

ThromboGenics' JETREA[®] granted EU approval for vitreomacular traction (VMT), including when associated with macular hole of diameter less than or equal to 400 microns

EU approval of JETREA[®] triggers a €45 million milestone payment from Alcon

Leuven, March 15, 2013 – ThromboGenics NV (Euronext Brussels: THR), an integrated biopharmaceutical company focused on developing and commercializing innovative ophthalmic medicines, today announces that the European Commission has approved JETREA[®] (ocriplasmin) in the European Union. 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. The EU approval triggers a €45 million milestone payment to ThromboGenics from its partner Alcon. The first sale of JETREA[®] in the EU by Alcon will trigger a further €45 million milestone payment to ThromboGenics.

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).

Dr Patrik De Haes, CEO of ThromboGenics, says: *“The European approval of JETREA[®] just weeks after the US launch is another major milestone for the Company as we maintain, with our partner Alcon, the momentum of the global roll out of this novel pharmacological treatment for symptomatic VMA. Today’s approval has triggered a €45 million milestone payment to ThromboGenics. We also anticipate a further €45 million as a result of Alcon’s first sale of the product in the EU which is expected to take place soon. Patients across Europe will now have access to our innovative drug for an important sight-threatening condition. VMT is a considerable unmet medical need and places a huge burden on patients across Europe who until now have had no treatment option other than watchful waiting or surgery.”*

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.

“Vitreomacular traction and macular hole formation are disabling eye diseases that influence visual function, and affect activities of patients in their daily life,” said **Prof. Dr. Peter Stalmans, Department of Ophthalmology, University Hospitals, Leuven, Belgium.** *“When the disease worsens, vitrectomy surgery is the only available treatment option. Release of the vitreous traction by pharmacologic vitreolysis can omit the need for vitrectomy.*

“The EU approval of JETREA[®] is a very positive development for patients with VMT and the wider European retina community. This novel pharmacological approach will enable us to improve the treatment of VMT by allowing patients to be treated earlier thereby avoiding the deterioration in their condition that takes place during watchful waiting as well as the risks associated with the surgery. I am looking at quickly integrating the use of JETREA[®] into my clinical practice as soon as it becomes available.”

European MAA

The EU MAA submission was based on data from two pivotal phase III clinical trials that evaluated the safety and efficacy of a single administration of JETREA[®]. Both studies met their primary endpoint and demonstrated that JETREA[®] successfully resolved VMT and macular holes compared to placebo.

All adverse reactions were ocular. The most commonly reported were vitreous floaters, eye pain and photopsia, as well as conjunctival haemorrhage resulting from the injection procedure. Most of the adverse reactions occurred within the first week after the injection. The majority of these reactions were non-serious, mild in intensity and resolved within 2 to 3 weeks.⁶

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 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.

In March 2012, 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.

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.

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