UK’s NICE Final Appraisal Determination (FAD) Confirms Positive Recommendation for ThromboGenics’ JETREA® for Treatment of Vitreomacular Traction and Macular Hole

Metamorphopsia confirmed as a severe and distressing symptom deserving immediate attention and early treatment with reimbursement

- NICE FAD recommending reimbursement of JETREA for treatment of VMT patients, from early stage to late-stage (full thickness macular hole (FTMH) ≤ 400 microns), when severe and distressing symptoms; patients with ERMs are excluded
- NICE FAD recommending reimbursement of JETREA for treatment of patients showing symptoms of metamorphopsia (blurred vision); metamorphopsia patient impact considered severe and distressing, and equal to loss of 2 lines in visual acuity
- Confirmation of reimbursement for patients suffering from VMT with FTMH ≤ 400 microns

Leuven, Belgium - September 2, 2013 – ThromboGenics NV (Euronext Brussels: THR) a biopharmaceutical company focused on developing and commercializing innovative ophthalmic medicines, announces that the UK’s National Institute for Health and Care Excellence (NICE) has confirmed, in its Final Appraisal Determination (FAD), its recommendation that JETREA® (ocriplasmin) is an innovative new treatment and should be reimbursed within the National Health Service (NHS) in England and Wales.

The NICE FAD confirms NICE’s earlier Appraisal Consultation Document (ACD), which initially recommended JETREA® as an option for treating vitreomacular traction (VMT) in adults, including when associated with a macular hole of less than or equal to 400 microns, when patients have severe symptoms and an epiretinal membrane is not present.

In its Final Appraisal Determination, NICE for the first time also characterized metamorphopsia as a ‘severe and distressing’ symptom with its impact on the patient being comparable to a loss of 2 lines in visual acuity.

As a result, NICE not only recommends full reimbursement of JETREA® for patients with VMT and FTMH, smaller or equal to 400 microns, it also recommends reimbursement for those VMT patients with early stage VMT symptoms including metamorphopsia.

There are no other pharmacological treatments in development for the treatment of VMT. Currently patients either have to watch and wait before they are considered eligible for surgery. Surgery is only performed at a later stage of a patient’s disease, once symptoms progress and their sight deteriorates significantly.

Dr Patrik De Haes, CEO of ThromboGenics, said:

“This further endorsement from UK NICE is great news for ensuring that physicians, who are treating patients with VMT and macular hole, will have access to JETREA®, the first and only pharmacological treatment for this progressive disease.

“We feel highly encouraged by the NICE FAD confirming that metamorphopsia is a ‘severe and distressing’ symptom that requires immediate treatment, and that an early treatment with JETREA® should be reimbursed by the NHS."
"There is growing evidence that prolonged VMT may lead to progressive loss of vision and increase a risk that subsequent intervention may be less successful. From our own market research, we also know that a high number of retina specialists feel that patients presenting themselves with metamorphopsia should be treated. With JETREA®, patients, could for the first time, be offered a reimbursed alternative to watchful waiting, meaning they will no longer have to wait until symptoms progress and vision deteriorates. We look forward to final NICE guidance later this year."

JETREA® is the first and only pharmacological treatment indicated for use in patients diagnosed with VMT and macular hole of diameter less than or equal to 400 microns and was approved in the European Union by the European Commission in March 2013. Alcon, a division of Novartis, acquired the rights to commercialize JETREA® outside the United States in March 2012. In April, Alcon launched JETREA® in the UK, its first market in Europe, resulting in ThromboGenics receiving €90 million in milestone payments.

The FAD is the last step in the appraisal process before final guidance on the reimbursement of JETREA® is issued to the NHS in England and Wales. Final NICE guidance is expected later this year.

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

VMT is a progressive, sight-threatening condition. It is caused by the vitreous humour having an abnormally strong attachment to the macula, 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 recognizing faces.

When the vitreous humor 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 the vitreous and the 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).

The current approach in the EU is ‘observation’, ‘watchful waiting’ or ‘watch and wait’ until a patient becomes a candidate for surgical treatment, usually at a late stage of the disease.\(^1,2\) 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.\(^3,4\)

ThromboGenics is continuing to work closely with Alcon to ensure patients across Europe and rest of the world can access this innovative medicine and receive JETREA® as soon as it becomes available in the respective countries.

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References

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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, Germany, Finland, Norway and Sweden.

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.