisal (STA) by the National Institute for Health and Care Excellence (NICE) as part of the process to gain reimbursement when used by the UK National Health Service. The outcome of the STA, in the form of NICE guidance, is expected in the final quarter of 2013.

Dr Patrik De Haes, CEO of ThromboGenics, says: “The launch of JETREA® in Europe by Alcon so shortly after gaining European approval is testimony of our joint commitment to ensuring patients in Europe have access to this innovative drug as soon as possible. The additional €45 million payment from Alcon for reaching this milestone means we are well placed to continue investing in the commercialization of JETREA® in the US via our own commercial organization. We expect that Alcon will roll out JETREA® into other European markets in the coming months and are working with our partner to ensure that all the support for physicians, payers and patients is fully in place.”

JETREA® contains the active substance ocriplasmin. It is administered through a one-time, single intravitreal injection to treat adults with vitreomacular traction (VMT).

VMT, which in the US is referred to as symptomatic VMA, is an age-related progressive, sight-threatening condition. It is caused by the vitreous humour having an abnormally strong attachment to the central part of the retina (the light sensitive membrane at the back of the eye). The macula provides central vision that is needed for everyday tasks such as driving, reading and recognising faces.

When the vitreous humour shrinks, the strong attachment results in a pulling force on the retina, which may lead to visual distortion, decreased visual acuity and central blindness. When the disease progresses the traction may eventually result in the formation of a hole in the macula (called a macular hole).

JETREA® breaks down the protein fibers which cause the abnormal traction between vitreous and macula that causes VMT. By dissolving these proteins, JETREA® releases the traction, and helps to complete the detachment of the vitreous from the macula.
JETREA® can also be used when VMT has progressed and caused a small hole in the macula (central part of the light-sensitive layer at the back of the eye).

It is estimated that 250,000 to 300,000 patients in Europe alone suffer from this condition.¹

Currently the only available treatment in the EU is ‘observation’ or ‘watchful waiting’ until a patient becomes a surgical candidate, usually at a late stage of the disease.²,³ A patient would then receive a surgical procedure and repair of the retina. However, for many patients this is not a suitable option, as irreversible damage to the retina may have already occurred.⁴,⁵

ThromboGenics is continuing to work with Alcon, across Europe, to ensure the necessary market access and reimbursement infrastructure in place so that patients can receive JETREA® as soon as it is available.

References
1. ThromboGenics and Alcon internal estimates

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About JETREA® (ocriplasmin)

JETREA® (ocriplasmin) is a truncated form of human plasmin. In the US, JETREA® is indicated for the treatment of symptomatic VMA. In Europe, JETREA® is indicated for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter ≤ 400 microns. JETREA® is a selective proteolytic enzyme that cleaves fibronectin, laminin and collagen, three major components of the vitreoretinal interface that play an important role in vitreomacular adhesion.

JETREA® has been evaluated in two multi-center, randomized, double-masked Phase III trials conducted in the U.S. and Europe involving 652 patients with vitreomacular adhesion. Both studies met the primary endpoint of resolution of VMA at day 28.

JETREA®’s Phase III program found that 26.5% of patients treated with ocriplasmin saw resolution of VMA, compared with 10.1% of patients receiving placebo (p<0.01). The Phase III program also showed that JETREA® was generally well tolerated with most adverse events being transient and mild in severity.

About ThromboGenics

ThromboGenics is an integrated biopharmaceutical company focused on developing and commercializing innovative ophthalmic and oncology medicines. The Company’s lead product, JETREA® (ocriplasmin), has been approved by the US FDA for the treatment of symptomatic VMA and was launched in January 2013.

ThromboGenics signed a strategic partnership with Alcon (Novartis) for the commercialization of JETREA® outside the United States. Under this agreement, ThromboGenics could receive up to a total of €375 million in up-front and milestone payments. It will receive significant royalties from Alcon’s net sales of JETREA®. ThromboGenics and Alcon intend to share the costs equally of developing JETREA® for a number of new vitreoretinal indications.

In Europe, JETREA® is approved for the treatment of vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns. Alcon has launched JETREA® in the UK.

ThromboGenics is also further exploring anti-PIGF (Placental Growth Factor), also referred to as TB-403, for the treatment of ophthalmic and oncology indications.

ThromboGenics is headquartered in Leuven, Belgium, and has-offices in Iselin, NJ (US) and Dublin, Ireland. The Company is listed on the NYSE Euronext Brussels exchange under the symbol THR. More information is available at www.thrombogenics.com.

Important information about forward-looking statements

Certain statements in this press release may be considered “forward-looking”. Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company’s Annual Report.

This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of ThromboGenics in any jurisdiction. No securities of ThromboGenics may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. state securities laws.